



Title:	Policy and Procedures for Handling Allegations of Research Misconduct
Department:	Mass General Brigham Research Compliance
Policy Type:	<input checked="" type="checkbox"/> Mass General Brigham System-wide <input type="checkbox"/> Mass General Brigham Corporate <input type="checkbox"/> Entity <input type="checkbox"/> Mass General Brigham System-wide Template <input type="checkbox"/> Mass General Brigham Corporate Departmental
Applies to:	All Mass General Brigham Entities, Employees and Agents
Approved by:	Paul J. Anderson, M.D., Ph.D., BWH Chief Academic Officer, BWH Sr. Vice President for Research, BWH Research Integrity Officer (RIO) Robert L. Damiano, Mass General Brigham Vice President of Compliance, Audit & Business Integrity Peter K. Markell, Mass General Brigham Executive Vice President for Administration and Finance, Chief Financial Officer, Treasurer Harry W. Orf, Ph.D., MGH Sr. Vice President for Research and RIO Kerry J. Ressler, M.D., PhD, McLean Chief Scientific Officer and RIO Ravi Thadhani, MD, MPH, Mass General Brigham Chief Academic Officer and RIO
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Contact Person:	See list of hospital Research Integrity Officers

KEYWORDS:

Research misconduct, scientific misconduct, allegation, fabrication, falsification, plagiarism, research integrity officer, respondent, complainant

PURPOSE:

This document sets forth the policy and procedures of Mass General Brigham, formerly Partners HealthCare, for responding to allegations of research misconduct. Mass General Brigham is committed to preserving the integrity of research, fostering a research environment that encourages appropriate behavior, ensuring compliance with regulatory requirements, and maintaining the confidence of our employees, patients, research subjects, and peer institutions.

DEFINITIONS:

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 an institutional or HHS official.

Complainant means a person or group of persons who in good faith makes an allegation of research misconduct.

Deciding Official means the president/CEO of Mass General Brigham or the relevant Mass General Brigham affiliate, or their designee, and shall not be the same individual as the Research Integrity Officer.

Fabrication means making up data or results and recording or reporting them.

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.

Plagiarism means the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit.

Research Integrity Officer means the official designated by the President/CEO of Mass General Brigham, or the relevant Mass General Brigham affiliate, responsible for assessing allegations of research misconduct, determining when such allegations warrant inquiries, conducting inquiries and investigations or staffing any committees constituted to undertake inquiries and investigations, and overseeing inquiries and investigations.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or difference of opinion.

Respondent means a person or group of persons against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

POLICY STATEMENT:

1. Scope

This Policy applies to all individuals who are engaged in research at Mass General Brigham, or who are otherwise, in their Mass General Brigham capacity, involved in or perceived to be involved in research. This Policy does not apply to authorship or collaboration disputes except to the extent such disputes involve an allegation of fabrication, falsification, and/or plagiarism.

2. Obligation to Report an Allegation of Research Misconduct

All members of the Mass General Brigham community have an obligation to report allegations of research misconduct to the appropriate hospital Research Integrity Officer (RIO) unless the allegation is clearly frivolous. Allegations should be as specific as possible. Ideally, they should be substantiated with documented observations, documents of facts, and/or any other form of proof from which the RIO can begin a formal review. The Complainant should not discuss the allegation with other members of the

hospital or Mass General Brigham research community prior to discussion with the RIO. The RIO is available to discuss any circumstances that may raise issues regarding the integrity of a research project.

3. Review of Allegations

The RIO shall review all allegations brought to their attention to determine the veracity of the allegation. Allegations may be submitted to the RIO by any means of communication. The RIO shall oversee the internal review process and on occasion may delegate review tasks to a member of their staff including but not limited to the Offices of Research Compliance and Research Operations.

If an allegation pertains to an individual who is affiliated with multiple Mass General Brigham entities, the RIO of the entity at which the research in question was conducted shall be primarily responsible for overseeing the internal review process. They may consult with the RIO of other Mass General Brigham affiliates as appropriate.

Allegations of research misconduct can vary significantly due to the nature of the misconduct alleged, the severity of the allegations, disputes over facts related to the allegation, and other factors. Due to these potential variations, this policy allows for flexibility, where possible, so that each allegation of research misconduct can be resolved equitably.

4. Time Limitations

The RIO may dismiss an allegation brought more than six (6) years after the alleged misconduct occurred. The six-year limitation does not apply when the research in question involves funding from the Public Health Service and either (a) the Respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation by citing, republishing, or otherwise using for their benefit the research record that is subject to the allegation(s); or (b) the Office for Research Integrity (ORI) or a Mass General Brigham institution, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public. In the case of (a), the six-year limitation period would begin at the time of the last citation, republication, or other use for the potential benefit of the Respondent.

