Harvard Medical School
Interim Policy and Procedures for Responding to Allegations of Research Misconduct

I. Basis for Policy

Integrity in scholarship and research is one of the University's fundamental values. Thus, allegations of misconduct in scholarship and research must be treated with the utmost seriousness and examined carefully and responsibly.

It is the shared responsibility of all members of our academic community to ensure that misconduct in scholarship and research is dealt with in a timely and effective manner, and that the reputation of the University for high standards of scholarly and research integrity is preserved. Harvard Medical School ("HMS") is committed to addressing allegations of research misconduct and has established this **Policy and Procedures for Responding to Allegations of Research Misconduct** (the "Policy") to guide the process of reviewing, investigating, and reporting such allegations.

II. Scope of Policy

This Policy is intended to comply with institutional responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. Other federal agencies have published their own research misconduct regulations; to the extent those regulations apply to an allegation of research misconduct and are inconsistent with this Policy, the University shall comply with the applicable regulatory requirements. This Policy also applies to research that is not federally funded, although such cases need not be reported to the federal government and may deviate from the procedures set forth herein in order to expedite reviews consistent with a thorough, competent, objective and fair research misconduct proceeding.

This Policy applies to allegations of research misconduct (as defined by this Policy) involving any person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was academically appointed at HMS through an HMS affiliated institution,[1] including without limitation HMS officials, tenured and non-tenured faculty and teaching staff, as well as HMS-appointed researchers, post-doctoral and other fellows, students and trainees, HMS employees, volunteers and agents conducting research funded through, or utilizing the resources of, HMS or an HMS affiliated institution. This Policy may be applied to any individual no longer affiliated with HMS if the alleged misconduct occurred while the person was employed by an agent of, or affiliated through an academic appointment with Harvard Medical School as described in the prior sentence and the work in question was conducted through, or utilizing the resources of, HMS or an HMS affiliated institution. These policies and procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six years of the date the University or the U.S. Department of Health and Human Services ("HHS") received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions articulated in 42 C.F.R. § 93.105(b) or any exception articulated in an HMS affiliated institution's policy.

With respect to students involved in allegations of research misconduct that involve federal funding, the

[1] Unlike many medical schools, HMS does not own or operate hospitals, relying instead on agreements with clinical affiliates and research institutes that provide patient care and clinical training. These hospitals and institutes employ many physicians and scientists with HMS faculty appointments.

relevant School's disciplinary board will be notified of the initiation of any inquiries and/or investigations and will be informed of the findings of any such inquiries and/or investigations, including receiving copies of all inquiry and/or investigation reports.

III. Other Professional Conduct Violations

In addition to allegations of research misconduct as defined by this Policy, HMS may, at its discretion, use this Policy as a general framework for reviewing other allegations of faculty conduct violations that are not research misconduct, including but not limited to the following:

- *Abuse of confidentiality*: releasing the ideas or data of others that were shared with the legitimate expectation of confidentiality (e.g., disclosing ideas from others' grant proposals, award applications, or manuscripts for publication when one is a reviewer for granting agencies or journals, or is an internal reviewer);
- *Sabotage or other property violations*: stealing, tampering with, or destroying property of others, such as experiments, research papers, supplies, equipment, or products of research or scholarship.
- *Failure to report observed research misconduct*: covering up or otherwise failing to report observed, suspected, or apparent research misconduct by others.
- *Retaliation*: Any act of retaliation as defined in this Policy; or
- Directing or encouraging others to engage in any of the above listed offenses.

Such cases, like those cases involving research that is not federally funded, need not be reported to the federal government.

IV. Definitions

Allegation: a disclosure of possible research misconduct through any means of communication.

Committee member: a member of any ad hoc committee appointed to conduct all or a portion of the research misconduct process under this Policy.

Complainant: a person who in good faith makes an allegation of research misconduct.

Conflict of interest: financial, personal, or professional relationships that may compromise, or appear to compromise a person's decisions.

Deciding Official (DO): the institutional official who makes final determinations about allegations of research misconduct and any institutional actions, ordinarily the Dean of the Faculty of Medicine, along with, in cases involving an HMS affiliated-institution, the President or Chief Executive Officer of the HMS-affiliated institution or any other person specified in that institution's own policy. The Deciding Official does not serve as the Research Integrity Officer and is not directly involved in the institution's preliminary assessment, inquiry, or investigation. The Deciding Official's involvement, if any, in the appointment of a person to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct involvement.

