

Scientific Integrity and the Consequences of Misconduct in Research

Procedures document

1. Preliminary Assessment of the Allegation

All employees or individuals associated with Tufts University should report observed, suspected, or apparent research misconduct. Reports of research misconduct may be made to the dean of the school where the misconduct occurred, the director of the Human Nutrition Research Center on Aging (HNRCA) where appropriate, relevant department chairs, and/or Provost or Vice Provost for Research (and in instances where a faculty member has a dual appointment with another institution, the Chief Executive Officer of an affiliated institution). All allegations of research misconduct, whether first reported to the Provost, deans/directors or department chairs (or their designee), are to be immediately forwarded to the Vice Provost for Research for preliminary assessment. The Vice Provost for Research serves as the Research Integrity Officer (RIO) for Tufts University.

If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the Vice Provost for Research (or the University ombudsman) to discuss the suspected research misconduct informally.

Upon receiving an allegation of research misconduct, the Vice Provost for Research consults in confidence with the Provost, deans, department chairs and other University personnel as deemed appropriate and applicable by the Vice Provost of Research, to determine whether the allegation meets Tufts University's definition of research misconduct. The purpose for this initial assessment is to determine the appropriate roles and responsibilities of Tufts University, its personnel, and its oversight agencies with respect to evaluating the allegations, as well as to identify individuals, information, and data relevant to the allegation.

Coordination with Other Institutions When Faculty Have a Dual Appointment

When the Vice Provost for Research has received a credible allegation of misconduct with respect to a faculty member who has a dual appointment with another institution, the Vice Provost for Research will coordinate with the Chief Executive Officer of the other institution (or his/her designee) to determine, after such consultation as may seem appropriate, whether primary responsibility for resolving the allegation rests with Tufts University or with the other institution. An affiliated institution that has received support for research by a Tufts University appointee may request, however, that allegations related to research by such appointees be dealt with by Tufts University. In any case, where the interests of two or more institutions are significantly implicated, it is expected that such inquiry and any investigation will proceed with the simultaneous participation of all concerned institutions, with agreement regarding which institution bears primary responsibility.

For example, for Tufts University School of Medicine faculty with a dual appointment at a hospital, the primary responsibility for resolving an allegation of misconduct in connection with care of a patient would ordinarily reside in a hospital. In the case of an allegation pertaining to externally funded research, primary responsibility ordinarily rests with the institution that has administered the research grant or contract.

Determination to Conduct an Inquiry

If, after assessing the allegation, the Vice Provost for Research determines that the allegation meets the definition of research misconduct as defined in Tufts University's Research Misconduct Policy and warrants further action, the Vice Provost for Research will initiate the research misconduct review process. The Vice Provost for Research serves as Tufts University's Research Integrity Officer (RIO), and the Office of the Vice Provost for Research (OVPR) will assist pre-inquiry activities by gathering and summarizing data and information related to the allegation for use by those evaluating the allegation.

Determination to Dismiss an Allegation

If, after assessing the allegation, the Vice Provost for Research determines that the allegation does not warrant further action and/or does not meet the definition of research misconduct as defined in this policy, the Vice Provost for Research will formally dismiss the allegations. The Vice Provost for Research need not notify the respondents of such allegations. However, the Vice Provost for Research may notify the complainant that the allegations will not be pursued under Tufts University's Research Misconduct Policy.

2. The Inquiry Process

Purpose of Inquiry

The purpose of the inquiry, to be performed by a fact finder as defined below, is to determine whether the allegation or apparent instance of research misconduct warrants an investigation based on an initial review of the available evidence. The purpose of the inquiry is NOT to make a final determination on the validity of the allegation based on its merits.

Timeframe

The entire inquiry process from initiation of the process by the Vice Provost for Research following receipt of an allegation to submission of the inquiry report to the Vice Provost for Research must be completed in sixty (60) calendar days. Any request by the fact finder for an extension must be justified and included in his or her final report. Only if exigent circumstances exist, the Vice Provost for Research may determine whether extending the 60 day period is warranted.

Initiation of Inquiry

The Vice Provost for Research determines if the alleged behavior meets the definition of misconduct in research as detailed in the University Policy and is sufficiently credible and specific so that potential evidence of misconduct in research may be identified. Additional information may be requested from the complainant as necessary if the issue of credibility remains in question. Once it is determined that the criteria for an inquiry are met, the Vice Provost for Research initiates the inquiry process.

