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**Boston  
Children's  
Hospital**

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Owner Fariba Houman

Department Compliance

Applicability Boston Children's  
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Research  
Integrity, RIO  
+ 4 more

## Research Misconduct Policy/Procedure

### Internal Approval

SVP, Compliance

### Scope

This policy applies to all Boston Children's Hospital (BCH) administrative, operational, research departments, clinical departments, and hospital licensed locations and all providers and staff (employees, contracted staff, Associated Personnel, members of the medical staff, and scientific research staff). The policy also applies to foundation practices leasing space at hospital-licensed locations.

### Definitions

**Accepted Practices of the Relevant Research Community:** practices established by applicable research misconduct regulation or by a sponsor's funding component (if applicable), as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive sponsored funding.

**Allegation:** a disclosure of possible research misconduct by any means of communication and brought directly to the attention of an institutional or HHS official.

**Assessment:** a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct, is subject to this Policy, and is sufficiently credible and specific so that

potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation. For purposes of evaluating applicable external notification and other requirements, the assessment will also evaluate whether the allegation relates to activities involving PHS support and/or other externally funded research.

**Complainant:** a person(s) who makes a good faith allegation of research misconduct.

**Evidence:** anything offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact. Evidence includes documents, whether in hard copy or electronic form, information, tangible items, and testimony.

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

**Falsification:** 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.

**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 Policy. 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:** preliminary information-gathering and preliminary fact-finding in accordance with the Policy to determine whether an allegation of research misconduct warrants investigation.

**Institutional Deciding Official (DO):** the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer.

**Institutional Record:** a) the records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include but are not limited to:

- 1) documentation of the assessment;
- 2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate;
- 3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted, and information the respondent provided to

the institution;

4) decision(s) by the DO, such as the written decision from the DO;

b) a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on; and

c) a general description of the records that were sequestered but not considered or relied on.

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

**Investigation:** the 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, including institutional actions.

**Knowingly:** to act knowingly means to act with awareness of the act.

**ORI:** the Office of Research Integrity in the U.S. Department of Health and Human Services (HHS); ORI is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service (PHS).

**Plagiarism:** Plagiarism means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. (a) 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. (b) 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:** proof by evidence that, compared with the evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

**PHS Support:** PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

**Recklessly:** 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:** a systematic experiment, study, evaluation, demonstration, or survey designed to develop or contribute to general knowledge or specific knowledge by establishing, discovering, developing, elucidating, or confirming information about the matters to be studied or the underlying mechanism(s) relating to those matters.

**Research Integrity Officer (RIO):** the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with

applicable regulations. This includes at a minimum: a. Reviewing allegations of research misconduct to determine if they fall within the definitions of research misconduct and warrant an inquiry; and b. Overseeing inquiries and investigations.

**Research Misconduct:** fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

**Research Record:** the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples of items, materials, or information that may be considered part of the research record include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, on-line content, lab meeting reports, journal articles, and correspondence.

**Respondent:** the person(s) against whom an allegation of research misconduct is directed, or who is the subject of a research misconduct proceeding.

**Retaliation:** an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct; or good faith cooperation with a research misconduct proceeding.

## Policy Applicability

Scientific progress is based on the pursuit of truth and the responsible conduct of research. 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. BCH is committed to fostering a research environment that promotes research integrity and responsible research practices in compliance with regulatory and institutional requirements, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

This policy describes BCH's response to allegations or apparent instances of research misconduct that are brought directly to the attention of a BCH or HHS Official. The Senior Vice President of Research Administration serves as the RIO and has primary responsibility for overseeing the proceeding in accordance with this Policy. The Chief Executive Officer serves as the DO. The Research Compliance Office assists in administering this Policy.

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

This Policy applies only to allegations of research misconduct that occurred within six years of the date BCH, HHS, or another U.S. governmental funding agency received the allegation, subject to the following exceptions:

- The six-year time limitation does not apply if the individual accused of research misconduct continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research

record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of that individual (“subsequent use exception”). For alleged research misconduct that appears subject to this subsequent use exception, but that BCH determines is not subject to the exception, BCH will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of seven years after completion of the institutional proceeding or the completion of any HHS proceeding, if applicable.