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

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

Falsification: 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

As applied to a complainant or witness: having a belief in the truth of one's allegation or testimony that a reasonable person in the same position could have, based on the information known to the person at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony.

As applied to a committee member: cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping the institution meet its responsibilities under the Policy. A committee member does not act in good faith if the committee member's acts or omissions on the committee 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.

Investigation: the formal development of a factual record and the examination of that record leading to a decision about whether to recommend a finding of research misconduct, which may include a recommendation for other appropriate actions, including institutional actions.

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

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

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

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, or the underlying mechanism relating to, the matters to be studied.

Research Integrity Officer (RIO): the institutional official responsible for, at a minimum: (1) reviewing allegations of research misconduct to determine if they fall within the definition of research misconduct

and warrant an inquiry; and (2) overseeing inquiries and investigations.

Research misconduct: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct includes fabrication, falsification, and plagiarism (as defined in this Policy). 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 or other scholarly endeavors, including but not limited to research proposals, laboratory records (physical and electronic), progress reports, abstracts, theses, oral presentations, internal reports, journal articles, correspondence, and any documents and materials provided to an institutional official in the course of a research misconduct proceeding.

Respondent: the person 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.

Standing Committee: the HMS Standing Committee on Faculty Conduct, charged with the responsibility to: (1) evaluate and affirm, remit or overturn any finding of an inquiry committee that no allegations proceed to investigation; and (2) to evaluate and affirm, remit or overturn the finding of an investigation committee on whether research misconduct has been committed. In each instance, the Standing Committee also is charged with the responsibility to propose recommendations regarding institutional actions in response to a matter to the Deciding Official(s), as appropriate. Members of the HMS Standing Committee may also be called upon to act as a member(s) of an inquiry committee. In such cases, the member(s) shall be recused from any subsequent deliberation of the allegations.

V. General Policies and Principles

A. Research Misconduct Prohibited, Standard of Proof

HMS prohibits research misconduct and investigates and responds to allegations of research misconduct in accordance with this Policy. Throughout the research misconduct process, which begins at the time an allegation is made, all participants shall bear in mind the importance, both in fact and in appearance, of thoroughness, fairness, and objectivity. Individuals subject to this policy found to have committed research misconduct ordinarily shall be subject to sanctions up to and including termination.

A finding of research misconduct requires that:

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

The destruction of research records, absence of research records, or respondent's failure to provide research

records adequately documenting the questioned research is evidence of research misconduct where the institution establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

HMS bears the burden of proof for making a finding of research misconduct. A respondent has the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised (such as honest error).

B. 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.

C. Cooperation with Research Misconduct Proceedings

All individuals subject to this Policy shall cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. All individuals subject to this Policy, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

D. Duty to Maintain Confidentiality

Because of the potential jeopardy to the reputation and rights of a respondent, the RIO and all Committee members (as defined in this Policy) as well as all others at the University who may be involved in the research misconduct proceeding shall to the extent possible: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. Where communications about research misconduct proceedings may be considered necessary or advisable, HMS officials should be guided by the Guiding Principles for Communication in Research Misconduct Proceedings.[2] Inappropriate dissemination of information may result in sanctions up to and including termination.

E. Rights and Responsibilities of Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. If the inquiry committee deems it necessary, the complainant may be interviewed at the inquiry stage and, if so, shall be given the transcript or recording of the interview for correction. The complainant ordinarily shall be interviewed during the investigation phase, and given the transcript or recording of the interview for correction. After making an allegation of research misconduct, the

[2] https://files.vpr.harvard.edu/files/vpr- documents/files/guiding_principles_for_communication_in_research_misconduct_proceedings.pdf

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.

F. Rights and Responsibilities of Respondent

The respondent is responsible for maintaining confidentiality 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. 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 but may not question witnesses or otherwise take part in the research misconduct proceedings. The respondent should be given the opportunity to admit that research misconduct occurred and that the respondent committed the research misconduct. With the advice of the RIO and/or other institutional officials, the Deciding Official may terminate HMS' review of an allegation that has been admitted, provided that, for federally funded research, HMS' acceptance of the admission and any proposed settlement is approved by the relevant federal agency.

G. Protecting Complainants, Witnesses, the RIO, and Committee Members

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

VI. PRELIMINARY ASSESSMENT OF ALLEGATIONS

When an allegation of research misconduct is brought to the attention of the RIO, the RIO first will determine whether coordination with an HMS-affiliated institution is required, as set forth below. If not, then the RIO immediately will assess the allegation to determine whether 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.