5. Finding of Research Misconduct

A finding of research misconduct under this policy requires that (a) there be a significant departure from accepted practices of the relevant research community; (b) the misconduct be committed intentionally, knowingly, or recklessly; and (c) the allegation be proven by a preponderance of the evidence.

6. Protections for Individuals Involved with the Allegation: Retaliation

Consistent with the Mass General Brigham Non-Retaliation Policy, Mass General Brigham protects those who in good faith report concerns or allegations under this Policy. It is against the Mass General Brigham Policy for Mass General Brigham individuals to retaliate against any other individual who in good faith reports concerns under this Policy and cooperates in research misconduct proceedings. Reporting an issue or concern in good faith under this Policy and cooperating in research misconduct proceedings will not reflect negatively on the employee or affect their employment. The RIO shall make reasonable and practical efforts to protect or restore the positions and reputations of Respondents, good faith Complainants, witnesses, committee members, and other individuals cooperating in the proceedings, as appropriate. Any concerns about retaliation should be directed to the RIO who will review all instances of alleged retaliation for appropriate action.

7. 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 to research misconduct allegations to the RIO or other institutional officials.

8. Confidentiality; Anonymity

All individuals involved in research misconduct proceedings, including the Respondent, Complainant, witnesses, and panel members, are responsible for maintaining confidentiality. Disclosure of an allegation and the institutional review of an allegation should be limited to those with a need to know about them. The identity of research subjects, if any, should be kept confidential. Any concerns about breaches of confidentiality should be directed to the RIO who will review all concerns for appropriate action.

If a Complainant requests anonymity, the RIO will make reasonable and practical efforts to honor that request, where appropriate. Anonymity may not be possible.

9. Conflicts of Interest

Individuals involved in a research misconduct proceeding shall have an opportunity to raise concerns regarding personal, professional, or financial conflict of interest that they may have with the Complainant, the Respondent, any witness, or any individual responsible for carrying out any part of a research misconduct proceeding. Any concerns regarding such conflicts should be addressed by the RIO. If the concern relates to a conflict with the RIO, such concern will be addressed by the Deciding Official.

10. Safety Concerns

Any relevant institutional, state or federal agency (as appropriate) should be notified if, during the course of a research misconduct proceeding, any concerns are raised pertaining to the health or safety of the public (including an immediate need to protect human or animal research subjects), there is reason to believe that research activities should be suspended, there is reasonable indication of violation of any law, or any other concern that warrants such notification. If the research implicated in the research misconduct proceeding involves funding from the Public Health Service, there are special notification requirements when exigent circumstances arise (see Procedures, Section 5.a.ii.)

PROCEDURES:

1. Preliminary Assessment

The RIO together with their designee, at the RIO's discretion, shall conduct a preliminary assessment to determine if (1) the allegation falls within the definition of research misconduct; and (2) the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

They are not required to conduct an exhaustive review of the evidence or conduct interviews. If the allegation falls within the definition of research misconduct and the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified, further institutional review must be conducted pursuant to Section 5.

If the RIO determines there is a need to consult with the Respondent in order to conduct the preliminary assessment, the relevant research records should be preserved in accordance with Section 2 and the

Respondent should be notified of the allegations in accordance with Section 3. If the RIO can conduct the preliminary assessment without consulting with the Respondent, the RIO does not necessarily need to preserve the research record or notify the Respondent of the allegation.

If the RIO concludes that the allegation does not fall within the definition of research misconduct or the allegation is not sufficiently credible and specific so that potential evidence of research misconduct may be identified, the RIO shall prepare a report that summarizes the allegation(s) and the reasons for closing the matter. This report shall be retained pursuant to Section 6 (record retention).

2. Preservation of Relevant Research Records

The RIO, or their designee, shall sequester all relevant research records or take other steps as determined appropriate to preserve the integrity of the records. Such actions should occur as early in the process as feasible, and prior to, or concurrently with, notification to the Respondent. As noted in Section 1, the RIO is not required to preserve the relevant research records during a preliminary assessment if they can conduct the preliminary assessment without consulting with the Respondent. During the inquiry and investigation, to the extent not done so already, the RIO shall sequester all relevant research records or take other steps as determined appropriate to preserve the integrity of the records, including sequestering and preserving additional items that become known or relevant to the inquiry or investigation.

3. Notice of Allegation to Respondent

Prior to the beginning of an inquiry (and during a preliminary assessment, if appropriate), the RIO shall inform the Respondent of the allegations. If the allegations change throughout the course of the internal review, the RIO shall promptly inform the Respondent of such new or altered allegations. As noted in Section 1, the RIO is not required to notify the Respondent of the allegations during a preliminary assessment if the RIO can conduct the preliminary assessment without consulting with the Respondent.

