Tufts Medicine System-Wide Policy	Title: Tufts Medicine Policy on Research Integrity and Misconduct in Research
Issuing Department: **Research Administration**	**Effective Date: April 29, 2026** **Date Last Reviewed: April 29, 2026** **Next Review Date: April 29, 2027**

I. Purpose

Tufts Medicine is committed to fostering an environment that promotes the responsible conduct of Research, encourages reporting of any research-related concerns, protects those who report such concerns in Good Faith, and promptly and effectively addresses any Allegations or credible evidence of Research Misconduct. This Policy governs the procedures taken to determine whether research misconduct has occurred, in alignment with the applicable regulations that address Research Misconduct.

II. Scope

This statement of policy and procedures is intended to carry out this institution's responsibilities for all research activities, including that conducted under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. The Tufts Medicine community must share responsibility for maintaining the highest standards of research conduct and must, when a deviation from these standards is uncovered or suspected, immediately report any suspected or discovered deviations. Therefore, this policy applies to all Tufts Medicine workforce members, which includes employees (including physicians and other clinicians), board members, board committee members, contractors, temporary employees, volunteers, students (including medical dental, nursing, and physician assistant students), and other individuals regardless of where work is performed.

This policy applies to all research activities undertaken across Tufts Medicine regardless of funding source. This includes, but is not limited to, (1) PHS supported biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) allegations of plagiarism or manipulation of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This also includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal resulted in a grant, contract, cooperative agreement, or other form of support.

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of research misconduct that occurred within six years of the date the institution (or HHS in the case of PHS-funded research) received the

allegation, subject to the subsequent use and health or safety of the public exceptions when applicable.

III. Definitions

Accepted Practices of the Relevant Research Community are those practices established by applicable law, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that conduct research.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be a written or oral statement to an institutional official.

Assessment is a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

Complainant is the person who in good faith makes an allegation of research misconduct. In the absence of an individual complainant, the Research Integrity Officer (RIO) may bring forth an allegation on behalf of Tufts Medicine, based on their knowledge of possible research misconduct.

Conflict of Interest as used in this policy is a real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The DO will not be the same individual as the RIO and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

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

Fabrication is the falsehood of data or results and recording or reporting them.

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

Good Faith

a) Good faith as applied to a complainant or witness means having a reasonable belief in the truth of one's allegation or testimony, based on the information known to the complainant or witness at the time. An allegation or cooperation with a

research misconduct proceeding is not in good faith if made with knowledge of or reckless disregard for information that would negate the allegation or testimony.

b) Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under this part. An institutional or committee member does not act in good faith if their acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry is the preliminary information gathering and preliminary fact finding to determine if an investigation is warranted.

Institutional Officials are individuals to whom reports of misconduct in research may be made. These include the Vice President, Research Administration, who serves as Tufts Medicine's Research Integrity Officer (RIO).

Institutional Record is the official record of research misconduct proceedings comprised of: (a) the records that Tufts Medicine compiled or generated during the research misconduct proceedings, except records that were not considered or rely on; (b) a single index listing all the research records and evidence that Tufts Medicine compiled during the research misconduct proceedings, except records that were not considered or rely on; and (c) a general description of the records that Tufts Medicine sequestered but did not consider or rely on.

Intentionally means to act intentionally means to act with the aim of carrying out the act.

Investigation is the official gathering of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which includes a recommendation for other appropriate actions, including administrative actions.

Investigator is any individual, regardless of academic or medical rank, who is engaged in proposing, designing, performing, or reviewing research or reporting research results.

Knowingly means to act with awareness of the act.

Office of Research Integrity (ORI) is the federal agency assigned to promote integrity in biomedical and behavioral research supported by the U.S. Public Health Service (PHS). ORI monitors institutional investigations of research misconduct and facilitates the responsible conduct of research (RCR) through educational, preventive, and regulatory activities.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the

limited use of identical or nearly identical phrases that describe a commonly used methodology. Additionally, plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

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

Recklessly means to act recklessly means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

Research is a systematic investigation that can include (but may not be limited to) an 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 matters to be studied.

Research Integrity Officer (RIO) means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct as described in this Policy, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquires and investigations; and (3) the other responsibilities described in this policy.

Research Misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or reporting research results. This includes oral research presentations. Misconduct does not include honest errors or differences of opinion. Failure to comply with federal, state, and municipal statutes and regulations governing research is unlawful and may be pursued by the institution as a violation of the research integrity process.

