

7.6.1 Research Misconduct

Chapter 7 - Research and Sponsored Programs	Original Effective Date: June 2000
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I. Purpose

To ensure compliance with the law and protect the credibility of all research conducted at and funded by UT Health San Antonio.

II. Scope

- A. This policy is intended to carry out this institution’s responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) involving:
 - 1. A person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution; and
 - 2. Biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, applications or proposals for funding support for biomedical or behavioral research, research training or activities related to that research or research training, or plagiarism of research records produced in the course of research, research training or activities related to that research or research training.
- B. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.
- C. This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution or HHS received the allegation, subject to the

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subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b)

III. Policy

UT Health San Antonio (UTHSA) strives to create a research climate that promotes adherence to high ethical standards in the conduct of research without inhibiting the productivity and creativity of persons involved in research. Research misconduct is an offense that damages not only the reputation of those involved, but also that of the entire academic community.

Research misconduct is a major breach of the relationship between faculty or staff and the institution. In order to maintain the integrity of research, every person engaged in research, including faculty, graduate and undergraduate students, postdoctoral fellows, and technicians, must keep a permanent auditable record of all experimental protocols, data, and findings. Co-authors on research reports of any type, including publications, must have a bona fide role in the research and must accept responsibility for the quality of the work reported.

A. Responsibility to Report

All institutional members will report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO). 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 RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

B. Protecting Individuals Involved

Any inquiry or investigation of allegations of research misconduct must proceed promptly and with due regard for the reputation and rights of all individuals involved. Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses, or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

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UTHSA will take all reasonable steps to assure that the persons involved in the evaluation of the allegations and evidence have appropriate expertise; no person involved in the procedures is either biased against the accused person(s) or has a conflict of interest; and, affected individuals will receive confidential treatment to the maximum extent possible.

C. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

D. Confidentiality

The RIO shall, as required by 42 CFR § 93.108:

1. Limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research 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 research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

This policy is based on a model policy from the U.S. Public Health Service (PHS). If funding sources are from other sources than PHS, it may be necessary to follow the policies of that grantor.

E. Requirements for Findings of Research Misconduct

A finding of research misconduct requires that:

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

F. Evidentiary Standards

The following evidentiary standards apply to findings:

1. Standard of proof. A finding of research misconduct must be proved by a preponderance of the evidence.
2. Burden of proof.

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- a. The institution has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, and maintained 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 community.
- b. 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 the institution 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.
- c. 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 research misconduct proceeding.

G. Initial Reporting

Allegations of research misconduct should be placed in writing and brought to the attention of the RIO. Officials of the institution (e.g., Dean, VP, or Chair) should refer allegations to the RIO. As appropriate, the RIO will consult with officials of the institution, Principal Investigator of the research program and any researchers or staff affected by the allegations.

H. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the research misconduct proceeding, the RIO 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 research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if he/she has reason to believe that any of the following conditions exist:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

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2. HHS resources or interests are threatened;
3. Research activities should be suspended;
4. Federal action is required to protect the interests of those involved in the research misconduct proceeding;
5. The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved;
6. The research community or public should be informed; or
7. There is a reasonable indication of possible violations of civil or criminal law.

I. Authorship or Credit Disputes

When an allegation involves a dispute over authorship (e.g., faculty, staff, or students who believe that they were not appropriately included on a publication, presentation, grant proposal, etc.) the complaint (in writing) is referred to the Principal Investigator (PI) or lead author in an attempt to resolve the issue at the lowest level. If the issue cannot be resolved, the complainant should contact (in writing) the chair or director of his/her academic unit(s), for review of such concerns. The chair or director will investigate whether appropriate authorship or acknowledgment was provided, based on accepted criteria for authorship or acknowledgment in the academic discipline/field, and mediate a resolution to the dispute. If the chair/director cannot resolve a dispute or if the complainant is a chair/director, disputes should be escalated to the respective dean.

J. Non-Research Misconduct Issues

When the institution's review of the allegation identifies non-research misconduct issues, the Vice President for Research should refer these matters to the proper institutional or federal office for action. Issues requiring referral are described below.

1. Potential violation of criminal law under HHS grants and contracts should be referred to the Office of the Inspector General (OIG). If the possible criminal violation is identical to the alleged research misconduct (e.g., alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.
2. Potential violations of human subject regulations should be referred to the Office of Human Research Protections.
3. Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare.
4. Potential violations of Food and Drug Administration (FDA) regulated research requirements should be referred to the FDA Office of Regulatory Affairs.

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5. Potential violations of cost principles or other fiscal irregularities should be referred as follows:
 - a. For all NIH Agencies—Office of Management Assessment, NIH.
 - b. For all other PHS Agencies- PHS Office of Grants and Contracts

K. Assessment into Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. An inquiry must be conducted if these criteria are met. The Institutional Compliance & Privacy Office may be requested to assist in the preliminary initial assessment.