4. Coordination with Other Academic Institutions

If the allegation warrants further institutional review (as outlined in Section 1), and if the Respondent had an appointment at Harvard Medical School (HMS) at the time of the alleged research misconduct, the RIO, or their designee, shall coordinate further institutional review with HMS. The RIO may wish to delegate significant oversight or other administrative responsibilities to HMS. In such cases, the review shall be conducted as a joint review on behalf of Mass General Brigham, or the Mass General Brigham affiliate, and HMS. The final adjudication of the matter rests jointly with the Deciding Officials of HMS and the Mass General Brigham affiliate. If the Respondent has an appointment at an academic institution other than HMS or another Harvard faculty, the review may proceed in a comparable manner.

5. Further Institutional Review

As determined by the RIO, the nature of the further institutional review depends on the funding source of the research in question. Certain additional regulatory procedural requirements are required if the research involves funding from the Public Health Service (see Subsection (a)), and there may be additional procedural requirements imposed by a federal sponsor other than the Public Health Service. Where appropriate, changes to these procedures may be implemented to ensure compliance with any requirements imposed by the federal funding entity.

The RIO shall conduct further review to determine whether the Respondent committed research misconduct. The requirements for making such a determination are set forth above in Policy, section 5. The RIO may create a panel of one or more individuals to review the allegation and evidence, and to

report its findings and recommendations to the RIO. Throughout the review, the RIO, or their designee, is responsible for ensuring that the Respondent has an opportunity to present their case, including being interviewed if desired, and an opportunity to review and comment on any reports generated by the RIO or any panel before they are finalized.

The RIO shall relay the findings to the Deciding Official, who will make a final determination as to whether research misconduct did or did not occur, and what sanctions or other actions are appropriate. In the event the investigation results in a finding that research misconduct occurred, but that there was not a preponderance of the evidence that an identifiable Respondent committed the research misconduct, the Deciding Official may still determine that sanctions (e.g., notification to the applicable journal) are appropriate. Sanctions will be addressed and adjudicated within applicable disciplinary policies and procedures of Mass General Brigham and/ or the relevant Mass General Brigham affiliate.

a. Research involving Public Health Service funding

i. Process

If the research involves funding from the Public Health Service (PHS), specifically falling in the categories of research outlined in 42 C.F.R. §93.102(b), the internal review must comply with 42 C.F.R. §93 (the “PHS Rule”). The following provides a general outline of the procedures; the PHS Rule should be consulted for further specificity. If the inquiry or investigation is conducted with a non-Mass General Brigham institution(s), any discrepancy or conflict between this policy and such institution’s policy will be resolved by consultation with the PHS Rule.

A. Inquiry

If the RIO determines that the allegation constitutes research misconduct and there is sufficient credible and specific evidence so that potential evidence of research misconduct may be identified, the RIO shall conduct an inquiry consistent with the requirements of the PHS Rule. The purpose of the inquiry is to determine if an allegation warrants an investigation. An investigation is warranted if there is (a) a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and (b) preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance. The RIO may appoint an individual or a panel to make recommendations as to whether an investigation is warranted.

If the RIO determines an investigation is not warranted, they shall make a recommendation to the Deciding Official to conclude the review, and the Deciding Official shall make the final determination to conclude the review. If the RIO determines an investigation is warranted, they shall inform the Deciding Official, and the matter shall proceed to investigation.

The findings of the inquiry shall be included in a written report, completed within 60 days of the initiation of the inquiry, unless circumstances clearly warrant a longer period.

If an investigation is warranted, the Office of Research Integrity (ORI) must be notified in writing within 30 days of such finding. ORI need not be notified if an

investigation is not warranted. However, ORI must be notified in advance if the institution seeks to close a case prior to investigation due to the Respondent admitting guilt or the Respondent reaching a settlement with the institution.

Regardless of whether ORI is notified, all records relating to the inquiry must be retained consistent with Section 6 (record retention).

B. Investigation

Within 30 days of determining an investigation is warranted, the RIO or an individual or panel appointed by the RIO, shall conduct an investigation consistent with the requirements of the PHS Rule. The purpose of the investigation is to determine, for each allegation, whether research misconduct did or did not occur, and if so, who was responsible. The requirements for making such a determination are set forth above in Policy, section 5.