Research Record is the record of data or results that embody the facts resulting from research inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided by a respondent in the course of the research misconduct proceeding.

Respondent is the individual against whom an allegation of misconduct in research is being made. If an allegation moves from the inquiry into the investigative stage of a misconduct proceeding, the federal ORI, or the equivalent office at other relevant funding agencies as appropriate, will be given the name of the respondent against whom an allegation of research misconduct was made.

Retaliation for this purpose of the policy means an adverse action taken against a complainant, witness, or committee member by Tufts Medicine or one of its members in

response to a good faith allegation of research misconduct; or good faith cooperation with a research misconduct proceeding.

Sequestration is the collection, segregation, and retention of research records (paper and electronic), equipment, and all other information for the specific purpose of assessing allegations of research misconduct.

Workforce Members refers to Tufts Medicine employees (including physicians and other clinicians), board members, board committee members, contractors, temporary employees, volunteers, students (including medical, dental, nursing, and physician assistant students), and other individuals regardless of where work is performed.

IV. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The Vice President, Research Administration (or designate) will serve as the RIO and will have primary responsibility for implementation of the institution's policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with Section V.A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI and/or other funding agencies, as appropriate, of special circumstances in accordance with Section IV.F. of this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V.C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by applicable law and institutional policy;
- Notify the respondent and provide opportunities for them to review/comment/respond to allegations, evidence, and committee reports;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;
- Keep the DO and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI and/or other funding agencies, as appropriate;
- Ensure that administrative actions taken by the institution (and ORI and/or other funding agencies, as appropriate) are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI and/or other funding agencies, as appropriate.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation and be given the transcript or recording of the interview for correction.

C. Respondent

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to:

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have their comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial

notice of investigation, within a reasonable time after the determination to pursue those allegations;

- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that they committed the research misconduct. With the advice of the RIO and/or other institutional officials, the DO may terminate the institution's review of an allegation that has been admitted, if the institution's acceptance of the admission and any proposed settlement is approved by ORI and/or other funding agencies, as appropriate.

D. Inquiry Fact Finder

The inquiry fact finder is responsible for conducting an initial review of the available evidence to determine whether an investigation is warranted. As determined by the RIO, the inquiry fact finder may be the RIO, another designated institutional official, or a committee. If needed, the inquiry fact finder may utilize one or more subject matter experts to assist in the inquiry review. It is not the responsibility of the Inquiry fact finder to make a final determination based on the merits of the allegations.

E. Investigation Committee

The investigation committee is selected by the RIO in consultation with relevant institutional officials and is responsible for conducting a thorough examination of all facts and evidence relevant to the allegations. The investigation committee determines, based on a preponderance of evidence, whether research misconduct has occurred, the nature and seriousness of the misconduct, and the responsible individual(s). While not required, the investigation committee may contain the same committee members from the Inquiry.

F. Deciding Official

The Chief Academic Officer (or designate) will serve as the DO. The DO will receive the inquiry report and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted. Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI and/or other funding agencies, as appropriate, together with a copy of the inquiry report within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that

detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI and/or other funding agencies, as appropriate, may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to ORI and/or other funding agencies, as appropriate.

V. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, the individual may meet with or contact the RIO at 617-636-2819 to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. Established reporting procedures, such as the institution's ethics hotline, may also be utilized; however, regardless of the reporting method, all reports or concerns involving actual or potential Research Misconduct must be promptly referred to the RIO.

If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will, as appropriate, refer the individual or allegation to other offices or officials with responsibility for resolving the matter.

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

B. Responsibility of the Institution to Respond to Credible Reports of Allegations of Research Misconduct

The RIO shall consider and act upon any specific and credible information that comes to their attention indicating that research misconduct may have occurred in a thorough, competent, objective, and fair manner. The RIO may determine whether it is appropriate to attempt to refer the relevant information to the authority at another institution or direct the complainant to the appropriate Tufts Medicine authority in situations where the allegations do not meet the definition of research misconduct.

The RIO and other institutional officials ensure that:

- Tufts Medicine responds to each allegation that falls under its jurisdiction, and the allegation assessment, inquiry, and investigation are completed in a timely, objective, thorough, competent, and fair manner;

- Each respondent is provided with a charge letter at the appropriate time(s) during the research misconduct proceeding to communicate findings and any proposed administrative actions; and
- Reasonable precautions are taken to avoid bias and conflict of interest on the part of those involved in conducting the Inquiry and Investigation.