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO 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. 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 proceedings.

L. Conducting the Inquiry

Following the preliminary assessment, if the RIO determines that the criteria for an inquiry is met, 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 conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

The RIO will determine whether any UT Health San Antonio affiliated organization/institution is also involved in the research thus possibly warranting a joint inquiry. If so, the appropriate institutional official should be contacted. Factors to be considered in the decision to conduct a joint inquiry would include source of pay for the investigator, presence or absence of joint appointment, presence or absence of “Without Pay” (WOC) appointments at Veteran’s Administration (VA) organizations, source of funding for the research, site where the research was conducted, subject population involved, etc. After consideration and discussion of these factors, the decision on whether a joint investigation is indicated would be made. If a joint investigation is warranted, a decision on which organization has the lead should be made. If there is significant involvement of these factors by the South Texas Veteran’s Health Care System, the VA should take the lead because of the additional Federal regulations applying to VA institutions. In most other scenarios with other affiliated organizations, UT Health San Antonio would be the lead organization.

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As soon as practical after it is determined that an inquiry is required, the RIO will:

1. Secure the relevant research records;
2. Notify the President, the Vice President for Research, the Office of Legal Affairs, appropriate Executive Committee (EC) members, the Office of Sponsored Programs (if applicable), the respondent, and ORI;
3. Appoint a person or persons to conduct an initial inquiry; and,
4. Notify ORI if PHS support and any of the conditions listed above under “Responding to Allegations” exist.

The RIO may consult with ORI at any time regarding appropriate procedures to be followed.

M. Notification of the Respondent

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. This notification may be sent simultaneously with sequestrating of records. See “Sequestration of Research Records” below.

The notification should identify the research project in question and the specific allegations; define research misconduct; identify the PHS funding involved; list the name or names of the person or persons conducting the initial inquiry and expert consultants (if any); explain the respondent's opportunity to challenge the person or persons designated for bias or conflict of interest, to be assisted by legal counsel, to be interviewed, to present evidence to the person or persons designated, and to comment on the inquiry report; and, describe the institution's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings.

N. Potential Respondents

If no specific respondent has been identified at this stage of the process, the RIO will notify each potential respondent that an inquiry will be undertaken, e.g., each co-author on a questioned article or each investigator on a questioned grant application.

O. Sequestration of the Research Records

To the extent it has not already been done at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. 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.

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Research records produced under PHS grants and cooperative agreements are the property of the institution, and employees cannot interfere with the institution's right of access to them. Under contracts, certain research records may belong to PHS, but the institution will be provided access to contract records in the custody of the institution for purposes of reviewing misconduct allegations.

The RIO should notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with location and identification of the research records. The Vice President for Research should obtain the assistance of the respondent's supervisor and legal counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification. In addition to securing records under the control of the respondent, the Vice President for Research may need to sequester records from other individuals, such as co-authors, collaborators, or complainants. As soon as practicable, a copy of each sequestered record will be provided to the individual from whom the record is taken, if requested.

A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

The RIO will store records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified.

P. Designation of an Official or a Committee to Conduct the Inquiry

The RIO, in consultation with other officials of the institution as appropriate, will appoint an inquiry official or committee. The person or persons designated to conduct the inquiry 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.

Q. Inquiry

The RIO will take reasonable steps to ensure that those conducting the inquiry and any expert consultants must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry.

The RIO will notify the respondent of the proposed person or persons to conduct the inquiry to give the respondent an opportunity to object to a proposed member(s) based

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upon a personal, professional, or financial conflict of interest. The respondent must submit a written objection within five (5) calendar days. The RIO will make the final determination of whether a conflict exists.

The person or persons conducting the inquiry and any expert consultants will agree in writing to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the inquiry they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the Vice President for Research to have knowledge of the inquiry.

The Vice President for Research's Office, in consultation with the legal counsel, will provide staff assistance and guidance to the committee and the experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report. Additional guidance may be found in the model policy posted on the ORI's web site at <http://ori.hhs.gov/misconduct/>.

R. Charge

The RIO will prepare a charge for the person or persons conducting the inquiry that:

1. Sets forth the time for completion of the inquiry;
2. Describes the allegations and any related issues identified during the allegation assessment;
3. States that the purpose of the inquiry is to make a preliminary evaluation 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;
4. States that an investigation is warranted if the official/committee determines:
 - a. there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and
 - b. the allegation may have substance, based on the committee's review during the inquiry.
5. Informs the inquiry official/committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

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 present or available throughout the inquiry to advise the committee as needed.

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S. Time to Completion

The inquiry, including preparation of the final inquiry report and the decision of the Deciding Official on 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 respondent will be notified of the extension.

T. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. After consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). 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 a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the institution shall promptly consult with ORI to determine the next steps that should be taken. See “Completion of Cases: Reporting Premature Closures to ORI” below.

