# Policy Number: RE0001
# The University of Tennessee Policy and Procedures on Responsible Conduct in Research and Scholarly Activities*

(Effective September 15, 2016)

* This document includes both policy and required procedures for implementing the policy. Use of the word "policy" within this document includes all related procedural requirements. This policy was approved and adopted by the President pursuant to the Board of Trustees' delegation of authority regarding research misconduct policy and procedures (October 2014) and supersedes the Policy on Misconduct in Research and Service approved and adopted by the Board of Trustees on October 28, 2005.

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# Section 1 - Introduction

Public confidence in the integrity of the research and scholarship conducted at The University of Tennessee is critical to fulfillment of the University's objectives as a public institution of higher education[1] and is a critical responsibility of individual educators and scholars. Effective self-enforcement of academic research integrity is essential to the success of the University as a whole.

The most effective way to support the University's interest in discovering and disseminating knowledge is to enforce standards of academic integrity in a climate of responsible research. Such integrity includes not only the avoidance of wrongdoing, but also the rigor, care, and accountability that are the hallmarks of good research and scholarship. Those who lead and supervise research have a responsibility to create an environment that encourages high standards through open discussion, publication, emphasis on quality, appropriate supervision, maintenance of accurate and detailed records, and the fair assignment of responsibility and credit in the specific discipline.

To facilitate compliance with federal regulations and prompt response to changes in regulatory requirements and interpretations, the Board of Trustees has

- affirm[ed] the University's commitment to integrity in research and to fostering a research environment that promotes the responsible conduct of research, discourages research misconduct, and deals promptly with allegations of research misconduct; and
- direct[ed] the administration to take practical steps to comply with the obligation to foster a research environment that promotes the responsible conduct of research and discourages research misconduct; and
- direct[ed] the administration to review and revise the University's research misconduct policy and procedures as necessary to ensure ongoing compliance with applicable federal regulations; and
- delegate[d] to the President the authority to approve the University's research misconduct policy and procedures after the campus faculty senates, or their delegates, and other relevant stakeholders have had an opportunity to review and comment; and
- repeal[ed] the [2005] policy and procedures on research misconduct effective as of the date established in the research misconduct policy and procedures approved by the President.[2]

**Revisions of this policy:** Absent extraordinary circumstances, the President's approval of substantive revisions of this policy should include consultation with the various participants in shared governance, including representatives of the faculties at each campus. Housekeeping and technical changes, as well as changes required to bring the policy into compliance with law or other University policy, may be approved by the President following consultation with University Counsel, Chief Research Officers, and Chancellors.

[1] Certain terms throughout this document are used without definition but with meaning specific to The University of Tennessee. "University" refers to The University of Tennessee and its component parts. "Campus" refers to UT Knoxville (including UT Space Institute), UT Health Science Center (including all of its statewide locations), UT Institute of Agriculture, UT at Chattanooga, and UT at Martin, the Institute for Public Service, and UT system administration. "Chancellor" refers to the chief executive officer of the campus. "Department" refers to the smallest academic unit, which in some cases may be a college, school, division, or center; similarly, "department head" may also be used to describe chair, director, or dean as the administrative head of the smallest academic unit. "Chief Academic Officer" refers to the highest campus official charged with supervision of academic matters. "Chief Research Officer" refers to the highest campus official charged with supervision of sponsored research programs.

[2] Resolution on Integrity in Research, University of Tennessee Board of Trustees, Oct. 2, 2014.

## Section 2 - Definitions

As used in this policy, the following terms carry the specific meanings described in this section, and are identified throughout this policy by the use of initial capitalization[3]:

1. Administrative Action means remedial (rather than punitive) action taken by administrators in response to an Allegation or finding of Research Misconduct (compare with Sanction).

2. Allegation means a disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to the Research Integrity Officer (RIO), the Chief Research Officer, or any academic administrator at the level of a department head or above. An Allegation may be refined, revised, narrowed, or expanded during the Research Misconduct Proceeding, as necessary to ensure a thorough review of possible Research Misconduct and to comply with federal regulations.[4]

3. Assessment means the initial, brief review of an Allegation by the RIO[5] to determine whether an Inquiry is warranted – that is, whether the Allegation (if true)
   - falls within the definition of Research Misconduct; and
   - is sufficiently credible and specific that potential evidence of Research Misconduct could be identified; and
   - includes conduct that appears to fall within the scope and application of this policy (see Section 3).

4. Authorship Dispute means conflict among collaborators which does not meet the definition of Research Misconduct and which may include: (1) who should be named as an author/contributor; (2) order of authorship; (3) expectations for contributors to a project; or (4) intellectual property or confidentiality issues affecting publication.

5. Chief Research Officer means the campus vice chancellor or, in the absence of a vice chancellor for research, the senior research administrator for the campus or institute.

6. Complainant means a person who in Good Faith makes an Allegation of Research Misconduct.[6]

7. Conflict of Interest / Unresolved Conflict for any University official or any participant in a Research Misconduct Proceeding means a past or continuing personal, professional, or financial relationship with another participant in the Research Misconduct Proceeding which creates an unmanageable (as determined by the RIO) bias for or against any Respondent, or which the participant him/herself personally believes renders him/her unable to participate in a manner that is thorough, competent, objective, and fair.[7]

8. Deciding Official (DO) means the institutional official designated by the Chancellor to make final determinations of whether (and by whom) Research Misconduct has been committed. The DO may also impose institutional Administrative Actions. Unless otherwise designated by the Chancellor, the Deciding Official is the Chief Research Officer for the campus.[8] The same person may not serve as both the Deciding Official and the Research Integrity Officer (RIO) during the same Research Misconduct Proceeding.

9. Fabrication means making up data or results and recording or reporting such data or results.[9]

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[3] Except where context requires otherwise, the singular includes the plural, the plural includes the singular, and the word "or" is used in the inclusive sense.
[4] 42 C.F.R. § 93.201.
[5] If a Respondent asserts that the RIO has a prohibited Conflict of Interest, the purported conflict will be reviewed by the Chief Research Officer in consultation with other officials as he/she may find appropriate. The Chief Research Officer's decision regarding the RIO's eligibility to serve in any particular case is the final decision. If the RIO is unable to serve in a particular case because of a prohibited Conflict of Interest or any other reason, the Chief Research Officer shall appoint an interim RIO as he/she deems appropriate. If a Respondent asserts that the Chief Research Officer has Conflict of Interest, the Chief Academic Officer will review the purported conflict and will act in place of the Chief Research Officer as he/she deems appropriate.
[6] *See* 42 C.F.R. § 93.210.
[7] *See* 42 C.F.R. § 93.300(b).
[8] Unless otherwise designated by the Chancellor, the DO for UT Knoxville and for UTHSC will be the Vice Chancellor for Research. The Deciding Official for the Institute of Public Service is the institute's chief executive officer.
[9] 42 C.F.R. § 93.103(a).

10. Falsification means 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.[10]

11. Good Faith as applied to a Complainant, Respondent, or witness means having a belief in the truth of one's Allegation or testimony that a reasonable person in the same position could have, based on the information known to the Complainant, Respondent, or witness at the time. An Allegation or cooperation with a Research Misconduct Proceeding is not in Good Faith if made with Knowing or Reckless disregard for information that would negate the Allegation or testimony. Good Faith as applied to a committee member means cooperating with the Research Misconduct Proceeding by carrying out impartially the duties assigned for the purpose of helping the University meet its responsibilities under this policy. A committee member does not act in Good Faith if his/her acts or omissions in the Research Misconduct Proceeding are dishonest or influenced by personal, professional, or financial Conflicts of Interest.[11]

12. Honest Error means an exception to the definition of Research Misconduct or an affirmative defense to an Allegation of Research Misconduct in which a Respondent asserts that the questioned conduct resulted from an unintended error rather than Intentional, Knowing, or Reckless distortion of the Research Record. The Respondent carries the burden of establishing that Honest Error (or other affirmative defense such as difference of opinion) more likely than not explains the Fabrication, Falsification, or Plagiarism.[12]

13. Inquiry means the preliminary information-gathering and fact-finding to determine whether an Allegation of Research Misconduct meets the criteria warranting an Investigation – that is, whether (1) there exists a reasonable basis for concluding that the Allegation (if true) falls within the definition of Research Misconduct (and is otherwise consistent with the scope and application of this policy); AND (2) preliminary information-gathering and preliminary fact-finding indicates that the Allegation may have substance.[13]

14. Investigation means the actions of a designated committee to develop a factual record by exploring the Allegation in detail and examining the evidence in depth, leading to conclusions and recommendations by the committee as to whether Research Misconduct was committed, to what extent, and who bears responsibility, together with any recommendations regarding Administrative Actions or Sanctions.[14]

15. Intentional means having the intent to perform an act even when the actor does not desire the consequences that result.[15]

16. Knowing means having or showing awareness or understanding; deliberate; conscious.[16]

17. Notice means any written Notice delivered by mail, tracked carrier, electronic delivery, or other method as the RIO finds appropriate and effective.

18. PHS Support for Research (triggering certain reporting obligations to federal oversight officials) has the meaning ascribed in regulations promulgated by the United States Public Health Service (PHS), and specifically includes PHS funding, applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that biomedical or behavioral research or training.[17]

19. Plagiarism means appropriation of another person's ideas, processes, results, or words without giving appropriate credit.[18] See also "Redundant Publication" below.

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[10] 42 C.F.R. § 93.103(b).
[11] 42 C.F.R. § 93.210.
[12] 42 C.F.R. §§ 93.103 and 93.106; *see also* PHS Comments on Final Rule, 70 F.R. 28370, at 28372, 28378 (May 17, 2005).
[13] 42 C.F.R. §§ 93.212 and 93.307(d).
[14] *See* 42 C.F.R. § 93.215.
[15] Black's Law Dictionary (9th ed. 2009) (definition of "intent/general intent").
[16] Black's Law Dictionary (9th ed. 2009) (definition of "knowing").
[17] *See* 42 C.F.R. § 93.221.
[18] 42 C.F.R. § 93.103(c).

20. Preponderance of the Evidence means proof by information that, compared with the information opposing it, leads to the conclusion that the fact at issue is more probably true than not.[19]

21. Reckless conduct means making a falsified, fabricated, or plagiarized statement, figure, or other representation in the Research Record with callous disregard as to whether the representation is true or requires attribution to another. Callous disregard may be shown by evidence that a representation is (1) false, misleading, or plagiarized AND (2) the Respondent was aware of the probable falseness or misleading nature of the representation or entertained his/her own serious doubts about the accuracy of the representation. Awareness of the probable falseness or misleading nature of a representation may be inferred from evidence of obvious reasons to doubt the accuracy of the representation where the Respondent did not take reasonable steps to dispel those doubts.[20]

22. Redundant Publication (sometimes called self-plagiarism) means either multiple publications of the same material, by the same author, to the extent that the core of the new document fails to constitute an original contribution to knowledge. Redundant Publication can constitute Research Misconduct, depending on the standards of the relevant discipline and scientific community.[21]

23. Research means a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge (basic Research) or specific knowledge (applied Research) by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to, the subject matter of any academic discipline (not just the physical sciences) in any University setting and includes development of a Research plan.[22] This definition is intended to include scholarship and all creative works.

