Research Misconduct Policy

Purpose

Scientific progress is based on the pursuit of truth and the responsible conduct of research. Boston Children's Hospital ("BCH") expects that its investigators practice with the highest ethical and research standards, and adhere to the core values of objectivity, honesty, openness, accountability, fairness, and stewardship.

This policy describes BCH's response to specific Allegations or apparent instances of Research Misconduct. The Vice President of Research Administration serves as the Research Integrity Officer ("RIO") and has primary responsibility for overseeing the proceeding in accordance with this Policy. The Research Compliance Officer ("RCO") assists in administering this Policy and has primary responsibility for managing the proceeding for BCH. The BCH CEO serves as the Deciding Official ("DO").

Scope

This Policy applies to all employees, faculty members, fellows, residents, students, visiting faculty or scientists, consultants, members of the medical or research staff and volunteers of BCH, whether compensated or not, who are involved in any research activities supported in whole or in part by funds, personnel, facilities, materials or other resources of BCH or administered by BCH who at the time of alleged Research Misconduct, were employed by, were an agent of, or were affiliated by contract or agreement with BCH. This Policy does not cover authorship and other credit disputes. This Policy is posted on the BCH Intranet and external website and applies to Research Misconduct proceedings initiated on or after the effective date of this Policy.

Definitions

Allegation	An Allegation is a disclosure of possible Research Misconduct by any means of communication. The disclosure may be written or oral.
Complainant	A person (s) who makes a good faith Allegation of Research Misconduct.
Inquiry	Preliminary information gathering and fact-finding to determine whether an Allegation warrants an Investigation.
Investigation	Formal development 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 may include a recommendation for other appropriate actions.
Preliminary Assessment	Initial review to determine if the Allegation meets the definition of Research Misconduct and there is sufficient information to proceed with an Inquiry.
Research Misconduct	Fabrication, Falsification, or Plagiarism in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up 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. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research Misconduct does not include honest error or differences of opinion.
Respondent	The person(s) against whom an Allegation of Research Misconduct is directed, or who is the subject of a Research Misconduct proceeding.

I. General Policy and Applicability

BCH is committed to fostering a research environment that promotes responsible research practices in compliance with regulatory and institutional requirements, and to helping prevent Research Misconduct. BCH will respond to each Allegation in a thorough, competent, objective, and fair manner, and will take reasonable steps to conduct an impartial and unbiased Research Misconduct proceeding. Individuals are required to inform the RIO immediately of any attempted violation of procedural integrity, or any breach of confidentiality or privacy. The RIO will address any concerns regarding personal, professional, of financial conflict of interest among individuals involved in the proceeding.

A. Non-Retaliation

Through the RIO, BCH will take all reasonable and practical steps to protect good faith Complainants, witnesses, and panel members, their positions and reputations, and counter potential or actual retaliation against them.

C. Confidentiality and Privacy

To the extent feasible, all individuals involved in a Research Misconduct proceeding shall make diligent efforts to limit disclosure of information only to those who have a need to know, in order to minimize damage to the reputation of individuals, protect the confidentiality of the Respondent and Complainant, and of research records or evidence from which research subjects might be identified. The RIO can, at his/her discretion, communicate any aspect of the matter covered by this Policy with other agencies, departments, and offices whose jurisdiction or interests are implicated by the alleged misconduct and take necessary actions to protect the scientific integrity of the project.

D. Cooperation

Individuals involved in a Research Misconduct proceeding are expected to fully participate and cooperate in good faith. Obstruction of any aspect of the proceeding may itself constitute evidence of Research Misconduct. Obstruction includes intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; falsifying evidence; encouraging, soliciting, or giving false testimony; and attempting to intimidate witnesses, potential witnesses, or potential leads to witnesses or evidence.

E. Coordination with Other Academic Institutions

Harvard Medical School ("HMS")-If the Respondent had an appointment as fellow or faculty at HMS at the time of the alleged Research Misconduct, the RIO shall confer and discuss the logistics of joint review with HMS. The RIO, following consultation with the Compliance Department, may choose to delegate any or all of the functions described in the Policy to HMS, for resolution according to the "Principles and Procedures for Dealing with Allegations of Faculty Misconduct." The decision of whether to delegate and what policy is applicable shall be made in accordance with the following criteria and conditions:

a. Substantial involvement of full-time Harvard faculty or fellow as co-investigators in a research project;
b. Substantial involvement of investigators from Harvard-affiliated hospitals other than the BCH in a research project;
c. Substantial involvement of Harvard students in a research project;
d. Involvement of BCH medical staff so senior as to call into question ability of BCH-specific processes to be fair and neutral; and
e. Funding by HMS or HMS is the primary site receiving sponsored funds.