- The six-year time limitation also does not apply if a U.S. government funding agency, including ORI, or BCH determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

## **I. Policy Statements**

### **A. Responsibility to Report Misconduct**

All individuals subject to this Policy 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, that individual may meet with or contact the RIO to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. If the circumstances described by the individual do not meet the definition of research misconduct, then the RIO may refer the individual or allegation to other offices or officials, where appropriate. 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, or financial conflict of interest among individuals involved in the proceeding.

### **B. Non-Retaliation**

Through the RIO, BCH will take all reasonable and practical steps to protect anyone participating in the research misconduct process, including good faith complainants, witnesses, and committee members and to protect these individuals from retaliation . Protect in this case includes their positions and reputations and countering potential or actual retaliation by respondents and/or other institutional members against them.

### **C. Confidentiality**

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, complainant, witnesses and of research records or evidence from which research subjects might be identified. Those who need to know may include institutional review boards, journals, editors, publishers, co-authors, and collaborating institutions. The limitation on disclosure no longer applies once BCH has made a final determination of research misconduct findings, but no disclosures should be made by anyone involved in the research misconduct proceeding unless and until they are granted permission by the RIO, acting on

behalf of BCH, to make such disclosure. 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.

Nothing herein shall prevent BCH or an individual from taking steps to manage published data or to acknowledge that data may be unreliable, provided that such steps do not otherwise disclose information relating to a research misconduct proceeding in violation of this paragraph.

## **D. Cooperation**

Individuals involved in a research misconduct proceeding are expected to fully participate and cooperate with the RIO or designee in the review of allegations and the conduct of research misconduct proceedings. All individuals subject to this Policy, in addition to respondent (s), have an obligation to provide information, research records or other evidence relevant to research misconduct allegations to the RIO or other institutional officials. The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations.

## **E. Non-Obstruction**

Obstruction of any proceedings under this Policy, or of proceedings of another institution that is taking the lead on an inquiry or investigation into alleged research misconduct is a violation of this Policy. Obstruction includes, but is not necessarily limited to, intentionally withholding or destroying evidence in violation of a duty to disclose or preserve; failing to maintain records as required; failing to produce existing records, data, or other evidence in a timely manner where the individual failing to produce the records, data or other evidence claims to possess the records but refuses to provide them up on request; falsifying evidence; encouraging, soliciting, or giving false testimony; and attempting to intimidate witnesses, potential witnesses, or potential leads to witnesses or evidence.

## **F. Rights and Responsibilities of the Complainant**

The complainant is responsible for making allegations in good faith, maintaining confidentiality as set forth herein, and cooperating with the inquiry and investigation. If the inquiry or investigation committee deems it necessary, the complainant may be interviewed at the inquiry or investigation stage and, if so, shall be given the transcript or recording of the interview for correction. After making an allegation of research misconduct, the complainant is responsible for providing evidence and information in connection with the research misconduct process but is not entitled to receive information about the status or outcome of that process. If BCH chooses to notify one complainant of the inquiry results in a case, all complainants relevant to that case will be notified, to the extent possible.

## G. Rights and Responsibilities of the Respondent

The respondent is responsible for maintaining confidentiality as set forth herein and cooperating with the conduct of an inquiry and investigation. The respondent is entitled to the procedural rights and protections set forth in this Policy, which include that BCH will make a good faith effort to notify the respondent(s) in writing of the allegations being made against them that have been advanced to inquiry or investigation. Respondents may choose up to two personal advisors for support during the process. Personal advisors may be present at any proceedings or interviews that the respondent attends, if authorized in advance by the RIO, and if BCH counsel is present, but may not question witnesses or otherwise take part in the research misconduct proceedings.

If additional respondents are identified during an inquiry or investigation, a separate inquiry need not be initiated for each new respondent. However, each additional respondent shall be provided notice of and an opportunity to respond to the allegations against them.

If requested and as appropriate, BCH will make reasonable and practical efforts to protect and restore the reputation of a respondent against whom no finding of research misconduct is made.

## H. Coordination with Other Academic Institutions

**Harvard Medical School ("HMS")**-If the respondent had an appointment at HMS (such as as fellow or faculty) at the time of the alleged research misconduct, the RIO shall confer and discuss the logistics of joint review with HMS. The RIO may choose to delegate any or all of the functions described in the Policy to HMS, for resolution according to the “**Harvard Medical School Interim Policy and Procedures for Responding to Allegations of Research 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;
- 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.