24. Research Integrity Officer (RIO) means the person (or persons) designated by the Chancellor or Chief Research Officer to administer this policy. A person may not serve as both the Deciding Official and the Research Integrity Officer (RIO) in the same Research Misconduct Proceeding.

25. Research Misconduct means Intentional, Knowing, or Reckless Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing Research, or in reporting Research results, which constitutes a significant departure from accepted practices of the relevant Research community. Research Misconduct does not include Honest Error or differences of opinion.[23]

    - Research Misconduct may include the destruction, absence of, or Respondent's failure to provide records adequately documenting the Research, where the institution or granting agency establishes by a Preponderance of evidence that (1) the Respondent Intentionally, Knowingly, or Recklessly created or possessed Research Records and destroyed them; (2) had the opportunity to maintain the Research Records but did not do so; or (3) maintained the Research 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.[24]

    - Intentional, Knowing, or Reckless failure to comply with the responsibilities of the Principal Investigator (PI) as described in Appendix B, in connection with an act of Fabrication, Falsification, or Plagiarism committed by a person under the PI's direction or control, can constitute Research Misconduct by the PI and the subordinate.

26. Research Misconduct Proceeding means any actions related to an Allegation of Research Misconduct taken pursuant to this policy or applicable law or regulation, including any actions taken by oversight officials.[25]

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[19] 42 C.F.R. § 93.219.
[20] *Brodie v. Dep't of Health and Human Svcs.*, 796 F. Supp.2d 145 (D.D.C. 2011), 715 F. Supp.2d 74 (D.D.C. 2010); *In re: Office of Research Integrity v. Brodie*, HHS Departmental Appeals Board No. CR2056, 2010 WL 338011, at *7 (Jan. 12, 2010).
[21] For developing guidance on redundant publication, dual publication, self-plagiarism, "salami-slicing" and similar topics, see, e.g., the ORI guidance web module: Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing, at http://ori.hhs.gov/avoiding-plagiarism-self-plagiarism-and-other-questionable-writing-practices-guide-ethical-writing.
[22] *See* 42 C.F.R. § 93.222.
[23] 42 C.F.R. § 93.103(d).
[24] 42 C.F.R. § 93.106.
[25] 42 C.F.R. § 93.223.

27. Research Record means the record of data resulting from the proposal, performance, review, or reporting of any Research. The Research Record includes (without limitation): proposals, laboratory records, x-ray film, slides, biological materials, equipment use logs, equipment readings, procurement records, human or animal subject proposals and protocols, consent forms, patient files, medical charts, progress reports, abstracts, theses, oral presentations, internal reports, manuscripts, formal proceedings, journal articles (published or unpublished), correspondence regarding Research Records, communications with journal editors or funding officials, or any other material provided by a Respondent to any University official or oversight officials during a Research Misconduct Proceeding.[26]

28. Respondent means the person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct Proceeding, including a Student Respondent.[27]

29. Retaliation means an adverse action by any University employee, taken against any Complainant, witness, committee member, or any other participant in a Research Misconduct Proceeding *in response to* either (1) a Good Faith Allegation of Research Misconduct or (2) Good Faith cooperation with a Research Misconduct Proceeding.[28] Retaliation is prohibited by this policy.

30. Sanction means action that is punitive in nature and is initiated or imposed by the University. Imposition of any Sanction will comply with procedures detailed in Board policies and faculty handbook procedures (for faculty); relevant HR policies (for staff); and applicable student disciplinary procedures (for students).

31. Sequestration of evidence means steps taken by the University (usually through the RIO) to (1) obtain custody of all the Research Record and evidence needed to conduct the Research Misconduct Proceeding, (2) inventory the records, (3) preserve the records in a secure manner, and (4) maintain the records as required by law and policy.[29]

32. Student Respondent means any: (1) currently-enrolled University student whose conduct is the subject of any Allegation of Research Misconduct, whether the Research was conducted at the University or at some other institution or entity; and (2) previously-enrolled University student whose conduct is the subject of an Allegation of Research Misconduct, when the questioned Research was conducted at the University, or when the former student remains otherwise affiliated with the University.

33. University Counsel means any attorney on the staff of the University's Office of the General Counsel who advises the RIO, the Inquiry and Investigation committees, the Deciding Official (DO), and other administrators with respect to legal issues arising within the scope of administrators' University responsibilities. University Counsel does not represent the Respondent, the Complainant, or any individual person participating in a Research Misconduct Proceeding.

[26] *See* 42 C.F.R. § 93.224.
[27] 42 C.F.R. § 93.225.
[28] 42 C.F.R. § 93.226.
[29] 42 C.F.R. § 93.305.

# Section 3 - Scope and Application[30]

## 3.1. Effective Date of This Policy and Subsequent Revisions

This policy is effective on the date specified by the President of the University at the time the policy, procedures, or revisions are approved and adopted. Nothing in this policy shall be interpreted to require the repeat or review of any portion of a Research Misconduct Proceeding in process or already completed as of the effective date of this policy.[31] When an Allegation involves conduct occurring before July 16, 2005, the Allegation will be evaluated under federal regulations in effect at the time of the alleged misconduct. Beginning on the effective date specified by the President, this policy, procedures, or revisions shall apply to any ongoing Research Misconduct Proceeding, at the start of the next procedural step, as determined by the RIO. In extraordinary circumstances, the RIO (after consultation with University Counsel) may determine that a recent policy revision will not apply to an ongoing Research Misconduct Proceeding when it would create an undue burden or substantial unfairness either to the University or a Respondent.

## 3.2. Application to Allegations of Research Misconduct

This policy governs the University's response to any report of concern or any Allegation of Research Misconduct in proposing, performing, reviewing, or reporting Research, *except* when law or contractual obligations require otherwise, or when the Deciding Official concludes, upon advice of University Counsel, that deviation from this policy is necessary or in the best interest of the University. Substantial deviation from this policy must be approved in advance by the Chancellor, upon advice of the Chief Research Officer, Chief Academic Officer, and University Counsel.

## 3.3. Application in Other Cases of Other Persistent Non-Compliance With Research Requirements

In certain cases where the University's interests are implicated, University officials may apply these or similar procedures as a mechanism for reviewing allegations of improper conduct in connection with Research which may not meet the definition of Research Misconduct. Examples include, without limitation: allegations of persistent non-compliance with (1) funding agency regulations, contract terms, or health and safety requirements, or (2) instructions from an Institutional Animal Care and Use Committee (IACUC) or an Institutional Review Board (IRB).

## 3.4. Research to which this Policy Applies

Research Misconduct involves Falsification, Fabrication, or Plagiarism in any portion of the Research Record, which is broadly defined under federal regulations and this policy. Research data or results need not be published formally to be covered by this policy.[32] The following examples (without limitation) of Research are covered by this policy:

- Manuscripts, masters' theses, and Ph.D. dissertations (and the data therein), whether formally published or not, when presented as a completed analysis or set of data;
- Data provided to a mentor or lab chief as representing the results of experiments;
- Reports to federal agencies (progress reports, renewal applications, extension requests, etc.);
- Preliminary data included as part of a funding proposal;
- Funding proposals withdrawn prior to consideration, denied without peer review, or unfunded;
- Research data or results referenced in funding applications, proposals, or reports;
- Abstracts, posters, oral presentations, or preliminary reports presented at conferences;
- Data reported to central databases, such as multi-center clinical trials or epidemiological Research;
- Statements contained in patent applications.[33]

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[30] Nothing in this policy shall be interpreted to limit the University's rights or obligations to enforce the "Board of Trustees Policies Governing Academic Freedom, Responsibility, and Tenure" or any other University policy.

[31] See ORI, Questions and Answers: 42 C.F.R. Part 93, at 1 (Dec. 22, 2011), http://ori.hhs.gov/print/QA-Reg-6-05 (describing the proactive application of 42 C.F.R. Part 93, with which this implementation schedule is consistent).

[32] 42 C.F.R. § 93.103; ORI, Handling Misconduct – Inquiry Issues, No. 15 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.

[33] ORI, Handling Misconduct–Inquiry Issues, Nos. 15, 19 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.

### 3.5. Application to Clinical Research

This policy applies to clinical Research, including (but not limited to) these specific examples of Research Misconduct in the clinical setting:

- Substituting one subject's research record for that of another subject;
- False reporting to a data coordinating center that procedures were performed by certified clinical trial staff;
- Altering dates or results from subject eligibility visits;
- Altering dates on subject screening logs or submitting the same log with altered dates on multiple occasions;
- Failing to update the subject's status (representing data from prior contacts as current);
- Altering the results of particular tests (e.g., blood tests or other samples) to show that a test accurately predicted a disease or relapse;
- Falsifying the times that blood samples were drawn from human subjects;
- Creating records of subject interviews that were never conducted ("curbstoning");
- Creating progress notes for patient visits that never took place; or
- Creating records of calls and follow-up contacts for subjects no longer participating in the study (e.g., deceased).

In contrast, the following types of conduct (without limitation) generally do not – standing alone – constitute Research Misconduct, although such conduct may be prohibited or regulated by other policies and regulations:

- Failing to report an adverse patient event to the sponsor or IRB;
- Deviating from IRB protocols (e.g., entering an ineligible subject in a trial or administering an off-protocol drug, so long as data from those erroneous subjects are not reported as valid data or included in the analysis);
- Failing to obtain IRB or funding agency approval for changes in a previously approved protocol;
- Forging a physician's signature on medical orders; or
- Breaching human subject confidentiality.[34]

### 3.6. Application to Faculty, Students, Staff, and Others Engaged in Research

This policy applies to any faculty member, academic or administrative staff member, Student Respondent, external collaborator, guest researcher, or affiliate who, at the time of the alleged Research Misconduct, is or was engaged in proposing, performing, reviewing, or reporting Research, regardless of the source of funding for the activity. This policy applies whether the conduct in question was in connection with paid employment or was unpaid.

**Students:** This policy applies to any currently-enrolled University student whose conduct is the subject of any Allegation of Research Misconduct, whether the questioned Research was conducted at the University or at some other institution or entity. Likewise, it applies to any previously-enrolled University student whose conduct is the subject of an Allegation of Research Misconduct, when the questioned research was conducted at the University, or when the former student remains otherwise affiliated with the University. This policy is *not* intended to govern the University's response to alleged breaches of academic integrity related to student work for which academic credit may be received *except* to the extent the alleged misconduct was part of the Research Record of an externally-funded project. The University may designate an academic administrator to provide guidance to a Student Respondent regarding academic issues that may arise related to the Research Misconduct Proceeding (e.g., if the work in question is a thesis or dissertation).

**Principal investigators:** Participants in collaborative Research (including scholarship) bear joint responsibility (sometimes to varying degrees) for ensuring the integrity of Research performed or published under their names. Principal Investigators (PIs) bear primary responsibility for ensuring the integrity of collaborative Research performed under their supervision. Investigators, department heads, and center directors are expected to make periodic and reasonable inquiries concerning the integrity of the Research activities conducted under their supervision. Intentional, Knowing, or Reckless failure to comply with the responsibilities of a Principal Investigator in connection with an act of Fabrication, Falsification, or Plagiarism committed by a person under the PI's direction or control can constitute Research Misconduct.