U. Inquiry Report

A written inquiry report must be prepared that includes the following information:

- a. the name and title of the person(s) conducting the inquiry and expert consultants, if any;
- b. a description of the allegations of research misconduct;
- c. the name and position of the respondent(s);
- d. the PHS support;
- e. a list of the research records and other relevant documents reviewed;
- f. summaries of any interviews;
- g. the basis for recommending or not recommending that the allegations warrant an investigation; and,
- h. any comments on the draft report by the respondent or complainant.

The Office of Legal Affairs should review the report for legal sufficiency. All relevant dates should be included in the report.

1. Notification to the Respondent and Opportunity to Comment

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The RIO will notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to 42 CFR Part 93 and the institution'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 committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

2. Institutional Decision and Notification

The RIO will transmit the final inquiry report and any comments to the Deciding Official, who will determine in writing whether an investigation is warranted. The inquiry is completed when the Deciding Official makes this determination.

The Vice President for Research will notify both the respondent and the complainant in writing of the decision whether to proceed with an investigation.

3. Notification to ORI

a. If the allegations warrant an investigation and PHS funding is involved, then the institution must provide ORI, within thirty (30) days, with provide ORI with the Deciding Official's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the Deciding Official's decision.

b. The institution must provide the following information to ORI on request:

- i. The institutional policies and procedures under which the inquiry was conducted;
- ii. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and,
- iii. The charges for the investigation to consider.

4. Documentation of Decision Not to Investigate

If the institution makes a decision not to investigate, the institution must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. The institutions must keep these records in a secure manner for at least seven (7) years after the termination of the inquiry, and upon request, provide them to ORI of other authorized HHS personnel.

V. Referral to Other Officials or Agencies

Information obtained during the inquiry regarding allegations other than research misconduct involving PHS funds should be referred to the responsible institutional officials or government agencies.

W. Conducting the Investigation

1. Initiation and Purpose

- a. 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. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she 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.
- b. 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 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. This is particularly important where the alleged misconduct involves 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 will be set forth in an investigation report.

2. Notifying ORI and Respondent; Sequestration of Research Records

- a. On or before the date on which the investigation begins, the RIO must:
 - i. notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and,
 - ii. notify the respondent in writing of the allegations to be investigated.

The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

- b. 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 the research misconduct proceeding that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

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3. The investigation, whether conducted by a committee or an individual, will follow each procedural step set forth below.

X. Appointment of the Investigation Official or Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an investigation official or committee and the committee chair as soon after the beginning of the investigation as is practical. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The RIO will notify the respondent of the proposed committee membership. The respondent is allowed five calendar days to object to a proposed member based upon a personal, professional, or financial conflict of interest. If the respondent submits a written objection to any appointed member of the investigation committee or expert the institution will make the final determination whether a conflict exists.

Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the Vice President for Research to have knowledge of the investigation.

Y. Charge to the Committee and the First Meeting

1. The RIO will define the subject matter of the investigation in a written charge to the committee that:
 - a. Describes the allegations and related issues identified during the inquiry;
 - b. Defines research misconduct;
 - c. Identifies the respondent;
 - d. Informs the committee that it must conduct the investigation as prescribed in this policy;
 - e. 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;
 - f. 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:

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- i. research misconduct, as defined in this policy, 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);
 - ii. the research misconduct is a significant departure from accepted practices of the relevant research community; and
 - iii. the respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- g. Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.
2. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Vice President for Research, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.
3. First Meeting

The RIO, with the assistance of legal counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality 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, the PHS regulation.

Z. Developing an Investigation Plan

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the complainant, respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and, a plan for the investigative report.

AA. General Approaches to Conducting the Investigation

1. During the investigation, the committee and RIO will take the following steps:
 - a. 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;
 - b. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

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- c. 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;
 - d. 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.
2. The Vice President for Research must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy.
 3. The Vice President for Research and the Office of Legal Affairs should be consulted throughout the investigation on compliance with these procedures and PHS regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The Office of Legal Affairs will be available throughout the investigation to advise the committee.

BB. Reviewing the Evidence

The investigation committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed. Also, the committee should pursue diligently all significant issues and leads discovered that are determined relevant to the investigation.

CC. Conducting the Interviews

The investigation committee will conform to the following guidelines:

1. The investigation committee will conduct the interviews as described in this policy, except that at the investigative stage interviews should be in depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.
2. The investigation committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss

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the issues. Committee deliberations should never be held in the presence of the interviewee.

3. The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.
4. Any interview with the respondent will be transcribed or recorded. Interviews with anyone else will be recorded. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The committee should consult with the Office of Legal Affairs on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. The committee may ask the Vice President for Research or Office of Legal Affairs to consult with ORI when deciding whether an admission has adequately addressed all the relevant issues such that the investigation can be considered completed. The investigation should not be closed unless the respondent has been appropriately notified and given an opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the Vice President for Research as the Deciding Official with recommendations for appropriate institutional actions and then to ORI for review.