BCH shall retain jurisdiction over part or all proceedings and apply this Policy when the following conditions are present:

a. All significant witnesses and all Respondents are employees of or otherwise directly affiliated with BCH;
b. BCH personnel have subject matter expertise and availability to undertake fact-finding in regard to the subject matter of the Allegations;
c. When other institutions' personnel are involved, the other institutions' RIOs express a preference for BCH' s process as opposed to HMS' s process and agree to full cooperation with the BCH process; and
d. Funding by BCH for the research or BCH is the primary site receiving funds.

Howard Hughes Medical Institute ("HHMI")-If the Respondent is an employee of HHMI at the time of the alleged Research Misconduct, RIOs will jointly decide whether BCH will apply this Policy or whether the HMS or HHMI Policy on Research Misconduct will apply.

Other Institutions-If the Respondent is an employee at other non-Harvard-affiliated institution at the time of the alleged Research Misconduct, the RIO shall coordinate further review with the other institution. RIOs at impacted institutions jointly determine which institution will bear primary responsibility. BCH is committed to sharing of information and keeping other institutions informed as to the proceedings, where the interest of both BCH and other institutions are significantly impacted.

II. Preliminary Assessment of an Allegation

A. Preliminary Assessment

The RIO, with assistance from the RCO, will promptly conduct a Preliminary Assessment to verify the Allegation is credible and specific, and falls within the definition of Research Misconduct. Where the Respondent has an appointment with HMS, the RIO shall promptly notify the HMS Dean for Faculty and Research Integrity. The RIO is authorized to take any preliminary administrative actions, as appropriate, to protect public health, research funds and equipment, and the integrity of the research process.

B. Preservation of Research Records

The RIO, through the RCO, and with authorization from the Office of General Counsel will seek assistance of relevant departments, such as Information Services, to promptly carry out this step as early in the process as feasible and prior to, or concurrently with notification to the Respondent. The RIO will take reasonable and practical steps to locate, take custody, inventory, and secure relevant research records and evidence in order to preserve the

integrity of the records. Throughout the proceeding, additional relevant records and items that are identified will be similarly preserved.

C. Decision to Dismiss

If the RIO, in consultation with the Compliance Department, concludes that the Allegation is not credible or does not fall within the scope of this Policy, the RCO will prepare a report to summarize the basis and rationale for the determination and close the case.

III. Admission of Research Misconduct

If the Respondent provides a signed and legally sufficient admission in writing, a case may be closed. The RIO (jointly with HMS if a joint process) will appoint a person or panel to review the details of the admission. Before settlement with the Respondent can been reached, the RIO will notify the Office of Research Integrity ("ORI") if the research in question is Public Health Services ("PHS")-related. With ORI review and concurrence, the RIO will ensure that there are sufficient bases to conclude that the extent of Research Misconduct has been identified.

Once ORI approves, the DO will review the appropriateness of institutional actions and sanctions. The RIO will ensure that the administrative actions by BCH and ORI are implemented and notifies other involved parties such as pertinent chief (s) or chair (s).

IV. Inquiry Proceeding

Once the DO ratifies the recommendation of the RIO that an Inquiry is warranted, notification of the Respondent starts the Inquiry timeline. The purpose of an Inquiry is to conduct an initial review of the evidence to determine if the Allegation may have substance and warrants further investigation, and to prepare an Inquiry report.

A. Notice to Respondent and Respondent's Rights

The RIO (jointly with HMS if appropriate) shall notify the Respondent in writing of the specific Allegations, and every time additional Allegations emerge. Research records are secured prior to, or at the time of notice to the Respondent. Throughout the proceeding, the Respondent shall have an opportunity to present his/her case, and to review and comment on draft reports generated by the Inquiry proceeding. The Respondent shall have a copy, or supervised access, to the evidence included in the panel report.

B. Designation of Individual or Panel

The RIO (jointly with HMS if a joint process), may appoint an individual or a panel with appropriate scientific and technical expertise, who can commit sufficient time to participate, and who do not have unresolved personal, professional, or financial conflict of interest. The RIO (jointly with HMS if appropriate) will provide the proper training, charge, staffing, and support to individual(s) to authoritatively evaluate whether the Allegation has substance.