The findings of the investigation shall be included in a written report, which will include information as required by 42 C.F.R. §93.313, and shall be transmitted to the Deciding Official. The Deciding Official shall make the final determination whether to accept the investigation report, its findings, and the recommended actions (if any). ORI shall be provided with a copy of the final investigation report and notice of any institutional administrative actions within 120 days of the initiation of the investigation, unless the Office of Research Integrity has granted an extension.

ii. Exigent Circumstances

ORI or other relevant institutional, state or federal entities (as applicable) should be notified promptly if any of the following concerns are identified during the course of a research misconduct proceeding:

- The health or safety of the public is at risk, including an immediate need to protect human or animal research subjects
- HHS resources or interests are threatened
- Research activities should be suspended
- There is 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 institution believes the research misconduct proceeding may be made public prematurely
- The research community or public should be informed.

6. Record Retention

The RIO will keep all documents and other evidence relating to all research misconduct proceedings for seven (7) years after the completion of the matter or the completion of any Public Health Service proceeding involving the research misconduct allegation.

OTHER APPLICABLE MASS GENERAL BRIGHAM POLICIES

Mass General Brigham Non-Retaliation Policy

REFERENCE:

42 C.F.R. § 93

INSTITUTIONS AND CONTACTS – RESEARCH INTEGRITY OFFICERS*

MASS GENERAL BRIGHAM

Research Integrity Officer: Ravi Thadhani, MD, MPH

BRIGHAM AND WOMEN’S HOSPITAL/FAULKNER HOSPITAL

Research Integrity Officer: Paul J. Anderson, MD, PhD

MASSACHUSETTS GENERAL HOSPITAL

Research Integrity Officer: Harry W. Orf, PhD

MASSACHUSETTS EYE AND EAR

Research Integrity Officer: Michael Gilmore, PhD

MCLEAN HOSPITAL

Research Integrity Officer: Kerry Ressler, MD, PhD

SPAULDING REHABILITATION HOSPITAL

Interim Research Integrity Officer: Heather Cosier, JD

NEWTON-WELLESLEY HOSPITAL

Research Integrity Officer: Julian N. Robinson, MD

NORTH SHORE MEDICAL CENTER

Research Integrity Officer: Mitchell Rein, MD

THE MGH INSTITUTE OF HEALTH PROFESSIONS

Provost and Vice President for Academic Affairs: Alex Johnson, PhD, CCC-SLP

*For an updated list of contact information for Research Integrity Officers and Deciding Officials, please see the Research Navigator:

<https://partnershealthcare.sharepoint.com/sites/phrmResources/c/rirc/Pages/ResearchIntegrity.aspx>

DEVELOPMENT AND CONSULTATION

Reviewed by:	Original Review Date:	Revision Approval Dates:
Anne Klibanski, M.D., Chief Academic Officer, Research Integrity Officer, PHS		March 18, 2016
Peter K. Markell, Executive Vice President Administration & Finance, Chief Financial Officer, Partners		March 18, 2016
Robert L. Damiano, Vice President of Compliance, Audit & Business Integrity, Partners		April 1, 2016
Paul J. Anderson, M.D., Ph.D., Senior Vice President for Research, Chief		February 29, 2016

Academic Officer, Research Integrity Officer, BWH/Faulkner		
Harry W. Orf, Ph.D., Senior Vice President for Research, MGH		February 29, 2016
F. Richard Bringhurst, M.D., Research Integrity Officer, MGH		February 29, 2016
Shelly F. Greenfield, M.D., M.P.H., Chief Academic Officer, McLean, McLean Hospital		March 1, 2016
Kerry J. Ressler, M.D., Ph.D., Chief Scientific Officer, McLean Hospital		February 29, 2016
Ross Zafonte, D.O., Vice President for Medical Affairs, Research, and Education, Spaulding Rehabilitation Hospital		March 8, 2016
Mitchell Rein, M.D., Chief Medical Officer and Senior Vice President for Medical Affairs, NSMC		February 29, 2016
Janet “Jodi” C. Larson, M.D., Research Integrity Officer, Acting Associate Chief Medical Officer and Medical Director of Quality & Patient Safety, NWH		March 3, 2016
Alex Johnson, Ph.D., CCC-SLP, Provost and Vice President for Academic Affairs, The MGH Institute of Health Professions		March 9, 2016
Paul Anderson, MD, PhD, BWH CAO & SVP for Research		July 29, 2020
Harry Orf, PhD, MGH SVP for Research		July 29, 2020
Kerry Ressler, MD, PhD, McLean Chief Scientific Officer		July 30, 2020
Ross Zafonte, DO, Spaulding VP for Research and Medical Affairs		July 30, 2020
Alex Johnson, PhD. Provost, IHP		July 30, 2020
John Fernandez, President, MEE		August 6, 2020
Ravi Thadhani, MD, MPH, Chief Academic Officer, Mass General Brigham Peter K. Markell, Executive Vice President Administration & Finance, Chief Financial Officer, Mass General Brigham		September 15, 2020