DD. Committee Deliberations

In reaching a conclusion on whether there was scientific misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence.

The committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific community at the time the actions were committed.

The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden of proving misconduct by a preponderance of the evidence. The committee will also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that research misconduct cannot be proven by a preponderance of the evidence.

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EE. The Investigation Report

Elements of the Investigation Report

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

1. Describe the nature of the allegation of research misconduct, including identification of the respondent;
2. PHS Support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support;
3. Describe the specific allegations of research misconduct for consideration in the investigation;
4. Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
5. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and,
6. Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:
 - a. identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
 - b. 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;
 - c. identify the specific PHS support;
 - d. identify whether any publications need correction or retraction;
 - e. identify the person(s) responsible for the misconduct; and
 - f. list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

FF. Comments on the Draft Investigation Report

The draft investigation report will be reviewed as follows:

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

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from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Complainant: The complainant may be kept apprised of the status of the investigation if requested. (Ongoing, completed, etc.)
3. Legal Counsel: The draft investigation report will be transmitted to the Office of Legal Affairs for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.
4. 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.

GG. Decision by Deciding Official

1. The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondents are included and considered, and transmit the final investigation report to the Deciding Official, who will determine in writing:
 - a. whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and,
 - b. the appropriate institutional actions in response to the accepted findings of research misconduct

If this determination varies from the findings of the investigation committee, the Deciding Official 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 Deciding Official may return the report to the investigation committee with a request for further fact-finding or analysis.

2. 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, the Deciding Official 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. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.
3. The findings of the investigation committee and the Vice President for Research's final determination regarding the report will be provided to the President of UT Health San Antonio. The President will determine the consequences for the respondent if the determination of research misconduct was made.

HH. Notice to ORI of Institutional Findings and Actions

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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 misconduct and, if so, who committed the misconduct; and,
4. a description of any pending or completed administrative actions against the respondent

II. 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. The RIO 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. a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

JJ. Institutional Administrative Actions

If the Vice President for Research determines that research misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The administrative actions may include:

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research 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 actions appropriate to the research misconduct.

KK. Other Considerations

1. The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

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2. If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the 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.
3. Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.
4. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Vice President for Research.
5. During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must 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 research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The Vice President for Research 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 Vice President for Research approves.
6. If relevant, the Vice President for Research will determine whether the complainant's allegations of research misconduct were made in good faith or whether a witness or committee member acted in good faith. If the Vice President for Research determines that there was an absence of good faith, he or she will determine whether any administrative action should be taken against the person who failed to act in good faith.

LL. Records Retention

The Vice President for Research will keep the complete file on all misconduct inquiries and investigations regardless of funding, including the records of any inquiry or investigation and copies of all documents and other materials furnished, for at least seven (7) years after completion of the case, or if ORI has advised the institution in

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writing that it no longer needs to retain the records. ORI or other authorized HHS personnel will be given access to the records upon request.

IV. Definitions

Allegation – Any written or oral statement or other indication of possible research misconduct made to an institutional official.

Complainant – A person who makes an allegation of research misconduct.

Conflict of Interest – The real or apparent interference of one person’s interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official – The Vice President for Research is the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution’s inquiry, investigation, or allegation assessment. A Deciding Official’s appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

Employee – Any person paid by, under the control of, or affiliated with UT Health San Antonio, including but not limited to faculty, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

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

Fabrication – Making up data or results and recording or reporting them.

Falsification – Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Good Faith Allegation – An allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

Inquiry – Preliminary information-gathering and fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

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Investigation – The formal development of a factual record and examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

ORI – The Office of Research Integrity, the office within the U.S. Department of Health and Human Services (HHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service (PHS).

PHS Regulation – The Public Health Service (PHS) regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Part 93, entitled "Public Health Service Policies on Research Misconduct".

Plagiarism – includes both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work.

1. The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review.
2. Substantial unattributed textual copying of another's work means the unattributed verbatim or nearly verbatim copying of sentences and paragraphs which materially mislead the ordinary reader regarding the contributions of the author.
3. Plagiarism does not include authorship or credit disputes.

Research Integrity Officer (RIO) – The Assistant Vice President for Research Administration is the institutional official responsible for:

1. Assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified;
2. Overseeing inquires and investigations; and,
3. The other responsibilities described in this policy.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

Research Record – Any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts;

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manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and, subject research files.

Respondent – The person against whom an allegation of research misconduct is directed or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation – Any action that adversely affects the employment or other status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of research misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

V. Related References

There are no related documents associated with this Policy.

VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
06/2000	Policy Origination		
11/2019	Policy Review with Changes		