[34] ORI, Handling Misconduct–Inquiry Issues, No. 23 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.

**External collaborators, guests, and affiliates:** This policy applies to non-employee and non-student external collaborators to the extent required by federal regulations or funding agreements, and to the extent a written agreement exists linking the work of the collaborator to the University or its faculty, staff, or students. In the case of an external collaborator accused of Research Misconduct who is neither a University employee nor student, the RIO may refer the Allegation to the collaborator's employer, affiliated institution, or to oversight officials, in lieu of conducting a Research Misconduct Proceeding at the University. The University will cooperate with any such proceeding at another institution consistent with funding agreements and applicable law.

**Unavailable respondent:** The unavailability of a Respondent for any reason, including voluntary or involuntary separation from the University, should not delay the initiation or continuation of a Research Misconduct Proceeding. In exceptional cases (for example, grave illness of the Respondent or among the Respondent's immediate family), the Chancellor may modify application of this policy upon advice of the RIO, the Chief Research Officer, and University Counsel.

### 3.7. Limited Application after Six Years

A Research Misconduct Proceeding generally will not be initiated if the Allegation involves conduct occurring more than six years prior to the University's receipt of the Allegation.[35] Any exception to this six-year limitation period must be approved in advance by the Chief Research Officer, with the advice of the RIO and University Counsel. Exceptions include (without limitation):

- referral of an Allegation of Research Misconduct to the University from a federal agency beyond the six-year period;
- the alleged Research Misconduct that was not reasonably discoverable at an earlier time;
- continued or renewed conduct involving the questioned Research through the citation, re-publication, or other use of the Research Record at issue;
- alleged Research Misconduct that could have a substantial adverse effect on public health or safety;
- application of this policy is required by law or is otherwise in the best interest of the University;
- application of a different limitation period (or no limitation period) imposed by contract or funding entity.

### 3.8. Impact of Missing or Destroyed Research Records

Research Misconduct may include the destruction, absence of, or Respondent's failure to provide records adequately documenting the Research, where the institution or granting agency establishes by a Preponderance of evidence that:

- the Respondent Intentionally, Knowingly, or Recklessly
    - destroyed significant records previously created or maintained; or
    - failed to maintain the Research Records when given the opportunity to do so; or
    - failed to produce significant requested records in a timely manner;
- AND the Respondent's conduct regarding the records constitutes a significant departure from accepted practices of the relevant Research community.[36]

### 3.9. Statements of Credentials and *Curriculum Vitae*

A review of the academic and publishing credentials of an author or researcher during a peer review process may be vital to determining whether an individual is capable of performing the proposed Research.[37] Fabrication or Falsification of a researcher's credentials, *curriculum vitae*, or publication list (including manuscripts) may be within the Research Record and therefore can constitute Research Misconduct. In addition "misrepresentation of academic credentials" is a misdemeanor in the State of Tennessee.[38]

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[35] 42 C.F.R. § 93.105.
[36] 42 C.F.R. § 93.106.
[37] ORI, Handling Misconduct–Inquiry Issues, No. 6 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.
[38] "A person commits the offense of misrepresentation of academic credentials who, knowing that the statement is false and with the intent to secure employment at or admission to an institution of higher education in Tennessee, represents, orally or in writing, that the person:

1. Has successfully completed the required course work for and has been awarded one (1) or more degrees or diplomas from an accredited institution of higher education;

Duty to Cooperate and Protection Against Retaliation

### 3.10. Duty to Cooperate With Research Misconduct Proceedings

All University students and employees are required to cooperate fully with any Research Misconduct Proceeding, whether conducted under this policy, by oversight officials, or otherwise pursuant to a sponsored research agreement. Failure or refusal to comply with this obligation may constitute "adequate cause" or other grounds for disciplinary action, including termination of employment or dismissal of a student.

### 3.11. Reporting of Observed, Suspected, or Apparent Misconduct

All members of the University community are expected to report any observed, suspected, or apparent Research Misconduct to the RIO or Chief Research Officer. A statement of concern or an Allegation of possible Research Misconduct may be disclosed through any means of communication and need not be made in writing.[39] When an academic administrator becomes aware of possible Research Misconduct, he/she ***must*** immediately report the concern or Allegation to the RIO or Chief Research Officer.

### 3.12. Informal Consultation with the RIO

Any person concerned about possible Research Misconduct, or who is uncertain about whether to report a possible Allegation of Research Misconduct, is free to engage the RIO informally. He/she may describe concerns of possible inappropriate conduct and receive guidance about procedures for reporting various types of misconduct, including Research Misconduct. If the concern is not in the nature of Research Misconduct, the RIO may refer the reporting individual or the concern to another appropriate office or administrator.

### 3.13. Duty to Maintain Confidentiality

Anyone involved in reporting, reviewing, or evaluating an Allegation of Research Misconduct under this policy **must** make every reasonable effort to maintain confidentiality to the extent permitted by law or other University policy. Disclosure of the identity of Complainants, Respondents, or Research subjects is limited to people with a "need to know" the disclosed information in order to conduct University business, including conducting a thorough, competent, objective and fair Research Misconduct Proceeding.[40] Any records of evidence from which participants in a Research Misconduct Proceeding (or Research subjects) might be identified should be treated as confidentially as possible.

**Required disclosures**: Limited disclosure of an Allegation may be necessary for the effective administration of the department, college, or Research office, or to comply with regulations or contractual obligations. For example, federal regulations and other funding agreements require the University to report the status of Allegations of Research Misconduct. Limited disclosure may also be required as part of University Sequestration efforts, in order to comply with health and safety rules or regulations, or to protect against physical or other damage to a person or University property.

**Permitted disclosures**: With advice of University Counsel, the RIO or Chief Research Officer may disclose limited information about an Allegation or evidence in a Research Misconduct Proceeding in order to protect the University from exposure to legal claims or other possible harm. In such a case, the University will limit any such disclosures as narrowly as may be feasible under the circumstances.

**Reporting a concern about possible improper disclosure**: The RIO will review any allegation that this confidentiality requirement has been breached. Violation of this requirement may constitute grounds for disciplinary action, including termination, depending on the circumstances, the nature, and the impact of the violation.

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2. Has successfully completed the required course work for and has been awarded one (1) or more degrees or diplomas from a particular institution of higher education;
3. Has successfully completed the required course work for and has been awarded one (1) or more degrees or diplomas in a particular field or specialty from an accredited institution of higher education."

Tenn. Code Ann. § 49-7-133 (Aug. 11, 2009).

[39] 42 C.F.R. § 93.201.

[40] 42 C.F.R. § 93.108.

### 3.14. Duty to Report Retaliation

Retaliation is strictly prohibited against any person who raises concerns, asserts an Allegation of Research Misconduct, or who participates in any way in a Research Misconduct Proceeding. Engaging in Retaliation constitutes "Adequate Cause" for Sanctions against a faculty member; is grounds for disciplinary action (including termination) under applicable Human Resources policies; and may constitute grounds for disciplinary action against a student.

Any alleged or apparent retaliation against a Complainant, witness, committee member, student, or subordinate of a Respondent, should be reported immediately to the RIO. The RIO will review the matter and take all reasonable and practical steps to counter any actual (or potential) retaliation and to protect and restore the position and reputation of the person against whom retaliation has been directed.

### 3.15. Questions of Good Faith Reporting or Participation[41]

Any person concerned that an Allegation of Research Misconduct has not been made in Good Faith, or that a participant in a Research Misconduct Proceeding has acted or failed to act (including any statement or omission) in Good Faith, should immediately report such a concern to the RIO. Raising a concern about lack of Good Faith does not entitle the Respondent to suspension or modification of an ongoing Research Misconduct Proceeding. The RIO will review the concern, interview witnesses as he/she deems appropriate, and will make a recommendation to the DO as to whether there is substantial evidence of the lack of Good Faith.

A finding that a person has acted without Good Faith must be based on (1) evidence that the actor subjectively knew his/her statements to be false or (2) information indicating that a reasonable person with the same knowledge would not have believed he/she was providing accurate information. The DO's findings regarding Good Faith are final. Administrative Actions or Sanctions imposed in response to such a finding, however, may be appealed through the normal appeals processes, except that (at the DO's discretion) the Administrative Actions or Sanctions need not be held in abeyance pending appeal.

[41] 42 C.F.R. § 93.310.

# Section 4 - Sequestration and Interim Administrative Actions

## 4.1. Immediate Sequestration and Handling of Evidence

Upon receiving information about possible Research Misconduct, the RIO will prepare to sequester all materials relevant and necessary to conduct the Assessment and to ensure preservation of the Research Record. The RIO is responsible for sequestering as much of the Research Record as possible before a Respondent receives Notice of the Allegation. The RIO should consider the following measures (and identify others) at the earliest practical time following a decision that further review is needed:

- Sequester evidence that the Complainant or other witness may provide or identify;
- Work with a Complainant or other witness to identify any potentially relevant evidence, where the evidence may be maintained, and who likely controls the evidence;
- If needed, review the Allegation with one or more subject matter experts to identify potentially relevant evidence and any special arrangements needed for secure storage;
- Develop a plan for obtaining relevant evidence that may be outside the University's control;
- Identify electronic evidence or data (including e-mail) and where it is stored;
- Sequester broadly; consider what unidentified data might exist and where it might be located - e.g., recent grant proposals, other publications by Respondent and collaborators, if any;
- Coordinate whatever Sequestration team is required under the circumstances (e.g., security and facilities staff; information technology staff; sponsored research personnel; University Counsel, subject matter experts);
- Attempt to minimize the intrusion into the ongoing work of others, while ensuring appropriate Sequestration is undertaken;
- Ensure that the lab and all potential evidence is protected while the RIO meets with the Respondent;
- Sequester appropriate electronic devices by obtaining forensically sound copies of hard drives, including data that may be stored on personal laptops, home computers, tablets, etc.;
- Continue Sequestration of data in other locations and/or in the custody of others, as it is identified and based on priority;
- When possible, provide an itemized receipt for evidence sequestered; and
- Arrange to provide Respondent and others with copies of data (or access to equipment) as needed for ongoing work; asking them to identify their most immediate needs.

## 4.2. Initial Meeting With the Respondent, Including Sequestration

In many cases, the RIO will set up an initial meeting with the Respondent to provide Notice of the Allegation and to continue the Sequestration process. At that meeting, the RIO should seek the Respondent's cooperation in making decisions about sequestering data related to specific aspects of the Allegation. The more forthcoming the Respondent is during the initial Sequestration, the more narrowly the RIO can focus the process. By contrast, if the Respondent resists or fails to provide information during the initial Sequestration meeting, the RIO must sequester much more broadly. The RIO should also work with the Respondent to provide copies of data and limited access to materials needed for ongoing work when feasible.

## 4.3. Missing or Destroyed Research Records

Missing evidence can confound a Respondent's ability to defend effectively against Allegations of Research Misconduct. Extra scrutiny must be used in reviewing evidence presented during the Research Misconduct Proceeding which was previously missing or reported as lost. Allegations that evidence has been altered during a Research Misconduct Proceeding are common, and it is in the Respondent's interest to protect against any such Allegation by providing all potentially relevant evidence at the outset of the proceedings.