If the Vice Provost for Research determines that the alleged behavior meets the definition and is sufficiently credible and specific, the Vice Provost for Research will appoint a fact finder to conduct an inquiry.

Notifications

Within 15 days of the determination to convene an inquiry, the Vice Provost for Research will notify the respondent of the allegation in parallel to taking custody of the records. A certified letter detailing the allegations will also be sent to the respondent at his/her home address. The respondent notification includes:

- The specific allegation(s)
- The rights and responsibilities of the respondent
- The role of the fact finder
- A description of the inquiry process
- Copies of Tufts University's Research Misconduct Policy and Procedures

The respondent will be notified that this is only the inquiry phase, and s/he will be given sufficient opportunity to respond to the allegations. If the allegations cannot be substantiated, the inquiry phase will end, and no notification of the inquiry will be made to the research sponsor (unless the sponsor brought forth the allegation and requires the outcome of the inquiry phase). The respondent will also be briefed on the consequences of spoliation (i.e. the intentional, reckless, or negligent withholding, hiding, altering, or destroying of evidence). At any point in the process, the respondent is free to obtain outside legal counsel at his/her expense, although this is not a requirement of the process.

Sequestration

Prior to or at the time of notification of the respondent, the Vice Provost for Research will contact the respondent's department chair and arrange for the immediate securing of the respondent's research records and any other evidence needed to conduct the research misconduct proceeding. The purpose of the Vice Provost for Research taking custody of the records is to protect all parties to the proceeding. If the respondent is a department chair, the Vice Provost for Research will take sole responsibility for securing the records.

In general, research records include but are not necessarily limited to any data, document, email computer file, computer storage device (e.g. flash drive) or any other electronic or hand-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted or reported research (see Research Misconduct Policy for full definition). These research records includes those found on personal devices, such as laptop computers, tablets, external drives, flash drives, etc., if those devices are used for Tufts-related research. All research files on personal devices are considered property of Tufts and part of the research record, and therefore these devices may be secured during the sequestration process.

Research records will be sequestered in a manner that causes minimal disruption to research. The OVPR will provide the respondent with an inventory of items sequestered and will generally provide copies of most sequestered items within two or three business days after sequestration, although specialty copies such as gels and films may require a longer period of time to duplicate. All reasonable attempts will be made to protect the confidentiality of the research records and of all activities and persons involved. Access to the records or copies thereof will be provided wherever possible for other members of the research team, and to the respondent, while under supervision. All records and evidence will be kept locked in a secure location within the offices of the Vice Provost for Research or maintained in a secure location as directed by the Vice Provost of Research. Biological materials that are sequestered will be properly stored in a secure environment.

Selection of Fact Finder

The Vice Provost for Research will appoint at least one full-time faculty members to serve as fact finder. The fact finder must have appropriate scientific expertise to evaluate the evidence and issues related to the allegation and must have no personal, professional, or financial conflicts of interest with the complainant or respondent.

The Vice Provost for Research will accept from the respondent in writing a list of specific names of faculty to which there is an objection towards being selected as a fact finder based on a personal, professional, or financial conflict of interest. The Vice Provost for Research may also consult with the relevant school deans (e.g. the potential fact finder's dean) as appropriate. The Vice Provost for Research makes the final determination of whether any such conflict exists that validates the objection(s).

Charge to Fact Finder

The Vice Provost for Research provides the charge to the fact finder, which includes:

- Purpose of the inquiry;
- Definition of research misconduct;
- Timeframe for completion;
- Identification of respondent;
- Specific allegation(s) to be evaluated;
- Responsibilities of the fact finder, including:
 - Initial review of evidence, including review of research records;
 - Interviews of complainant, respondent and/or others if deemed necessary and appropriate;
 - Preparation of a final report; and
- Copies of Tufts University's Research Misconduct Policy and Procedures.

Responsibilities of Fact Finder

The fact finder is responsible for determining whether the allegation or apparent instance of research misconduct warrants an investigation based on an initial review of the available evidence. The fact finder may also request to interview the complainant, respondent, and/or others, if necessary and appropriate. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. Therefore, the fact finder is not responsible for making a final determination based on the merits of the allegation, but rather to determine if there is sufficient reason to convene an investigation.