**Multiple 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(s) including Howard Hughes Medical Institute. RIOs at impacted institutions jointly determine which institution will bear primary responsibility and serve as the lead institution. 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. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken ordinarily will be made by the institutions jointly.

## II. Assessment

Upon receipt of an allegation, the RIO or designee will promptly conduct an assessment to verify the allegation falls within the definition of research misconduct and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If it appears that the RIO has any unresolved personal, professional, or financial conflicts of interest with those involved in the allegations, then the DO shall appoint another qualified individual to serve as acting RIO with respect to reviewing the allegation and conducting any research misconduct proceeding. An assessment is intended to be a review of readily accessible information relevant to the allegation. In conducting the assessment, it is not necessary to interview the complainant, respondent, or other witnesses, or to gather data beyond any that may have been submitted with the allegation.

If the RIO or another institutional official determines that the allegation meets the criteria to require an inquiry, they will promptly: (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence. If the RIO determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why BCH did not proceed to an inquiry and securely retain this documentation for seven years.

Where the respondent has an appointment with HMS, the RIO shall promptly notify the HMS RIO. If RIOs jointly determine that the allegation warrants further review through an inquiry, the joint review will be administratively staffed and managed by HMS, on behalf of both institutions. The final adjudication of the matter rests jointly with the DOs of both institutions.

### A. Sequestration of Research Records

The RIO/designee with support from the Office of General Counsel will seek assistance of relevant departments, or external forensic vendors, 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/designee will take reasonable and practical steps to locate, obtain custody, inventory, and secure the original or

substantially equivalent copies of research records, BCH email records, and other evidence that are pertinent to the proceeding. Throughout the proceeding, additional relevant records and items that are identified will be similarly preserved. The inventory of sequestered research records contains documentation of the devices, platforms, and methodologies used (e.g., forensic imaging of electronic devices, capture from specific cloud-based platforms, etc.). The respondent (s) and all other individuals subject to this Policy must provide immediate assistance in response to any request by the RIO/designee to identify and secure research records relevant to the research misconduct proceeding. Where applicable, the RIO/designee will transfer the sequestered records and evidence, along with the accompanying inventory and device/methodological documentation to the lead institution.

## **B. Notification of Respondent**

At the time of or before beginning the inquiry, BCH will make a good-faith effort to notify the respondent(s), in writing, that an allegation(s) of research misconduct has been raised against them, the relevant research records have been sequestered, and an inquiry will be conducted to decide whether to proceed with an investigation. If additional allegations are raised, BCH will notify the respondent(s) in writing. When appropriate, BCH (or HMS if a joint proceeding) will give the respondent(s) copies of, or reasonable supervised access to, the sequestered materials. If additional respondents are identified, BCH will provide written notification to the new respondent(s). All additional respondents will be given the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

## **III. Inquiry**

The purpose of an inquiry is to conduct an initial review of the available evidence to determine if the allegation may have substance and warrants an investigation, and to prepare an inquiry report.

### **A. Inquiry initiation**

The RIO (jointly with HMS if appropriate), will conduct the inquiry provided they utilize one or more faculty subject matter experts as needed to assist them. Alternatively, the RIO may delegate the conduct of inquiry and appoint an individual or a committee 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 will provide the proper training, charge, staffing, and support to individual(s) to authoritatively evaluate whether the allegation has substance.

### **B. Inquiry Process**

The RIO or inquiry committee, as applicable, will conduct a preliminary review of the evidence. In the process of fact-finding, the RIO, or inquiry committee, as applicable, may interview the respondent and/or witnesses, which may include a complainant. If interviews are conducted, transcripts will be provided to the interviewee for correction. The respondent(s) will not be present during the witnesses' interviews, but will be provided a transcript of each interview as part of delivery of the draft report, with redactions as BCH deems appropriate to maintain confidentiality.

The RIO or inquiry committee, as applicable, will evaluate the evidence and determine whether an investigation is warranted. An investigation is warranted if there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct, and preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance.

The inquiry will not determine if research misconduct occurred, nor assess whether the alleged misconduct was intentional, knowing, or reckless. This determination may only be made by an investigation committee during investigation. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, with respect to federally-funded research, the RIO shall consult promptly with the relevant federal agency to determine the next steps that should be taken.