**Negative Inference Based on Missing Records**: The RIO, members of an Inquiry or Investigation committee, the DO, and oversight officials **may** make a negative inference from the absence or loss of evidence which, under the standards of the relevant scientific community, is normally maintained. Moreover, the Respondent's responses to requests for records and information during a Research Misconduct Proceeding are defined as part of the Research Record. Any Knowing, Intentional, or Reckless Falsification or Fabrication of evidence during a Research Misconduct Proceeding may constitute a separate instance of Research Misconduct.

To protect against these complications, the RIO and Respondent should work together to itemize all possible evidence and plan to search in all possible locations for records that are missing or still to be obtained. The RIO will anticipate that the Respondent may struggle to locate potentially relevant evidence during the initial meeting, so developing a plan for seeking additional and/or missing evidence will protect the Respondent during the Sequestration process.

### 4.4. Sequestration When a Respondent is Unavailable or Uncooperative

If a Respondent is not available to meet with the RIO and conduct the initial Sequestration, the RIO may proceed in the Respondent's absence. In that situation, the RIO will make efforts to communicate with the Respondent once Sequestration is in process, in order to focus the process as much as possible. In the event that the Respondent refuses to provide access to evidence identified by the RIO as requiring Sequestration, the RIO has the obligation and authority to enter any University-owned or -controlled property (with the law enforcement assistance if necessary) to retrieve University property.

### 4.5. Interim Administrative Action(s)

Throughout a Research Misconduct Proceeding, the RIO will monitor the situation to determine whether there exists any threat of harm to the public health, externally supported funds and equipment, or the integrity of the research process. In the event of a credible threat of this or similar nature, the RIO (in consultation with other institutional officials and ORI, as appropriate) will take interim Administrative Action. Such action is appealable through the normal appeal process but remains in effect during the appeal. Such action may include (without limitation):

- Protective action taken to preserve and protect human or animal subjects, the safety of research personnel, the Research Record, equipment, data, or other property owned by the University or entrusted to its control;
- Monitoring of the Research process and the handling of funds and equipment;
- Withdrawal or correction of pending or published abstracts or manuscripts;
- Reassignment or removal of personnel in connection with the project (including a PI or other investigator);
- Monitoring of ongoing Research and reporting;
- Delayed or limited approval or submission of manuscripts, publications, funding proposals, or reports;
- Required training (or additional training) in the responsible conduct of research.

In addition, federal regulations require that institutions notify oversight officials immediately if any of the following circumstances arise during a Research Misconduct Proceeding involving PHS-supported Research[42]:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- The resources or interests of the sponsor or research partner are threatened;
- Research activities are suspended, or the University determines that suspension is necessary;
- There is a reasonable indication of possible violations of civil or criminal law;
- Action by government oversight officials is required to protect the interests of those involved in the Research Misconduct Proceeding;
- The University anticipates that the Research Misconduct Proceeding may be made public prematurely; or
- The University determines that the Research community or public should be informed of the proceedings before completion of the full process.

### 4.6. Storage, Control, and Access to Sequestered Evidence

The RIO will catalog all evidence collected, establish a chain of custody, and ensure secure storage of evidence. Access to sequestered evidence by any person other than the RIO, a committee member, or University Counsel should be monitored.

[42] 42 C.F.R. § 93.318.

# Section 5 - Initial Assessment of Allegations

Upon receiving information regarding possible Research Misconduct, the RIO will immediately initiate an Assessment. At the Assessment phase, the RIO need not interview the Complainant, Respondent, or other witnesses, or gather data, except as he/she deems necessary to complete the Assessment. The Assessment period should be brief, preferably concluded within two business weeks when possible. In conducting the Assessment, the RIO has the discretion to request additional information from the Complainant or consult with experts in the discipline to aid in evaluating the conduct in question.

The purpose of the Assessment is to determine whether the Allegation (if true):

1. falls within the definition of Research Misconduct; and
2. is sufficiently credible and specific that potential evidence of Research Misconduct could be identified; and
3. includes conduct that appears to fall within the scope and application of this policy (see Section 3).

If an Allegation meets those three criteria and involves conduct that may have been committed by a person to whom this policy is applicable, OR a situation in which this policy *may* be applied, then further review under this policy **must** be undertaken.

If the RIO determines that further review of the Allegation under this policy is appropriate, the RIO will (with the advice of the Chief Research Officer and University Counsel) either initiate an Inquiry or a full Investigation. While an Inquiry is normally conducted before an Investigation is undertaken, the RIO may proceed directly to an Investigation (after consulting with the Chief Research Officer and University Counsel) in the following (and similar) circumstances[43]: minimal fact-finding substantiates the Allegation; the Allegation is referred from a sponsoring entity, including a federal oversight office; a Respondent has admitted to some or all of the alleged conduct; the Allegation has been substantiated by an ongoing or completed audit or other preliminary fact-finding process.

If the three criteria listed above are **not** met, the RIO **should** consult with the Chief Research Officer and University Counsel to determine whether further action is appropriate. Such action may include further review of the Allegation under this policy or referral to other institutional compliance officials. When a report of possible Research Misconduct also contains an allegation of other inappropriate conduct, the allegations will be severed and referred to other offices as the RIO finds appropriate.

## 5.1. Anonymous Allegations

The purpose of this policy is to ensure the integrity of Research, including scholarship. To that end, any anonymous Allegation, or an Allegation reported by an entity, even if no individual Complainant is identified, will be handled in the same way as any other Allegation. That is, when the Allegation is adequately specific and credible to permit meaningful review and is otherwise within the scope of this policy, the RIO will apply the same standards and criteria for review of all Allegations.

## 5.2. Notice of Allegation(s) to Administrators or Oversight Officials

If the RIO determines that an Allegation merits further review under this policy, the RIO (in consultation with University Counsel and the DO) will notify appropriate University officials. Such notification may include the department head/chair, director, and/or dean, as well as the Chief Academic Officer. The RIO, DO, and/or Chief Research Officer may consult with other University officials as needed during the Research Misconduct Proceeding. Because each Research Misconduct Proceeding involves competing concerns, notice to key officials may be determined on a case-by-case basis.

## 5.3. Identifying External Funding and Reporting Obligations

As part of the Assessment, the RIO should identify any external funding that may trigger obligations to federal agencies or other sponsors. The RIO should consult with University Counsel to determine what reporting obligations may be triggered to sponsors when a report of possible Research Misconduct is received. For example, PHS funding is "involved" when a proposal seeking PHS funds is submitted, regardless of whether the proposal is ever reviewed substantively or ultimately funded.[44]

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[43] ORI, Handling Misconduct–Inquiry Issues, No. 21 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.
[44] 42 C.F.R. § 93.221; ORI, Handling Misconduct–Inquiry Issues, Nos. 14, 19 (May 30, 2013), http://ori.hhs.gov/ori-responses-issues.

### 5.4. Possible Outcomes of the Assessment

The Assessment is complete when the RIO notifies the Respondent of one or more of these actions:

1. **Dismissal of the Allegation:** The RIO determines that the concern or Allegation (if true) does not meet the definition of Research Misconduct as defined in this policy. The Allegation is dismissed, and the Research Misconduct Proceeding is closed. This includes situations where the RIO concludes that there is not sufficient evidence or information to permit meaningful evaluation of an Allegation.
2. **Internal Referral:** The RIO determines that the conduct reported does not meet the definition of Research Misconduct but merits review by another institutional office or official (e.g., IRB, IACUC, Export Control, or referral to the department head or dean).
3. **External Referral:** The RIO determines that the conduct reported involves a person who is not affiliated with the University such that resolution of the Allegation requires referral to an external entity or institution. Such an external entity includes (but is not limited to) a sponsoring entity, government office or agency, law enforcement, publisher, or other academic institution.
4. **Inquiry:** The RIO determines that an Inquiry is required because the Allegation (if true) (1) falls within the definition of Research Misconduct; (2) is sufficiently credible and specific that potential evidence of Research Misconduct may be identified; (3) includes conduct that appears to fall within the scope and application of this policy (see Section 3).
5. **Investigation:** In rare situations, the RIO may determine that initial fact-finding conducted through some other internal or external review process indicates that the Allegation may have substance, in which case the RIO may proceed directly to an Investigation.

### 5.5. Written Report of the Assessment

To finalize the Assessment, the RIO will prepare a brief written report containing the following information:

- the name and credentials of each Respondent (including *curriculum vitae* if possible);
- the source and date of the Allegation;
- a statement of the Allegation with enough specificity to enable the Inquiry committee to conduct a fair and effective review of the conduct reported. The RIO may frame the Allegation more precisely than originally presented by the Complainant. Allegations should be further refined and restated by the RIO or the review committees during the Research Misconduct Proceeding. At a minimum, the Allegation should include:
- the nature of the alleged conduct (Fabrication, Falsification, or Plagiarism);
- the context in which the conduct in question occurred; and
- the specific method of Fabrication, Falsification, or Plagiarism alleged or suspected;
- a description of the evidence collected, reviewed, or sequestered during the Assessment;
- a clear statement of what action should be taken with regard to each Allegation, for each Respondent (e.g., dismissal, referral, Inquiry, or Investigation) and the rationale for each action; and
- any notes or guidance to the committee(s) about issues a committee may need to review.

### 5.6. Written Notice to the Respondent

The timing of Notice to a Respondent may vary depending on the need to obtain the Respondent's assistance during Sequestration efforts. In any event, the RIO must make a Good Faith effort to notify the Respondent in writing, either before or at the time an Inquiry begins, if the Respondent is known. If no Respondent has been identified, the RIO will notify each potential Respondent that an Inquiry will be undertaken (e.g., each co-author on a questioned publication or each investigator on a questioned grant proposal). Written Notice to the Respondent should include (without limitation):

- a description of the Research being questioned and any external funding involved;
- a statement of the Allegation;
- the definition of Research Misconduct and a copy of (or reference to) this policy; and
- reference to (1) the prohibition against Retaliation, (2) confidentiality requirements, and (3) the Respondent's duty to cooperate with the Research Misconduct Proceeding.

# Section 6 - Appointing an Inquiry or Investigation Committee

An Inquiry and an Investigation differ in both purpose and scope. Under this policy, Allegations of Research Misconduct are reviewed by one or more qualified scholars with the qualifications detailed below.

## 6.1. Appropriate Committee Structure – Specific to Each Proceeding

Whether charged to conduct an Inquiry or Investigation, the process for appointing the review committee is fundamentally the same. The RIO, in consultation with the Chief Research Officer and University Counsel, has broad discretion in setting up a review committee most appropriate to the circumstances of a particular Allegation.

| INQUIRY COMMITTEE MEMBERSHIP | INVESTIGATION COMMITTEE MEMBERSHIP |
|---|---|
| The RIO appoints an Inquiry committee consisting of at least one person who meets the requirements for committee membership outlined in Section 7.2. | The RIO appoints an Investigation committee consisting of at least three people who meet the requirements for committee membership outlined in Section 7.2. |

## 6.2. Identifying Committee Nominees

The RIO may solicit recommendations for committee membership from any source, and will ensure that anyone consulted in that process is aware of the University's confidentiality obligations. The RIO will contact each potential member of the committee to determine whether he/she is available to serve, to confirm that he/she has the required expertise, and to identify any potential Conflict of Interest.