C. Written Report

The panel will conduct its review. The draft report will be shared with the Respondent (and Complainant if appropriate), and their comments will be incorporated in the report. For joint proceedings with HMS, the final report with its conclusions and recommendations is sent for consideration of the HMS Standing Committee on Faculty Conduct before sharing it with the DO at each institution.

V. The Investigation

The DO will review the final Inquiry report and decide whether there is a reasonable basis for concluding the Allegation falls within the definition of Research Misconduct and has substance, and if so, will declare in writing that an Investigation is warranted. If the DO ratifies that an Investigation is not warranted, the RIO will make reasonable and practical efforts, if requested and appropriate, to restore the reputation of the Respondent(s) before closing the case. Notification to the Respondent starts the Investigation timeline.

A. Investigation Panel and Charge

The RIO (jointly with HMS if a joint process) may keep the same Inquiry panel, modify it based on the nature of new Allegations, or appoint a new panel and provide them with training, charge, and support. The panel shall make diligent efforts to ensure that the review is thorough, sufficiently documented, and includes examination of all significant issues and leads, research records, and evidence that are relevant to reaching a decision on the merits of the Allegation(s).The Investigation proceedings will include audio recording each interview that will be recorded and transcribed. The interviewee will be given the opportunity to review and correct the transcript. Interviewees may bring personal legal counsel or representative with them to an interview, if authorized in advance by the RIO, and if BCH counsel is present. Personal counsel may observe but may not speak during the proceeding.

B. Written Report

In order to make a finding of Research Misconduct, the Allegation must fit the definition of Research Misconduct, must be a significant departure from accepted practices of the research community, and must be proven by a preponderance of evidence. The Investigation report should specify whether Falsification, Fabrication, or Plagiarism occurred; who committed it, and whether it was intentional, knowing, or in reckless disregard of the truth. The report may also include recommendations for administrative actions or other appropriate sanctions. The draft report will be shared with Respondent (and Complainant if appropriate) to review; their written responses will be considered and addressed by the panel and attached to the final Investigation report.

C. Final Resolution and Outcome

For joint proceedings with HMS, the final report with its conclusions and recommendations is sent for consideration of the HMS Standing Committee on Faculty Conduct before sharing it with the DO at each institution. The DO will review and will make final determination on the merits of Allegations of Research Misconduct in writing as to whether BCH accepts the report, its findings, and the recommended corrective actions. The letter may also specify

other appropriate institutional actions. The RIO is responsible for ensuring that actions and sanctions are implemented promptly and appropriate parties are notified.

VI. Public Health Service Funding

For PHS-related research, BCH will carry out the proceeding with full adherence to the Public Health Service Policies on Research Misconduct codified in 42 CFR Part 93 including notifying ORI at appropriate times and of any facts that may be relevant to protect public health, federal funds and equipment, and the integrity of the PHS-supported research process. BCH will cooperate with ORI during its oversight review, administrative hearings, and/or appeals. BCH will assist ORI in administering and enforcing any HHS administrative action imposed on BCH staff and personnel.

VII. Time Limitations and Record Retention

The RIO may dismiss an Allegation brought more than six (6) years after the alleged Research Misconduct occurred, unless (1) the Respondent continues or renews any incident through citation, re-publication, or other use of the research record that is alleged to have been Fabricated, Falsified, or Plagiarized; or (2) the alleged Research Misconduct, would possibly have a substantial adverse effect on the health or safety of the public.

BCH shall retain all records related to Research Misconduct proceeding for seven (7) years after completion of the institutional or PHS-related proceeding, whichever is later. This includes documentation of rationale for excluded documents that were deemed irrelevant or duplicate. At the end of the seven years, records are subject to the BCH Record Retention Policy.

Related Policies and References

- BCH Record Retention Policy

External (non-BCH) References

- HMS Principles and Procedures for Dealing with Allegations of Faculty Misconduct
- HHMI Research Misconduct Policy
- PHS Policies on Research Misconduct
- NOT-OD-19-020, Responsibilities of Recipient Institutions in Communicating Research Misconduct to the NIH
- The National Academies of Sciences, Engineering, and Medicine. 2017. Fostering Integrity in Research. Washington, DC: The National Academies Press.

Documents Attributes

Title	Research Misconduct Policy		
Author	Fariba Houman, Research Compliance Officer	**Effective**	01/24/2019
Copyright	© Boston Children's Hospital 2019	**Revised**	
Approved	**Signature on File** Sandra L. Fenwick Chief Executive Officer		