## C. The Inquiry Report

At the conclusion of the inquiry, regardless of whether an investigation is warranted, a written inquiry report must be prepared that includes the following information:

- The names, professional aliases and positions of the respondent and complainant(s) (where applicable);
- A description of the allegation(s) of research misconduct;
- The funding support, including, for example, grant numbers, grant applications, contracts and publications listing all support;
- The composition of the inquiry committee, if used, including name(s), position(s) and subject matter expertise;
- An inventory of sequestered research records and other evidence and a description of how sequestration was conducted;
- Transcripts of any transcribed interviews;
- The inquiry timeline and procedural history;
- Any scientific or forensic analysis conducted;
- The basis for recommending that the allegation(s) warrant an investigation; or the basis on which any allegation(s) do not merit further investigation;
- Any comments on the draft report by the respondent;
- Any institutional actions implemented, including external communications with journals or funding agencies;
- Documentation of potential evidence of honest error or difference of opinion.

## D. Completing the Inquiry

The draft report will be shared with the respondent for review and an opportunity to provide comments within ten (10) business days. Relevant portions of the report may be shared with a complainant for comment, and their comments will be attached to the report. The final inquiry report and any comments will be submitted to the DO, who will make a written determination as to whether an investigation is warranted. The inquiry is completed when the DO makes this determination. 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 as detailed in the HMS Policy prior to sending to the DOs. If the DO decides that an investigation is not warranted, BCH shall secure and maintain for seven (7) years after the termination of the inquiry, sufficiently detailed documentation of the inquiry to permit a later assessment of the reasons why an investigation was not conducted. If an investigation is warranted, BCH must: (a) within a reasonable amount of time after this decision, provide written notice to the respondent(s) of the decision to conduct an investigation of the alleged misconduct, including any allegations of research misconduct not addressed during the inquiry; and (b) within thirty (30) days of determining that an investigation is warranted, provide ORI with a copy of the inquiry report. Notification to the respondent starts the investigation timeline.

## **IV. Investigation**

### **A. Investigation Initiation and Purpose**

The purpose of the investigation is to formally develop a factual record, pursue leads, examine the record, and recommend findings to the DO, who will make the final institutional decision, based on a preponderance of the evidence, on each allegation and any institutional actions. If new allegations are identified during an investigation, the RIO must give the respondent written notice of such allegations within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notification of the investigation.

If any additional respondents are identified during the investigation, the RIO will notify them of the allegation(s) and provide them with an opportunity to respond consistent with this Policy. Ordinarily, respondents identified during an ongoing investigation and relevant to such investigation will be added to the ongoing investigation without conducting a separate inquiry.

### **B. Sequestration of Research Records**

On or before the date on which the respondent is notified, or the investigation begins, whichever is earlier, or the date on which a new respondent is notified as part of an ongoing investigation, the RIO must take all reasonable and practical steps to obtain custody of and sequester in a secure manner all the research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records may occur for any number of reasons, including BCH's decision to investigate additional allegations or an additional respondent not considered during the inquiry stage or identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same as those that apply during the inquiry.

### **C. Investigation Committee**

The RIO in consultation with other institutional officials as appropriate, will appoint an *ad hoc* investigation committee. The investigation committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the

investigation and should include individuals with appropriate scientific expertise. The RIO 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. For research that does not involve any federal funding, the RIO may choose to appoint a committee of one or more individuals to conduct combined inquiry and investigation for a more streamlined and timely review. Prior to the initiation of the investigation, the respondent will be notified of the investigation committee's membership and shall be afforded five (5) calendar days to lodge objections based upon a committee member's alleged personal, professional, or financial conflict of interest. The RIO will make the final determination as to whether a conflict exists.

The RIO will provide an orientation to the committee, review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality. Orientation will include describing the subject matter of the investigation and the allegations and related issues identified during the inquiry, identifying the respondent(s), informing the committee that it must conduct the investigation as prescribed by this Policy, defining research misconduct, and instructing the committee on the burden of proof. The RIO will explain that the committee has to evaluate the evidence and testimony of the respondent and other witnesses as applicable to determine whether, based on a preponderance of the evidence, research misconduct occurred. The RIO will also inform the committee that a written investigation report that meets the requirements of this Policy must be prepared reflecting the committee's work. The investigation committee will be provided with a copy of this Policy, and applicable federal regulations. The RIO will explain that the committee will conduct interviews, pursue leads, and examine all research records and other evidence relevant to reaching a decision on the merits of the allegations.