The fact finder will consider all statements and evidence initially reviewed and will recommend to the Vice Provost for Research whether or not the allegation falls within the definition of misconduct in research, and whether or not the allegation may have substance.

The fact finder may also identify, in the course of his or her duties, if there are issues that would justify broadening the scope of the misconduct proceeding beyond the initial allegation.

Upon determining whether an investigation is warranted, the fact finder will report the recommendations in writing to the Vice Provost for Research.

The fact finder will come to a determination of whether an investigation is warranted based on the initial review of the available evidence. The findings and recommendations are summarized in a written report to the Vice Provost for Research. The inquiry, including the final report and decision of whether an investigation is warranted, should generally be completed within 60 days of the convening of the inquiry.

3. The Inquiry Report

At the conclusion of the inquiry, the fact finder prepares a written report for the Vice Provost for Research. This report, which will become a permanent part of the record, must be in sufficient detail to allow the Vice Provost for Research to make a determination of whether or not a full investigation is required.

Content of Inquiry Report

The required elements of the final inquiry report include:

- Name(s) of fact finder(s);
- Fact finder charge, i.e. the identification of respondent and a description of allegation(s);
- Process used in accordance with Tufts University's Research Misconduct Policy and Procedures;
- Inventory of evidence reviewed;
- The basis for the fact finder's recommendations for each allegation;
- Identification of any federal support; and
- Respondent comments (if any) on the fact finder's summary report.

Opportunity to Comment on Inquiry Report

A copy of the report will be provided to the respondent for comments. Relevant portions of the report may also be provided to the complainant for information and/or comment as deemed appropriate by the Vice Provost for Research. The respondent and complainant (if applicable) are given 10 days for their responses. Any comments by the respondent or complainant will be included in the final inquiry report to the Vice Provost for Research and will remain part of the inquiry document as it moves through the investigation and decision phases.

Actions Taken on the Basis of Inquiry Report

If, based upon a review of the inquiry report, the Vice Provost for Research determines that the allegation does not fit within the definition of misconduct, or cannot be substantiated, all parties will be notified and a concerted effort will be undertaken to restore the reputations of any individuals who may have been adversely affected by the allegation and the proceedings. The research records will be restored appropriately as well. Copies of the inquiry report and supporting documents and decision-making must be retained for seven (7) years. No further action will be taken by the institution and no reports will be made to funding agencies unless they are specifically required under the circumstances of the allegation or unless the funding agency is aware of the allegation.

If the fact finder conveys to the Vice Provost for Research that there is substance to the allegation within the definition of misconduct in research, or if the Vice Provost for Research determines that further investigation is warranted, an investigation committee will be convened. If the fact finder is unable to make a determination one way or the other, an investigation must be conducted unless the respondent admits to the allegation.

4. The Investigation Process

Purpose of Investigation

Once the criteria for initiation of an investigation have been met, the Vice Provost for Research initiates the investigation process. The purpose of the investigation is to determine, based on a preponderance of evidence, whether research misconduct has occurred and, if so, to determine the responsible person and the nature and seriousness of the research misconduct.

Timeframe

Within thirty (30) days of the determination that an investigation is warranted, the investigation must be started. Thus, unless an extension has been provided to the fact finder, the investigation phase will begin within 90 days of the determination by the Vice Provost for Research that the allegation is credible.

Sequestration

The Vice Provost for Research will take all reasonable or practical steps to obtain custody of and sequester in a secure manner any additional research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.

Notification of Office of Research Integrity (ORI) and Other Federal Agencies of Initiation of Investigation

If the Public Health Service (PHS) sponsors the respondent's research, it must be notified in writing of the investigation within the above-cited 30-day period. Other funding sources or sponsors may also be alerted to the initiation of an investigation, as deemed appropriate by the Vice Provost for Research. The Vice Provost for Research may choose to restrict the respondent's participation in University activities during the investigation phase, or initiate other personnel actions as s/he determines are in the best interest of research subjects, the public and University programs. At all times, the health and safety of the public and University personnel will be the paramount determination for all subsequent notifications and actions by the University.

The written inquiry report sent to ORI must include:

- Name and position of respondent;
- Description of allegations;
- Listing of any PHS (or other) support involved;
- Listing of relevant or potentially relevant publications and/or pending grant applications;
- The basis for initiating the investigation phase; and
- Comments on the inquiry report by the respondent and/or complainant.