Committee members will be selected based on their expertise and integrity, and:

- Must have appropriate expertise to evaluate the evidence and issues related to the Allegation, interview the principals and key witnesses, and otherwise be capable of conducting a full and fair review;
- Must not have any unresolved personal, professional, or financial Conflicts of Interest with any Respondent, Complainant, or anyone expected to be a critical witness;
- May be drawn from the same campus or from other UT campuses, and may include members from outside the University if adequate expertise and independence is not available within the University, or if the RIO determines that outside perspective is necessary to conduct an effective Inquiry;
- May have served on a previous committee in this (or another) Research Misconduct Proceeding or in any other capacity in any previous proceeding, so long as he/she otherwise meets the requirements for committee membership.[45]

## 6.3. Prohibited Conflicts of Interest

Unresolved Conflicts of Interest among key participants in a Research Misconduct Proceeding are prohibited. As defined in Section 2, a Conflict of Interest for the purpose of this policy means a past or continuing personal, professional, or financial relationship with another participant in the Research Misconduct Proceeding which creates an unmanageable (as determined by the RIO) bias for or against any Respondent, or which the participant him/herself personally believes renders him/her unable to participate in a manner that is thorough, competent, objective, and fair.[46]

Standing alone, service in some other role during a Research Misconduct Proceeding (the same proceeding or a different one) does not constitute a Conflict of Interest. Specifically, service on an Inquiry committee in the same Research Misconduct

[45] ORI, Sample Policy and Procedures for Responding to Allegations of Research Misconduct, § VII (Aug. 23, 2012), http://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations.
[46] *See* 42 C.F.R. § 93.300(b).

Proceeding does not create a Conflict of Interest relevant to that person's service on a later Investigation committee in the same (or other) Research Misconduct Proceeding.

If a Respondent asserts that the RIO has a prohibited Conflict of Interest, the purported conflict will be reviewed by the Chief Research Officer in consultation with other officials as the Chief Research Officer may find appropriate. The Chief Research Officer's decision regarding the RIO's eligibility to serve in any particular case will be final. If the RIO is unable serve in a particular case because of a Conflict of Interest or any other reason, the Chief Research Officer shall appoint an interim RIO as he/she deems appropriate. If a Respondent asserts that the Chief Research Officer has a Conflict of Interest, the Chief Academic Officer shall review the purported conflict and will act in place of the Chief Research Officer as he/she deems appropriate.

### 6.4. Respondent's Opportunity to Challenge Committee Nominations

The RIO will provide the Respondent an opportunity to object in writing to the appointment of any person to the committee on the basis that the person has an unresolved Conflict of Interest. To challenge the appointment of any nominee, the Respondent must identify and explain in writing the perceived Conflict of Interest **within 5 calendar** days of RIO's transmittal of the nomination. If the Respondent provides a timely written objection to a nominee, the RIO will review the purported Conflict of Interest with the nominee and other appropriate officials and will make a decision on the nominee's eligibility for service on the committee. The RIO's decision regarding composition of the committee is final.

## 6.5. Finalizing Committee Appointments

Once the membership of the committee is finalized, the RIO shall select a chair. Letters appointing members of the committee (but not identifying the Respondent by name) will be provided to each committee member, with a copy provided to his/her department head unless otherwise requested. Service on a Research Misconduct committee is challenging and time-consuming; such service should be recognized and rewarded as may be appropriate under relevant departmental, college, or campus evaluation criteria.

### 6.6. RIO's First Meeting with Committee

The RIO and University Counsel will be present or available throughout the proceeding to advise and support the committee. At the committee's first meeting, the RIO should:

- Review the charge;
- Summarize procedures for conducting the Inquiry/Investigation, and identify available resources;
- Describe Sequestration efforts to date and any security measures in place;
- Lead an initial discussion of the nature of the Allegation(s);
- Identify documents to be requested, Sequestration to be undertaken, or other support the RIO can provide;
- Guide the committee in organizing and planning the Inquiry/Investigation process, including establishing a schedule of meetings, and the eventual need to prepare a written report.

# Section 7 - Conducting an Inquiry or Investigation

## 7.1. Standard for Initiating an Inquiry or Investigation

| WHEN TO CONDUCT AN INQUIRY | WHEN TO CONDUCT AN INVESTIGATION |
|---|---|
| An Inquiry or other Research Misconduct Proceeding will be initiated after the RIO has conducted an Assessment and determined that an Inquiry is appropriate, that is whether the Allegation (if true)<br>• falls within the definition of Research Misconduct; and<br>• is sufficiently credible and specific that potential evidence of Research Misconduct could be identified; and<br>• includes conduct that appears to fall within the scope and application of this policy. | An Investigation will be initiated when the DO concludes (after reviewing the report of an Inquiry committee or other preliminary review of the Allegation):<br>• there exists a reasonable basis for concluding that the Allegation (if true) falls within the definition of Research Misconduct; and<br>• preliminary information-gathering and preliminary fact-finding indicate that the Allegation may have substance.[47] |

## 7.2. Written Notice Required *Before* Beginning an Inquiry or Investigation

| BEFORE AN INQUIRY | BEFORE AN INVESTIGATION |
|---|---|
| The RIO must make a good faith effort to notify the Respondent in writing, **either before or at the time an Inquiry begins**, if the Respondent is known. If not, the RIO will notify each potential Respondent that an Inquiry will be undertaken (e.g., each co-author on a questioned publication or each investigator on a questioned grant proposal). Written Notice to the Respondent should include (without limitation):<br>• a description of the Research being questioned and any external funding involved;<br>• a statement of the Allegation<br>• the definition of Research Misconduct and a copy of (or reference to) this policy, and<br>• reference to (1) the prohibition against Retaliation, (2) confidentiality requirements, and (3) the Respondent's duty to cooperate with the Research Misconduct Proceeding. | When the DO determines that Investigation is warranted:<br>• When PHS Support for the Research is involved, the RIO must notify ORI within 30 days of the decision to proceed to a full Investigation as detailed in the PHS regulations. The Notice must be provided to ORI **before the Respondent is notified** of the Investigation.[48] Notice requirements may vary for other oversight agencies or sponsors.<br>• The RIO must provide Notice of the Investigation to the Respondent (usually within **30 days** of the DO's decision) including a statement of the Allegation(s) to be investigated with respect to each Respondent.[49] |

## 7.3. Timeframe for Completion; Extensions of Time

| INQUIRY TIMEFRAME | INVESTIGATION TIMEFRAME |
|---|---|
| The University attempts to complete an Inquiry within 60 days from the date the committee is charged. The committee should attempt to complete its review during the first 30-45 days, to allow time to draft a report and obtain review by the RIO and University Counsel. | The University attempts to complete an Investigation within 120 days from the date the committee is charged. The committee should attempt to complete its review during the first 90 days, to allow time to draft a report, obtain review by the RIO and University Counsel, provide a draft report to the Respondent (with 10 calendar days to respond in writing), consider the Respondent's response, and finalize the report. |

[47] 42 C.F.R. § 93.307(d).
[48] 42 C.F.R. § 93.309.
[49] 42 C.F.R. § 93.310.

If Allegations or Respondents are added during the proceeding, the time for completion will normally be extended. All extensions should be documented, including the reasons supporting the extension. The RIO will notify the Respondent of extensions.

The RIO may grant an extension (or request an extension from oversight officials) whenever he/she deems it necessary in the interest of providing a fair process for any Respondent, witness, or other participant in the proceeding OR when it is otherwise in the best interest of the University to do so.[50] Continuation of the case over the summer months is not a valid reason for an extension. Committee members are expected to make themselves available (at least by phone or videoconference) for a series of meetings during the projected time span of the Inquiry/Investigation.

### 7.4. Adding / Revising the Allegation(s) or Adding Respondent(s) – Required Notice

During the Research Misconduct Proceeding additional instances of possible Research Misconduct may be discovered, which may require expanding the scope of the review beyond the Allegation(s) stated in the charge to the committee. Federal regulations and this policy require that the University attempt to discover any similar Research Misconduct that may have occurred by the same Respondent (e.g., in other publications). If the RIO, Inquiry committee, or Investigation committee identifies evidence that creates a reasonable basis to conclude that newly discovered conduct falls within the definition of Research Misconduct, the newly discovered conduct must undergo further review, either as a part of a revised Allegation or as a new Allegation, as determined by the RIO. Federal regulations and this policy require that the University attempt to discover any similar Research Misconduct that may have occurred by the same Respondent.[51]

The RIO will promptly notify a Respondent of any new or revised Allegation or any new Allegation identified during the Inquiry or Investigation, and will provide initial Notice to any new Respondent of the ongoing proceedings.[52] Although the Research Misconduct Proceeding does not begin anew for such a Respondent, his/her fundamental rights are nonetheless preserved: specifically, each Respondent is given written Notice of the Allegation and the opportunity to respond to the Allegation.

### 7.5. Substantive Questions for the Committee's Consideration

| INQUIRY QUESTION TO BE ANSWERED | INVESTIGATION QUESTION(S) TO BE ANSWERED |
|---|---|
| The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether the Allegation meets the criteria warranting an Investigation.<br>Specifically, the committee is charged to make findings of fact and recommendations as to whether:<br><br>1. there exists a reasonable basis for concluding that the Allegation (if true) falls within the definition of Research Misconduct (and is otherwise consistent with the scope and application of this policy); AND<br><br>2. preliminary information-gathering and preliminary fact-finding indicates that the Allegation may have substance. | The purpose of an Investigation is to develop a factual record by exploring the Allegation(s) in detail and examining the evidence in depth, leading to conclusions and recommendations by the committee using the following standard:<br>In the process of proposing, conducting, reviewing or reporting Research, a Respondent has committed Research Misconduct when a Preponderance of the Evidence supports a finding that<br>1. the Research Record contains information that is Falsified, Fabricated, or Plagiarized; AND<br>2. the Falsification, Fabrication, or Plagiarism is of such a nature or degree that it constitutes a significant departure from the accepted practices of the relevant Research community; AND<br>3. the Respondent's conduct (whether commission or omission) regarding the Falsification, Fabrication, or Plagiarism was Knowing, Intentional, or Reckless.[53]<br><br>Any defense raised by the Respondent (such as Honest Error or difference of opinion) must be established by a Preponderance of the Evidence. The absence of Research Records may be evidence of Research Misconduct when it is established by a Preponderance of the Evidence that the Respondent once had possession of the records but significantly departed from accepted practices of the relevant Research community when he/she Intentionally, Knowingly, or Recklessly destroyed, failed to maintain, or failed to produce such records in a timely manner. |

[50] *See* 42 C.F.R. § 93.311(b),(c)
[51] 42 C.F.R. §§ 93.307(b) and 93.310(h); ORI, Handling Misconduct-Technical Assistance, (Mar. 7, 2011), http://ori.hhs.gov/institutional-decision.
[52] 42 C.F.R. §§ 93.307(b) and 93.310(c).
[53] 42 C.F.R. §§ 93.104 and 93.106.