The investigation committee and the RIO must use diligent efforts to ensure that the review is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation; take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical; offer each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, the opportunity to be interviewed. BCH will record and transcribe interviews during the investigation and make the transcripts available to the interviewee for correction; and include the transcripts with any corrections and exhibits in the institutional record of the investigation. The respondent will not be present during the witnesses' interviews but shall be provided a transcript of each interview as part of the draft investigation report, with redactions as BCH deems appropriate to maintain confidentiality. The committee will pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instance (s) of possible research misconduct, and continue the investigation to completion.

## **D. The Investigation Report**

The investigation report for each respondent will include:

- Description of the nature of the allegation(s) of research misconduct, including any additional allegation(s) addressed during the research misconduct proceeding;
- Description and documentation of financial support for the research subject to the allegations,

including, for example, the numbers of any grants that are involved, grant applications or other proposals for support, contracts, progress reports, presentations, posters and publications or submitted manuscripts listing support (this includes known applications or proposals for support that the respondent has pending with potential funders);

- Description of the specific allegations of research misconduct considered in the investigation of the respondent;
- Composition of the investigation committee, including names(s), positions(s) and subject matter expertise;
- Inventory of sequestered research records and other evidences, except records the institution did not consider or rely on; and a description of how any sequestration was conducted during the investigation;
- Transcripts of all interviews conducted;
- Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material;
- Any scientific or forensic analysis conducted;
- A copy of the institutional policies and procedures under which the investigation was conducted;
- Any comments made by the respondent and complainant(s) (if applicable) on the draft investigation report and the committee's consideration of these comments; and
- A statement for each separate allegation of whether the committee recommends a finding of research misconduct.

If the committee recommends a finding of research misconduct for an allegation, the investigation report will present a finding for each allegation. These findings will identify the individual(s) who committed the research misconduct; indicate whether the misconduct was falsification, fabrication, and/or plagiarism; indicate whether the misconduct was committed intentionally, knowingly, or recklessly; identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence; summarize the facts and analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent; identify the specific funding support (if any); and state whether any publications need correction or retraction. Where findings of research misconduct have been made, the investigation committee may recommend institutional action(s).

If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion. The investigation committee may recommend corrective actions even if no finding of research misconduct has been recommended, including, for example, correction or retraction of published or submitted work that is necessary to ensure the integrity of the scientific record.

Where the investigation committee simultaneously is considering allegations of research misconduct that involve federal funding and allegations of other professional conduct violations, the committee and the RIO may separate the findings into two reports: one report concerning research misconduct findings

that must be reported to federal agencies and a second report concerning findings that need not be reported to federal agencies, including allegations concerning non-federally funded research or other professional conduct violations. The Office of the General Counsel shall be available to advise the investigation committee and the RIO with respect to the report.

The RIO will give the respondent a copy of the confidential draft investigation report and exhibits for comment and, concurrently, a copy of, or supervised access to the evidence that the investigation committee considered or relied on. The respondent will be allowed thirty (30) calendar days from receipt of the draft report to submit comments to the RIO. The RIO will assist the investigation committee in finalizing the investigation report, including by ensuring that any comments provided by the respondent are considered by the investigation committee and added to the investigation report.

## **E. Institutional Decisions and Actions**

The DO will review the investigation report which may include recommendations for institutional administrative actions, including without limitation: correcting the public research record; requiring additional training or mentorship of the respondent; notification of a current employer or other third party who may be depending on the reliability of respondent's research results. The DO will make a final written determination of whether the institution accepts the finding of research misconduct and the recommended institutional actions and finds them appropriate. If this determination varies from the findings of the investigation committee, the DO will explain in detail the basis of a different decision. Alternatively, the DO may request the investigation committee to conduct further fact-finding and analysis.

In consultation with institutional officials, the DO will also determine whether any other party should be notified of the outcome of the case, including without limitation: law enforcement agencies, professional societies, professional licensing boards, editors of journals in which fabricated, falsified or plagiarized reports may have been published, the respondent's collaborators in the work in question, current employers, or other relevant parties.