C. Cooperation with Research Misconduct Proceedings

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

D. Burden of Proof

The burden of proof rests with Tufts Medicine for making a finding of misconduct in research. Once Tufts Medicine has met that burden, the respondent has the burden of proving any mitigating facts or details which would constitute an affirmative defense of honest error or difference of opinion. In addition, the destruction of or failure to provide relevant research records by the respondent in a reasonable period of time can be used as evidence of research misconduct.

E. Confidentiality

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

F. Sequestration of Research Records

The RIO has the authority and responsibility for sequestration of research records related to allegations of research misconduct at Tufts Medicine. Research records are to be sequestered in a manner that minimizes disruption to the research being conducted by the affected researchers. The RIO will provide the respondent or other affected parties with an inventory of items that were sequestered and, if possible and appropriate, will provide copies of, or supervised access to, sequestered items.

G. Legal Counsel and Advisors

The respondent may seek the assistance of legal counsel or a non-attorney advisor throughout the research misconduct review process. Upon approval from the RIO, the respondent's legal counsel or non-legal advisor may attend and observe interviews with the inquiry fact finder or investigation committee but may not participate in or speak during the interview.

H. Coordination with Other Institutions When Multiple Institutions Have Interest in Responding to Allegations

The RIO and other Tufts Medicine officials may consult with officials from other institutions regarding the allegations of research misconduct for purposes of inter-institutional considerations, such as (A) evaluating whether another institution has an institutional interest in review of any allegations, (B) identifying and contacting possible respondents or witnesses who are members of another institution's workforce, and/or (C) identifying research records located at another institution that may be relevant to the assessment of any allegations. Based on its assessment of inter-institutional considerations, Tufts Medicine may determine that it will (1) proceed to review the allegations according to this Policy, (2) work collaboratively with one or more other institutions by reviewing allegations in accordance with this policy, or by ceding primary review of the allegations to another institution, or by arranging with the other institution(s) to engage in a collaborative inquiry or investigation process, or (3) conclude that Tufts Medicine lacks jurisdiction to review the allegations and will refer the allegations to another institution.

I. Requirements for Findings of Research Misconduct

A finding of research misconduct requires that:

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

J. Responsibility of the Institution to Notify Funding and Oversight Agencies and Affiliated Institutions of Special Circumstances

At any time during the research misconduct proceedings, Tufts Medicine will notify the appropriate funding and oversight agency(ies) and affiliated institution(s) (if applicable) if:

- Public health or safety is at risk;
- Agency resources or interests are threatened;
- Research activities should be suspended;
- Possible violations of civil or criminal law are indicated;
- Federal action is required to protect the interests of those involved in the investigation; or
- The research community or public should be informed.

K. Institutional Records Retention

The RIO ensures that the institutional record and all sequestered evidence, including physical objects, will be kept in a secure location under the control of the RIO for seven (7) years after the completion of the research misconduct proceedings or completion of any oversight agency proceedings, whichever is later.

L. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

M. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in this policy, as well as copies of the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case (these individuals may not participate in or speak during the interviews or meetings).

N. Restoration of Reputations

If requested and appropriate, Tufts Medicine will make all reasonable and practical efforts to protect and restore the reputations of individuals alleged to have engaged in research misconduct when such allegations are not sustained or when no finding is made.

O. Deviations from Research Integrity and Other Misconduct

If Tufts Medicine's review of the allegations identifies misconduct other than research misconduct, the RIO may investigate or refer these matters to the proper institutional office for further review. Investigations will comport with the fundamental principles of due process and adhere to applicable Tufts Medicine policies and procedures.

P. Statute of Limitations

An allegation must be received within six (6) years of the alleged act of misconduct in research for it to be viable for institutional consideration. The exceptions to this limitation, also known as subsequent use, are that the claim would be viable if the portion of the research record involved in the allegation has been cited, republished, or otherwise used or referenced by the individual against whom the allegation is made during the six (6) years prior to the allegation, or at any time the health or safety of the public is in jeopardy. In the case of the former, the six-year limitation period would begin at the time of last citation, republication, or reference. In the case of the latter, there is no time limit. In all cases, Tufts Medicine has discretion in determining whether a subsequent use exception applies to a given situation.

Q. Interim Administrative Actions and Notifying ORI of Special Circumstances

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

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