## 7.6. Key Elements of the Review

| KEY COMPONENTS OF THE INQUIRY | KEY COMPONENTS OF THE INVESTIGATION |
|---|---|
| **Data and Materials:** The Inquiry committee (through the RIO) requests or collects any documents, data, or other materials which the committee finds necessary to complete its charge.[54] | **Data and Materials:** The Investigation committee (through the RIO) requests or collects any documents, data, or other materials which the committee finds necessary to complete its charge.[55] |
| **Interviewing the Respondent:** The Inquiry committee should interview each Respondent unless the Respondent:<br>• declines to be interviewed or<br>• cannot respond (by interview or other means) to the Allegation.<br>• In such a case, the Inquiry committee will move forward with its conclusions and report after making all practical attempts to involve the Respondent.[56]<br><br>A Respondent may provide information to the committee in person, by phone or videoconference, and/or in writing, at the Respondent's discretion.[57] | **Interviewing the Respondent:** The Investigation committee must interview each Respondent unless the Respondent:<br>• declines to be interviewed or<br>• cannot respond (by interview or other means) to the Allegation.<br>• In such a case the Investigation committee will move forward with its conclusions and report after making all practical attempts to involve the Respondent.[58]<br><br>A Respondent may provide information to the committee in person, by phone or videoconference, and/or in writing, at the Respondent's discretion.[59] |
| **Interviewing the Complainant:** The Inquiry committee **will normally** interview the Complainant. | **Interviewing the Complainant:** The Investigation committee **must** interview each Complainant unless the Complainant declines to be interviewed or fails to respond to a request for an interview.[60] |
| **Interviewing Other Witnesses:** If the Inquiry committee concludes that interviewing additional witnesses is necessary to complete its limited charge, it may do so, but the committee **should not** conduct exhaustive interviews or analysis. | **Interviewing Other Witnesses:** The Investigation committee **must** interview any other available person who has been reasonably identified as having information regarding any relevant aspect of the Investigation, including witnesses identified by the Respondent.[61] |
| **Recording Interviews:** An interview of the Respondent **must** be recorded or transcribed. All other interviews **should** be recorded or transcribed but if not, a written summary of the interview **must** be prepared. The recording, transcript, or summary will be provided to the interviewee for correction and **must** be included in the record of the Investigation.[62] | **Recording Interviews**: All interviews **must** be recorded or transcribed. The recording or transcript will be provided to the interviewee for correction and **must** be included in the record of the Investigation.[63] |
| **New or Revised Allegations**: The Inquiry committee should revise, eliminate, or add Allegations as the evidence suggests, and should add other Respondents as deemed necessary. | **New or Revised Allegations**: The Investigation committee must pursue diligently all significant issues and leads discovered that are determined, by the committee or the RIO, to be relevant to the Investigation, including evidence of additional instances of possible Research Misconduct, and must complete a full Investigation unless otherwise advised by the RIO. |
| **Conclusion**: The Inquiry committee must recommend whether an Investigation is warranted, but should *not* make any determination of whether Research Misconduct occurred. | **Conclusion**: The Investigation committee must conclude whether Research Misconduct occurred, and if so, who was responsible. |

[54] 42 C.F.R. § 93.310(e).
[55] 42 C.F.R. § 93.310(e).
[56] 42 C.F.R. § 93.310(g); ORI, Questions and Answers: 42 C.F.R. Part 93, at 8 (Dec. 22, 2011), http://ori.hhs.gov/print/QA-Reg-6-05.
[57] The Respondent may (at his/her own expense and initiative) retain and consult with legal counsel or other adviser who is not also a witness in the proceedings. Any such adviser may attend the Respondent's interview with the Inquiry committee and provide advice to the Respondent during the interview, so long as the adviser does not address the committee directly or otherwise interfere with the proceedings.
[58] 42 C.F.R. § 93.310(g); ORI, Questions and Answers: 42 C.F.R. Part 93, at 8 (Dec. 22, 2011), http://ori.hhs.gov/print/QA-Reg-6-05.
[59] The Respondent may (at his/her own expense and initiative) retain and consult with legal counsel or other adviser who is not also a witness in the proceedings. Any such adviser may attend the Respondent's interview with the Investigation committee and provide advice to the Respondent during the interview, so long as the adviser does not address the committee directly or otherwise interfere with the proceedings.
[60] 42 C.F.R. § 93.310(g); ORI, Questions and Answers: 42 C.F.R. Part 93, at 9 (Dec. 22, 2011), http://ori.hhs.gov/print/QA-Reg-6-05.
[61] 42 C.F.R. § 93.310(g); PHS Comments on Final Rule, 70 F.R. 28370, at 28373 (May 17, 2005).
[62] 42 C.F.R. §§ 93.310(h) and 93.316(a).
[63] 42 C.F.R. §§ 93.310(h) and 93.316(a).

### 7.7. Written Report of the Committee's Conclusions and Recommendations

The committee will document its findings and recommendations in a written report containing at least the elements listed below.[64] The committee must submit a draft of the report to the RIO and University Counsel for review of compliance with this policy and legal sufficiency.

| INQUIRY REPORT CHECKLIST | INVESTIGATION REPORT CHECKLIST |
|---|---|
| 1. Name and position of the Respondent: Although a separate report must be prepared for each Respondent, portions of the reports may be similar (e.g., background and factual summaries); | |
| 2. List (with supporting documents attached) of funding sources related to the Research under review, particularly any basis for federal oversight jurisdiction (e.g., PHS support, citation of PHS-funded Research as preliminary data), including any relevant grant or proposal numbers, contracts, or publications; | |
| 3. Name and title of each committee member, attaching a current curriculum vitae for each member; | |
| 4. List of interviews conducted, attaching transcripts or interview summaries; | |
| 5. A copy of the written charge to the committee, with any attachments; | |
| 6. Statement of the specific Allegation(s) reviewed; | |
| 7. Summary of Sequestration undertaken and, if possible, a copy of the evidence log; | |
| 8. Narrative summary of the evidence and records reviewed (with a list of attachments, where appropriate); | |
| 9. For each Allegation of Research Misconduct, an explanation of the basis for the Inquiry Committee's recommendation that an Investigation is or is not warranted. | 9. For each Allegation of Research Misconduct, a detailed explanation of the Investigation committee's findings regarding:<br>• the nature of the Alleged conduct (Fabrication, Falsification, or Plagiarism);<br>• description of the method of fabricating, falsifying, or plagiarizing involved;<br>• key facts and analyses supporting the conclusion(s);<br>• the extent, seriousness, or impact of the Fabrication, Falsification, or Plagiarism based on the standards of the relevant research community; and<br>• the level of intent with which the Respondent committed the Fabrication, Falsification, or Plagiarism (Intentionally, Knowingly, or Recklessly). |
| | 10. Discussion of plausible mitigating explanations provided by Respondent; |
| | 11. Citation information for any publications in need of correction or retraction; and |
| | 12. Impact of any written response to the draft report submitted by the Respondent. |

### 7.8. Respondent's Opportunity to Comment on the Committee's Written Report

| RESPONDENT'S REVIEW OF INQUIRY REPORT | RESPONDENT'S REVIEW OF DRAFT INVESTIGATION REPORT |
|---|---|
| The RIO **must** give each Respondent Notice of the Inquiry committee's findings and recommendations including:<br>• a copy of the Inquiry report,<br>• a copy of or reference to this policy,<br>• and a copy of or reference to any applicable federal regulations.<br>• The Respondent may submit a written response to the report within **10 calendar days** of transmittal from the RIO. | The RIO **must** provide each Respondent with a *draft* of the Investigation report. The Respondent may submit a written response to the *draft report* within **10 calendar days** of transmittal from the RIO. |

[64] 42 C.F.R. § 93.309.

### 7.9. Complainant's Opportunity to Respond to the Committee's Written Report

At the RIO's discretion, the University may[65]:

- notify a Complainant of the Inquiry committee's findings; or
- provide the Complainant with a copy of the Inquiry report (in draft or final form) or relevant portions of the report; or
- invite a written response from the Complainant to the findings or the written report (or portions thereof).

If the RIO permits a written response from the Complainant, that response will be reviewed and considered by the committee if it is received within 10 calendar days of the date on which it is provided to the Complainant. If the committee receives and considers a Complainant's response, it will be included as an attachment to the final report.[66]

### 7.10. Possible Actions by the Deciding Official (DO)

After reviewing the findings and recommendations of the committee, together with any further information or recommendations provided by the RIO (normally within **30 days** of receiving the report) the DO will take one or more of the following responses:

1. Accept the report in full;
2. Return the report to the committee with instructions or questions for further consideration;
3. Make alternative findings, including a detailed explanation for doing so; OR
4. Reject the report in full, with a written explanation for the rejection.

[65] 42 C.F.R. §§ 93.308(b) and 93.312(b).
[66] 42 C.F.R. § 93.304(f).

# Section 8 - Making and Reporting a Finding of Research Misconduct

## 8.1. DO Finding of Research Misconduct Based on an Investigation Report

After reviewing the findings and recommendations of the Investigation committee, together with any further information or recommendations provided by the RIO (normally within **30 days** of receiving the report) the DO will take one or more of the following actions:

- Accept the report (in whole or in part);
- Make alternate findings by offering a detailed explanation of his/her reasons for doing so; or
- Return the report to the RIO and Investigation committee for further action. Specifically, the DO may return the report to the RIO and the committee with a request for further review, additional findings of fact, or clarification.

The DO's written decision is provided to the Respondent, to appropriate University officials, and to any oversight officials as required by applicable regulations or contracts.

## 8.2. DO Finding of Research Misconduct Based on a Fully Acceptable Admission[67]

Except in rare and specific circumstances, all Inquiries and Investigations will be carried through to completion, and all plausible and significant concerns of possible Research Misconduct will be reviewed. The RIO must notify appropriate oversight officials in advance if the University considers closing a case prior to completion of a full Investigation for any reason, including (without limitation) an admission of guilt by the Respondent or resolution of the Allegation through a negotiated agreement.

In a Research Misconduct Proceeding over which federal oversight officials (particularly PHS-ORI and NSF-OIG) have jurisdiction, the University is not permitted to accept an admission of guilt or other settlement arrangement without advance approval from oversight officials. If the RIO finds that it may be appropriate to negotiate a resolution or close a case prior to completion of the Investigation, he/she will first review the issue with the Chief Research Officer and University Counsel before taking further action to close the matter or seeking permission from oversight officials to close the Research Misconduct Proceeding before completion of a full Investigation.

Normally, an admission of Research Misconduct *is* a sufficient basis for proceeding directly to the Investigation stage. However an admission *may not* be a sufficient basis for closing a Research Misconduct Proceeding.