Sanctions for research misconduct shall be based on the seriousness of the misconduct, including but not limited to, the degree to which the misconduct was intentional, knowing or reckless; an isolated event or part of a pattern; had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare; and the degree to which the respondent may continue to conduct or contribute to research. The DO may decide on corrective actions based on the conduct detailed in the investigation report, even if no findings of misconduct have been made. The range of administrative actions includes, but is not limited to: the correction of the public record including the withdrawal or correction of all pending or published abstracts and papers emanating from the research where misconduct was found; removal of the responsible person from the particular project; special monitoring of future work; probation, suspension, leave without pay, salary reduction, or initiation of steps leading to rank reduction or termination of academic appointment or employment; restitution of funds as appropriate; suspension or termination of an active award, letters of reprimand; notification of current employer; and other action appropriate to the research misconduct.

After the DO has made a final determination of research misconduct findings, BCH will add the DO's

written decision to the investigation report, notify the respondent and organize the institutional record in a logical manner to transmit to ORI.

## **V. Other Procedures**

### **A. Interim Institutional Actions**

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 research process. In the event of such a threat, the RIO will, in consultation with other institutional officials, and ORI, as necessary, take appropriate interim actions 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. With respect to federally-funded research, BCH shall, at any time during a research misconduct proceeding, notify ORI (or the relevant federal agency) immediately if there is reason to believe that any of the following conditions exist: a) health or safety of the public is at risk, including an immediate need to protect human or animal subjects; b) federal resources or interests are threatened; c) research activities should be suspended; d) there is a reasonable indication of possible violations of civil or criminal law; e) federal action is required to protect the interests of those involved in the research misconduct proceeding; f) in case the research misconduct proceeding may be made public prematurely and federal action may be necessary to safeguard evidence and protect the rights of those involved, or g) the research community or public should be informed.

The RIO in consultation with other institutional officials and subject matter experts, may seek correction or retraction of published or submitted research at any time during a research misconduct proceeding when there is clear evidence of false, fabricated, or plagiarized research, whether due to honest error or for any other reason, or if BCH finds there are no research records available to support the published or submitted research.

### **B. Respondent Admission**

If the respondent provides a signed and legally sufficient admission in writing, a case may be closed. For each allegation, the statement must a) describe the type of research misconduct; b) identify the affected research records; c) explain whether it was committed, knowing, intentionally or recklessly; and d) acknowledge that the actions were a significant departure from accepted practices of the relevant research community. The RIO (jointly with HMS if a joint process) will appoint a person or committee to review the details of the admission. Before settlement with the respondent can be reached, the RIO will notify ORI for PHS-supported research. 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).

## C. Respondent Termination or Resignation

The termination of the respondent's employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of BCH's responsibilities to pursue allegations.

If the respondent, without admitting to misconduct, elects to resign the respondent's position after BCH receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

## VI. Time Limitations and Record Retention

An inquiry will be completed within ninety (90) days of initiation unless circumstances warrant a longer period, in which case BCH will document the reasons for the extension in the inquiry report. An investigation will be completed within one hundred eighty (180) days of its initiation unless circumstances warrant a longer period. However, if the RIO determines that the investigation will not be completed within this 180-day period, the rationale for the delay will be documented and the RIO will, if applicable, notify federal agencies as required and in accordance with federal regulations.

It is expected that all individuals subjects to this Policy shall comply with applicable BCH Record Retention Policy. BCH will maintain the institutional record and all sequestered evidence, including physical objects (regardless of whether the evidence is part of the institutional record), in a secure manner for seven (7) years after the completion of the proceeding or the completion of any HHS proceeding, whichever is later, unless custody has been transferred to HHS. After this period, records are subject to the BCH Record Retention Policy.

## Related Content

- [BCH Record Retention Policy](#)
- [Research Data Management Policy/Procedure](#)

## External (non-BCH) References

- [PHS Policies on Research Misconduct](#)
- [HMS Interim Policy and Procedures for Responding to Allegations of Research Misconduct](#)
- [HHMI Research Misconduct Policy](#)

## Approval Signatures

Step Description	Approver	Date
Co-chair Approval	David Davis	4/22/2026
Site Administrator: Education/ Training Requirement	Dwight Mayfield	4/22/2026
Steering Committee	Dwight Mayfield	4/22/2026
Required Departmental Review/Approval	Timothy Hogan	4/7/2026
Committee Chair(s)	Fariba Houman	4/6/2026
Contributor(s)	Fariba Houman	4/6/2026
Document Owner	Fariba Houman	4/6/2026

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## Applicability

Boston Children's Hospital- Policies & Procedures

## Chapter / Tags

Investigation, Office of Research Integrity, RIO, Research Integrity Officer, fabrication, falsification, plagiarism