If requested by ORI and/or appropriate funding source or sponsor, the University must provide a copy of Tufts University's Research Misconduct Policy and Procedures that guided the inquiry; research records and evidence; transcripts or recordings of the inquiry proceedings; and the charges to be investigated.

If required, the Vice Provost for Research notifies other appropriate federal agencies in writing of any decision to open an investigation within 30 days of the determination that an investigation is warranted. This written communication includes a copy of the fact finder report and other information and references as required by federal oversight agencies.

Notification to Respondent of Initiation of Investigation

Within 15 days of the determination to convene an investigation, the Vice Provost for Research notifies the respondent in writing of the decision to convene an investigation. Respondent notification includes:

- The specific allegation(s);
- The rights and responsibilities of the respondent;
- The role of the investigation committee;
- The investigation process timeline;
- Copies of Tufts University's Research Misconduct Policy and Procedures; and
- The right to respond

The respondent's dean and/or department chair, or equivalents thereof, are also notified in writing of the determination to convene an investigation.

Selection of Investigation Committee

The Vice Provost for Research appoints full-time faculty members to serve on the investigation committee. The Vice Provost for Research may consult with the relevant school deans (e.g. the dean[s] of the potential committee members) as appropriate. This committee will consist of at least three members meeting the following criteria:

- Have appropriate scientific expertise to evaluate the evidence and issues related to the allegation; and
- Have no personal, professional, or financial conflicts of interest with the complainant or respondent.

In situations where investigation of an allegation requires expertise not already present among Tufts faculty, the Vice Provost for Research may appoint an additional member or members from outside of Tufts University as needed to serve for the duration of the investigation. The committee may also call upon outside experts, including from the ORI, for assistance as needed.

The respondent will be notified, in writing, of the proposed investigation committee membership. The respondent will be given an opportunity to object to any proposed member based on a personal, professional, or financial conflict of interest. The respondent must submit any objections within 7 days of notification of the potential committee membership. The Vice Provost for Research makes the final determination of whether any such conflict exists.

Charge to Investigation Committee

The Vice Provost for Research provides the charge to the investigation committee, which includes:

- Purpose of the investigation;
- Definition of research misconduct;
- Requirements for findings of research misconduct;
- Timeframe for completion;
- Identification of respondent;
- Specific allegation(s) to be evaluated;

- Responsibilities of the investigation committee, including:
 - o Examination of evidence, including review of all relevant documentation;
 - o Interviews of complainant and respondent;
 - o Interviews of other persons as necessary and appropriate;
 - o A finding, for each allegation, determining whether research misconduct occurred, and if so, to determine the responsible person and the nature and seriousness of the research misconduct;
 - o Preparation of a final report; and
- Copies of Tufts University's Research Misconduct Policy and Procedures

Responsibilities of Investigation Committee

The investigation committee is responsible for conducting a thorough examination of all facts and evidence relevant to the investigation. The investigation committee may also identify, in the course of its duties, if there are issues that would justify broadening the scope of the misconduct proceeding beyond the initial allegation(s). If the scope of the proceeding is broadened, the respondent may be notified of the expanded scope.

The investigation committee may interview the complainant(s), the respondent, and any other available persons who have been reasonably identified as having information relevant to the investigation. The investigation committee: (i) comes to a finding for each allegation; (ii) determines whether research misconduct occurred; (iii) identifies the perpetrator(s) and extent of the misconduct; (iv) takes into account that a finding of research misconduct requires a preponderance of evidence, involves a significant departure from accepted practices in the relevant scientific community, and is committed intentionally, knowingly or recklessly. The investigation committee summarizes its findings and recommendations in a written report to the Vice Provost for Research. The investigation, including the final report and findings for each allegation, should generally be completed within 90 days of the convening of the investigation.

All investigation committee proceedings will be recorded or transcribed, including all interviews of respondent, complainant(s), witnesses, co-workers, and any research subjects. The interviewee will have an opportunity to review the interview transcript for correction. These recordings/transcriptions will be secured and released only upon request from legally-sanctioned organizations, such as ORI and Health and Human Services (HHS).