An Investigation is usually required to determine (or confirm) the extent of the Research Misconduct or to explore other possible instances of Fabrication, Falsification, or Plagiarism or to consider other possible Respondents who may share in the responsibility for Research Misconduct. Specifically, an admission of Research Misconduct during the early stages of a Research Misconduct Proceeding does not eliminate the need for the RIO to sequester evidence confirming the extent of the Research Misconduct. Federal regulations require that the University preserve all potential evidence of Research Misconduct until the case is concluded by federal oversight officials, including approval of an admission.[68]

An admission of Research Misconduct requires specific admission of all elements of the evidentiary standard and must:

- be made in writing, signed, dated, and witnessed;
- be made freely, without coercion or duress;
- identify the specific instances of Fabrication, Falsification, or Plagiarism;
- explicitly acknowledge that the conduct admitted constitutes Research Misconduct;
- explain the manner in which the Fabrication, Falsification, or Plagiarism was conducted or included in the Research Record; and
- identify any PHS or other external funding involved in the conduct at issue.[69]

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[67] 42 C.F.R. § 93.316.
[68] 42 C.F.R. §§ 93.316 and 93.317.
[69] ORI, Handling Misconduct – Inquiry Issues, No. 2 (Mar. 7, 2011), http://ori.dhhs.gov/ori-responses-issues.

If the Research Misconduct Proceeding is closed based on an approved admission, a report summarizing the steps taken in accepting the admission (including documentation of approval of the admission by federal oversight officials) will be sent to the DO, including any recommendations for Administrative Action or Sanctions.

### 8.3. Appeal Rights after a Finding of Research Misconduct

A decision by the DO that a Preponderance of the Evidence supports the finding that a Respondent committed a specific act of Research Misconduct is final and unappealable.[70]

In contrast, Administrative Actions or Sanctions imposed in response to a finding of Research Misconduct may be appealed through the normal appeals processes applicable to the Respondent, except that (at the DO's discretion) such actions need not be held in abeyance pending appeal. For example, faculty appeals may be taken through the process described in Board policies and the applicable faculty handbook; students may appeal in a manner described in the applicable student handbook; and staff may appeal under applicable HR policies.

### 8.4. Reporting to Oversight Officials

In cases where external funding is involved, the DO will report a finding of Research Misconduct to the appropriate officials within the granting agency or as required under the contract. The report should include actions proposed or imposed by the University in response to a finding of Research Misconduct. Such actions may include remedial, administrative, or disciplinary action against a Respondent, as well as lab-, department-, or campus-wide training initiatives. Revision of policies may also be recommended to the appropriate University office (e.g., safety policies, IRB approval processes).

Internal referral of a concern (including limited disclosure to a University official regarding the University's response to a finding of Research Misconduct) is consistent with the confidentiality requirements of the PHS regulations and this policy and procedures.

[70] ORI, Institutional Decision, http://ori.hhs.gov/institutional-decision (March 7, 2011); *see also* ORI Sample Policy, at p. 18.

# Section 9 - Closure of a Proceeding, Administrative Actions, and Sanctions

## 9.1. Initiating Remedial, Administrative, or Disciplinary Actions

This policy identifies some of the common remedial, administrative, and disciplinary actions the University may take in response to a finding of Research Misconduct; however, no list of possible responses could cover every case. The DO will consult with University Counsel before initiating any action in response to a finding of Research Misconduct.

- For remedial and Administrative Actions, the DO will advise the Chief Academic Officer and other appropriate academic officials of the actions proposed or imposed by the DO.

- For disciplinary action, the DO will consult with academic administrators, HR officials, or student disciplinary officials about possible disciplinary action. After consultation, the DO may conclude that the disciplinary action should be initiated by a department head, dean, Chief Academic Officer, or other administrator. The procedure for imposing disciplinary action is governed by policy and procedures applicable to each particular Respondent – staff (HR policies), faculty (HR policies, Board policies, and the Faculty Handbook), or students (student handbook and disciplinary processes).

## 9.2. Mitigating and Aggravating Circumstances[71]

In determining appropriate Administrative Action (remedial in nature) or in recommending Sanctions (disciplinary in nature), the University, at the DO's discretion, may consider information deemed relevant by the DO, including (without limitation) whether the:

- Respondent's actions were Knowing or Intentional, as opposed to Reckless;
- Research Misconduct was an isolated event or part of a pattern of improper conduct;
- Research Misconduct had a significant impact on the proposed or reported Research Record, subjects, other researchers, institutions, or the public health or welfare;
- Respondent accepted responsibility for the Research Misconduct by: (1) admitting the conduct; (2) cooperating with the Research Misconduct Proceeding; (3) demonstrating remorse and awareness of the significance and seriousness of the Research Misconduct; or (4) taking steps to correct or prevent the recurrence of the Research Misconduct;
- Respondent blamed others rather than accepting responsibility for the questioned conduct;
- Respondent retaliated (or attempted to retaliate) against any Complainant, witness, committee member, or others; and
- Respondent is presently responsible to conduct Research (e.g., has not been debarred from federally-sponsored research), including externally supported Research.

## 9.3. Implementing Administrative Actions

Upon finalizing his/her review of the Investigation report, the DO may impose Administrative Actions including (without limitation):

- Action taken to preserve and protect human or animal subjects, the safety of personnel, the Research Record, equipment, data, or other property owned by the University or entrusted to its control;
- Required training (or additional training) in the responsible conduct of research;
- Reassignment or removal of personnel in connection with any funded project (including a PI or other investigator);
- Monitoring of the Research process and the handling of funds and equipment;
- Enhanced review or regular audits of IRB or IACUC protocols and compliance;
- Withdrawal, correction, or retraction of pending or published abstracts or manuscripts (may be required as a condition for continued employment);
- Correction or retraction of published materials, including working with journal editors and co-authors to ensure that the Research Record is corrected;
- Internal review of proposals and manuscripts prior to external submission;

[71] *See* ORI, Questions and Answers: 42 C.F.R. Part 93, at 17 (Dec. 22, 2011), http://ori.hhs.gov/print/QA-Reg-6-05.

- Withdrawal or ongoing monitoring of Research proposals;
- Monitoring of ongoing Research and reporting;
- Required use of plagiarism-detecting software; or
- Delayed or limited approval or submission of manuscripts, publications, funding proposals, or reports.

The Respondent may appeal Administrative Actions through normal appeal procedures, but Administrative Actions will not be held in abeyance pending conclusion of the appeal.

### 9.4. Performance Evaluation Following a Finding of Research Misconduct

If a member of the University staff or faculty is found to have committed Research Misconduct, the employee's performance evaluation should reflect that finding in enough detail to permit later review by administrators who conduct or review performance evaluations for that employee. Depending on the nature and severity of the Research Misconduct, an overall negative performance rating may result, and corresponding salary implications may follow (e.g., loss of eligibility for merit pay or ineligibility for an across-the-board salary increase). A finding of Research Misconduct should also be considered in tenure and promotion decisions.

### 9.5. Disciplinary Sanctions

Sanctions in response to Research Misconduct may include a range of actions, up to and including termination of employment, pursuant to the procedures set out in the applicable Board policies and faculty handbooks. Sanctions specifically appropriate to cases of Research Misconduct may include (without limitation) one or more of the following:

- Suspension or termination of graduate teaching faculty credentials;
- Bar from recruiting or hiring graduate students or post-doctoral associates;
- Bar from submitting proposals for internal University grants or other competitive funding (e.g., industry grants);
- Limits on access to (or spending of) funds allocated to the faculty member's discretionary use (e.g., finance and administrative funds or travel funds);
- Limits on the types of Research in which a researcher may engage (e.g., involving human subjects);
- Suspension of employment, with or without pay, for a defined period of time;
- Termination of employment.

Debarment from participation in federal-wide research support (e.g., by PHS or other agency) meets the standard of "Adequate Cause" for termination or other Sanction pursuant to Board Policies Governing Academic Freedom, Responsibility, and Tenure. In any case of federal debarment, the Chief Research Officer will review the circumstances and consider whether Sanctions, up to an including termination of employment, should be imposed.

A Respondent may appeal any Sanction in any manner permitted based on the nature of the Respondent's employment/affiliation with the University. For example, faculty appeals may be taken through the process described in Board policies and the applicable faculty handbook; students may appeal in a manner described in the applicable student catalog or handbook; and staff may pursue any appeal available under HR policies.
Sanctions against faculty members will be held in abeyance while an appeal is pending only if abeyance is required by Board policy.

### 9.6. Preventing or Mitigating Retaliation

Even after a Research Misconduct Proceeding is concluded, any concern about possible Retaliation against a Complainant or participant in a Research Misconduct Proceeding should be immediately reported to the RIO. The RIO will review the matter with University Counsel and, as necessary, make all reasonable and practical efforts to counter any actual (or potential) Retaliation and to protect and restore the position and reputation of the person against whom the Retaliation has been directed.

### 9.7. Closure of Research Misconduct Proceedings

After consultation with the Chief Research Officer, University Counsel, and federal oversight officials where appropriate, the RIO will provide Notice (to Respondents, Complainants, witnesses, University administrators, and committee members)

explaining that the Research Misconduct Proceeding is closed and providing any necessary instructions regarding the RIO's collection and retention of records.

In cases where an agency's oversight review is likely to continue, the RIO cannot close the case but may collect and retain records, explaining the impact of ongoing agency review. The University's Research Misconduct Proceedings may be closed by the RIO after the DO's final decision; however, the University remains obligated to assist ORI or other oversight officials in any further review. The University's proceedings may be reopened at the request of oversight officials.

### 9.8. Measures to Protect or Restore Respondent's Reputation

The University will undertake all reasonable and practical efforts (if requested, and as appropriate) to protect or restore the reputation of any Respondent against whom no finding of Research Misconduct is made.[72] The Respondent should consult with the RIO to identify and discuss possible restorative measures.

### 9.9. Records Retention

This policy and federal regulations require that the University maintain records of a Research Misconduct Proceeding for at least seven years after *all* proceedings are completed, including any action taken by oversight officials. The seven-year retention period begins when all proceedings have been closed, including any review or action by oversight officials.[73]

### 9.10. Ongoing Compliance with Administrative Actions, Debarment, or Supervised Research

PHS regulations require that (upon request) the University assist ORI in implementing Administrative Actions imposed by PHS, either during a Research Misconduct Proceeding or after a proceeding is concluded, including (without limitation): debarment from receiving federal grant and contract funds; certification of sources; certification of data; supervision of Research; retraction or modification of articles.[74] The RIO should monitor retractions and modifications by tracking the articles in question for at least one year and should notify editors if modified or retracted publications appear without proper notice of modification or retraction.

[72] 42 C.F.R. § 93.304(k).
[73] 42 C.F.R. §§ 93.316 and 93.317.
[74] 42 C.F.R. §§ 93.300(h) and 93.407.

# Appendix A: Sharing, Retention, and Ownership of Research Data

Research Data are a valuable asset to the University. This policy protects the property rights of individual researchers and the University by addressing definition, responsibility, control, and distribution of certain data. This policy is applicable to Research Data developed by University employees in performing the duties of their University employment or through substantial use of funds and facilities provided by the University. This policy assures that Research Data are adequately recorded, archived, retained, and accessible for sufficient time to support the associated Research that produced the data and any intellectual property based on that Research.

## Definition of Research Data

For purposes of this policy, Research Data includes all records necessary for the reconstruction and evaluation of reported results of Research and the events and processes leading to those results, regardless of form or media. Research Data may include laboratory notebooks, databases documenting Research, and other compilations of information developed during Research. Research Data are distinct from, but may be associated with, other intellectual property such as patentable or copyrightable works, and trademarks, which are addressed by other University policies.

## Control of Research Data

The University supports the principle of openness in Research. Free dissemination of data, processes, and results of Research and other sponsored activity is crucial to a vibrant and healthy academic environment. The University promotes the prompt and open exchange of Research Data with scientific colleagues outside the investigator's immediate laboratory or department, subject to relevant grants, contracts or other binding agreements, compliance requirements, or the protection of intellectual property.

In the case of externally sponsored Research involving a grant, contract, or other agreement, the Principal Investigator (PI) is responsible for controlling storage, use, and distribution of Research Data arising from the Research activity, subject to provisions of the applicable grant, contract, or other agreement, University policy, or applicable law. Data generated at the University generally is owned by the University.

If a PI leaves the University and a Research project is to accompany the PI to a new institution, ownership of the Research Data may be transferred with the approval of the Chief Research Officer and with written agreement from the PI's new institution that ensures clarity regarding in handling:

- custodial and other responsibilities for the Research Data;
- access to the Research Data by the University and other sponsors; and
- protection of the rights of human and animal subjects.

Questions of Research Data ownership or other matters pertaining to the Research Data policy will be resolved by the Chief Research Officer in conformance with University policies. When necessary to assure access to Research Data, the University has the option to take custody of the data in a manner specified by the Chief Research Officer.

## University Responsibility for Research Data

The University is ultimately responsible for the accuracy and sufficiency of Research Records, the cornerstone of rigorous Research. Therefore, the University is responsible for Research Data developed by personnel while performing their assigned duties or through substantial use of facilities or funds provided by the University. Such responsibility applies to Research funded by external sources and managed by the University, unless the University agrees to another arrangement in a grant, contract, or other agreement. Specifically, University obligations regarding Research Data include (without limitation):

- Ensuring the academic freedom of the faculty in pursuit of the University's mission of developing and disseminating new knowledge;
- Securing and protecting intellectual property rights connected with Research Data and commercialization of those rights where appropriate and feasible;

- Protecting the right of access to Research Data, of faculty, postdoctoral scholars, students, and staff;
- Avoiding undue interference with appropriate dissemination of Research Data in the academic community;
- Complying with the terms of sponsored grants, contracts, other agreements, or applicable law;
- Reviewing all charges of Research Misconduct, Conflict of Interest, or similar charges or disputes; and
- Ensuring the appropriate care of animals, human subjects, recombinant DNA, radioactive materials, controlled substances and the like.

**Responsibilities of the PI or Laboratory/Department Head Regarding Research Data**

Final responsibility and control of Research Data remains at all times subject to the other provisions of this policy. Specifically, however, the PI or the laboratory/department head is responsible for the following:

- Collection of Research Data, including production of defensible laboratory notebooks;
- Management of Research Data to ensure efficient and effective retrieval by the PI, other personnel within project team, or appropriate administrative personnel or research sponsors;
- Development of a formal Research Data plan and procedures where appropriate;
- Consideration of a system for preserving Research Data in the event of a natural disaster or other emergency;
- Retention of Research Data for the requisite period of time (see below);and
- Documented communication of the management system and description of the data managed to members of a research group and to the Chief Research Officer.

**Specific Obligations Regarding Preservation of Research Data**

**The PI or the laboratory/department head must preserve Research Data for a minimum of six (6) years after the final project close-out**, with original data retained where feasible, and unless otherwise required by law. The following circumstances may require longer retention:

- If data supports a patent (or patent application), such data must be retained as long as the patent and any derivative patents are valid;
- If Allegations of scientific Research Misconduct, conflict of interest, or other charges arise, data must be retained until such charges are fully resolved plus seven (7) years;
- If a student participates in the project, Research Data must be retained at least until the degree is awarded or the student has unambiguously abandoned the work; and
- As required by the terms of a grant, contract, other agreement, or applicable law.

Beyond these periods, destruction of the Research Record is at the discretion of the PI or the laboratory/department head. Research Data will normally be retained in the administrative unit where generated. Research Data must be retained in a University facility unless specific permission to do otherwise is granted by the Chief Research Officer.

## Appendix B: Expectations of the Principal Investigator

The University values and relies on the intellect and oversight responsibilities of individuals serving in the role of Principal Investigator (PI) with respect to Research activities. Consistent with the prestige and impact associated with PI status, each PI takes final responsibility to ensure compliance with all the rules and regulations that may apply to his/her Research. The University community is mindful that regulatory definitions of a PI identify this person as the primary individual responsible for the preparation, conduct, and administration of a grant, cooperative agreement, training or public service project, contract, or other project in compliance with applicable laws, regulations and institutional policy governing the conduct of research.

PIs must ensure that approval has been obtained from the appropriate review committees prior to initiating or becoming involved in Research that involves human subjects, vertebrate animals, radiation or radioactive compounds, biohazards, toxic substances, or any other material or activity covered by University, state or federal regulation.

The University expects individuals identified as Principal Investigators to meet the following minimum standards of professional conduct:

1. Read and comply with the University's Research Misconduct Policy and Procedures;

2. Create an environment that encourages and rewards integrity through open discussion, emphasis on quality, appropriate supervision, maintenance of accurate and detailed records, and the fair assignment of responsibility and credit in the specific discipline;

3. Maintain high standards of professional and ethical conduct (including discipline-specific expectations) throughout all phases of their projects, including conception, initiation, implementation, and reporting;

4. Monitor ongoing Research and other scholarly activities to ensure compliance with approved protocols and established professional norms, and make timely requests for extensions of time or protocol revisions;

5. Ensure that all personnel involved in Research and scholarly activities are fully trained in accordance with the relevant regulations, including an understanding of the University's Research Misconduct Policy and Procedures;

6. Promptly report to the RIO or Chief Research Officer any observed, suspected, or apparent concerns of possible deviations from the accepted practices of the relevant research community;

7. Cooperate with the University or other institutions conducting Research Misconduct Proceedings, to the extent permitted by law and in consultation with University administration, University Counsel, or the RIO;

8. Cooperate fully with any Research Misconduct Proceedings administered directly by a federal funding agency (or its designee) or conducted pursuant to a sponsored research agreement.

## Appendix C: Summary of Protections and Obligations Applicable to the Respondent*

During the course of a Research Misconduct Proceeding, the University will make all practical efforts to ensure that core procedural protections are afforded to the Respondent, consistent with obligations to funding agencies and other sponsors.

The Respondent has the right to receive Notice of an Allegation of Research Misconduct and an opportunity to respond to the Allegation. Coincident with those rights are the *responsibilities* of the Respondent, which are included in the following summary.

Specifically, the University will:

1. Make a good faith effort to provide written Notice of the Allegations to the Respondent at the time of, or before, beginning an Inquiry;

2. After Sequestration, except as may be deemed necessary by the RIO, provide the Respondent with copies of, or reasonable supervised access to, the Research Record;

3. Provide the Respondent an opportunity to comment on the Inquiry report and draft Investigation report and attach to the final report any written comments from the Respondent received within the comment period;

4. Notify the Respondent of the outcome of the Inquiry and provide a copy of the final Inquiry report with attachments;

5. Provide the Respondent with written Notice of any revised or new Allegations as they may be identified by the RIO, Inquiry committee, or Investigation committee;

6. Provide the Respondent a full opportunity to respond to the Allegation in writing, in an interview with the Inquiry or Investigation committee, or both (as the Respondent may choose);

   NOTE: While the policy does not require that the Respondent be interviewed during an Inquiry, the Respondent may request an opportunity to respond to the Allegations in an interview with the Inquiry committee, and a timely request to do so will normally be granted, in the RIO's discretion. Any interview with the Respondent will be recorded or transcribed.

7. Interview any witness who has reasonably been identified by the Respondent (during the Investigation) as having information on relevant aspects of the Investigation. Interviews with witnesses will normally be recorded or transcribed;

8. Permit the Respondent, at his/her own expense and initiative, to retain and consult with legal counsel or other adviser (who is not also a witness in the proceedings). Respondent's legal counsel or other adviser may attend the Respondent's interview with an Inquiry or Investigation committee and provide advice to the Respondent during the interview, so long as the legal counsel or adviser does not address the committee directly or otherwise interfere with the proceedings.

9. When no finding of Research Misconduct is made, undertake all reasonable and practical efforts to protect or restore the reputation of such a Respondent, if requested and as appropriate, and in consultation with the Respondent;

10. Provide an opportunity for the Respondent to appeal – pursuant to the applicable appeal procedures – any Administrative Actions or Sanctions imposed as a result of a finding or admission of Research Misconduct.

* This appendix includes a summary of specific procedural protections and obligations related to the Respondent but does not replace or alter the specific requirements of the policy or applicable regulations.

During a Research Misconduct Proceeding, the Respondent must continue to comply with all applicable University rules and policies. The University expects that the Respondent will:

1. Conduct him/herself professionally and in accord with specific instructions of the RIO, DO, Chief Research Officer, or other University official implementing this policy;

2. Cooperate fully in the Research Misconduct Proceeding;

3. Provide the RIO with all requested information or evidence, including relevant aspects of the Research Record of which the RIO may not be aware, and assist the RIO in locating any evidence that may be relevant but not within the Respondent's immediate control; and

4. Refrain from any form of Retaliation against any Complainant known or suspected by the Respondent. Retaliation for making a Good Faith Allegation or for Good Faith participation in a Research Misconduct Proceeding is specifically prohibited by federal law and by this policy.

5. The Respondent should take care to avoid even the appearance of Retaliation against a person making an Allegation or cooperating with the Research Misconduct Proceeding. If the Respondent has a question about whether contemplated action might constitute prohibited Retaliation, he/she should seek the advice of the RIO.

6. If a Respondent believes that an Allegation has been made in bad faith, he/she should provide a written explanation of that concern to the RIO, who will follow this policy with respect to an Allegation made in bad faith. Raising a concern of bad faith does not entitle the Respondent to suspension or modification of ongoing Research Misconduct Proceedings.

_____ Date: _____

Respondent acknowledges receipt of Summary of
Protections and Obligations Applicable to the Respondent

_____ Date: _____

Research Integrity Officer

## Appendix D: Sample Allegation Intake Form

| | |
|---|---|
| Date | |
| Case ID | |
| Research Integrity Officer (RIO) | |
| Complainant (contact information and relationship to possible Respondents or witnesses) | |
| Possible Respondent(s) (title and contact information) | |
| Other collaborators, co-authors, or witnesses, at UT or elsewhere | |
| Possible funding sources | |
| Human or animal subjects | |
| Hazardous materials or biologics | |
| ALLEGATION(S) (identify available detail about specific Falsification, Fabrication, or Plagiarism alleged | |
| Possible evidence in support (or rebuttal) of Allegation(s) | |
| Location and nature of possible evidence requiring Sequestration | |
| Concerns and warnings against Retaliation | |
| RIO notes (including any concern about whether the Allegation was not made in Good Faith) | |