5. The Investigation Report

At the conclusion of the investigation, the investigation committee will prepare a written report that summarizes its findings and conclusions. The final report must include:

- Names of investigation committee members;
- Committee charge, e.g., the identification of respondent and a description of allegations;
- Process used in accordance with Tufts University's Research Misconduct Policy;
- Inventory of evidence reviewed;
- A finding as to whether research misconduct occurred for each separate allegation identified during the investigation, and whether it was committed intentionally, knowingly, or recklessly;
- Identification of each finding of research misconduct as plagiarism, falsification, fabrication, or other serious deviation from accepted practices;
- Identification of the individual responsible for each finding of research misconduct;
- Summary of the facts and analysis supporting the conclusion, as well as the merits or lack thereof of the respondent's explanations;
- Identification of any federal support;
- Identification of any publications and/or pending grant applications that require correction or retraction;
- Any comments on the draft investigation committee report by the respondent (see below); and
- Any recommendations regarding corrective actions.

Review of Investigation Report

The committee must give a copy of the committee's draft final investigation report to the respondent for comment, as well as a copy of, or supervised access to, the evidence on which the report is based. The respondent must be given 30 days to comment on the draft final investigation report or its relevant portions. After considering the comments from the respondent, the investigation committee may revise its draft report as appropriate, and prepares its final report. Recordings or transcripts from all interviews must be attached to the final investigation committee report. Any written comments provided by the respondent must be attached to the final investigation committee report. The investigation committee report with all attachments is submitted to the Vice Provost for Research.

Institutional Decision

The Vice Provost for Research will make the final decision in response to the investigation committee's final report; he or she may accept the recommendations of the investigation committee or come to a different determination. The final investigation report must be in writing and submitted to the Vice Provost for Research in a timely fashion such that s/he may review the report, determine whether to accept the findings and recommendations of the committee as written, to reach a different finding, or to return it to the committee for further deliberations or fact finding and allow for submission of the report to ORI or the appropriate sponsor no later than 120 days from the date the investigation began if there is a finding of misconduct. Since the initiation of allegation inquiry, a total of 210 days or approximately 7 months may have elapsed. In the event that the Vice Provost for Research's determination varies from that of the investigation committee, he or she must explain in detail the reasons for rendering a different decision in his or her letter notifying ORI of the outcome of the investigation. The Vice Provost for Research's decision will be the final institutional action.

The respondent will not have an opportunity for appeal, but the respondent's rebuttal response to the investigating committee's decision may be appended to the final report. The Vice Provost for Research will consider this in his or her decision, which will be final on the part of the University, but subject to review and acceptance by the ORI or other relevant agency. Funding agencies may undertake their own review or request further action by the University.

Notifications

The respondent is notified in writing of the results of the investigation, including a copy of the final investigation committee report with all attachments and the final institutional decision. The notification will outline plans for any pending disciplinary action against the respondent (see section 7 below). The Vice Provost for Research notifies the respondent's dean and/or department chair, or equivalents thereof (and in instances where a faculty member has a dual appointment with another institution, the Chief Executive Officer of an affiliated institution), of the results of the investigation.

As required, the Vice Provost for Research notifies federal oversight agencies in writing of the investigation committee's findings, whether the institution accepts the investigation committee's findings, the final accepted institutional findings, and any completed or pending institutional actions or sanctions. This notification will include a copy of the investigation report with all attachments. The Vice Provost for Research may also notify the complainant of the results of the investigation.

6. Hearings and Disciplinary Actions

ORI and HHS Hearings and Administrative Actions for Cases of Misconduct in Research Involving PHS Funds, Including Debarment

Refer to 42 CFR Part 93, beginning with section 400, for a complete description of the ORI and HHS process for resolving allegations of misconduct in research.

Illustrative Disciplinary Actions by University in Findings of Misconduct (possible disciplinary actions include but are not limited to the following):

- Letter of reprimand
- Special monitoring of future work
- Probation
- Removal from a particular project
- Suspension
- Rank reduction
- Termination of employment of faculty/staff
- Expulsion of a student

7. Record Retention

All documentation and records related to allegations of research misconduct, regardless of whether they resulted in an inquiry or investigation, will be retained and secured by the Vice Provost for Research for a period of seven years from the date of the receipt of the allegation.

8. References

Tufts University acknowledges that these procedures were modeled on and referenced content from the federal Office for Research Integrity's *Sample Policy and Procedures for Responding to Allegations of Research Misconduct* and institutional policies and procedures at the University of Pennsylvania, Indiana University and Northwestern University.