An inquiry must be conducted if these criteria are met.

Coordination with HMS-Affiliated Institutions. If a respondent had an HMS academic appointment, but was employed by or associated with an HMS affiliated institution (and not employed by HMS), at the time of the alleged research misconduct and conducted the research in question under an award to that affiliated institution, then HMS will refer the matter to the relevant affiliated institution's RIO for preliminary assessment, pursuant to that institution's applicable policy and procedures. If an affiliated institution finds the allegations warrant further institutional review through an inquiry, then the RIO of the affiliated institution shall notify the RIO of HMS and the two institutions shall jointly initiate an inquiry. In such cases, ordinarily a joint review will be conducted by HMS on behalf of both institutions. The final adjudication of the matter rests jointly with the Deciding Officials of HMS and the affiliated institution.

If, upon receipt on the allegation, it appears that the RIO has any unresolved personal, professional, or

financial conflicts of interest with those involved in the allegations, then the Deciding Official shall appoint another qualified individual to serve as Interim RIO with respect to reviewing the allegation and conducting any research misconduct proceeding.

The assessment period when conducted by HMS should be brief, preferably concluded within a week. Where it is not feasible to conclude the assessment within a week, the process should proceed expeditiously. 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, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The preliminary assessment shall be documented and all records pertaining to the review of allegations will be retained by the RIO for a period of seven (7) years following the completion of the proceeding.

VII. Sequestration of Research Records and Notice to Respondent

A. Sequestration of Research Records

This Policy governs access to research records, including without limitation Harvard email records, for purposes of conducting research misconduct proceedings.[3] Those engaged in administering this Policy have all rights necessary to access research records created or maintained by individuals subject to this Policy.[4]

As to timing, on or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO of the institution where the research in question was conducted, which may be the RIO at an HMS affiliated institution, must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding. The relevant RIO also shall sequester any additional research records that become pertinent to an inquiry or investigation after the initial sequestration. In any case where the work in question was conducted primarily at an HMS affiliated institution, and not at HMS itself, the RIO for the HMS affiliated institution shall follow that institution's own applicable policies and procedures for sequestration.

The RIO is responsible for inventorying the records and evidence and sequestering them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

Where applicable, the RIO at an HMS-affiliated institution is responsible for transferring sequestered records and evidence, along with the accompanying inventory, to HMS for access in connection with any joint process that may be conducted by HMS on behalf of both institutions. Where appropriate, HMS shall give the respondent copies of, or reasonable supervised access to, the research records.

[3] For clarification, Harvard's Policy on Access to Electronic Information specifically states that it does not apply to reviews of research misconduct allegations. Section I, Internal Investigations of Misconduct, p. 4.

[4] Harvard's Research Data Ownership Policy makes clear that "the University asserts ownership over research data for all projects conducted at the University, under the auspices of the University, or with University resources," and further states that "[w]hen it is necessary to secure access (e.g. during a research misconduct proceeding) the University may take custody of research data." Policy and Procedures, Section 1.B, p. 2.

B. Notice to Respondent

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

VIII. THE INQUIRY

A. Initiation and Purpose of the Inquiry

The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

B. Appointment of the Inquiry Committee

The inquiry committee will be appointed by the RIO or their designee, in consultation with other institutional officials as appropriate. Ordinarily the inquiry committee will be comprised of a single member of the Standing Committee, although, at the discretion of the RIO or their designee, it may include more than one member of the Standing Committee or another faculty member or scientist, either from HMS or from another institution, in order to secure appropriate expertise and/or to avoid a personal, professional, or financial conflict of interest with those involved with the research misconduct proceeding. The inquiry committee should include individuals with the appropriate subject-matter expertise to: evaluate the evidence and issues related to the allegation; interview the principals and key witnesses; and conduct the inquiry.

Prior to the initiation of the Inquiry, the respondent will be notified in writing of the inquiry 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 or their designee will make the final determination of whether a conflict exists.

C. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that sets forth the purpose of the inquiry and the expected timeframe, the committee's responsibilities, the allegations, and any related issues identified during the preliminary assessment. The charge also shall inform the committee that an investigation is warranted if the committee determines, based on its review during the inquiry, that: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and (2) the preliminary information- gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

D. Inquiry Process

The inquiry committee ordinarily will interview the respondent and key witnesses, which may include a

complainant, as well as examining relevant research records and materials. Any interviews will be recorded or transcribed, with recordings or transcripts provided to the interviewee for correction. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry. In consultation with the RIO, the committee members will decide whether an investigation is warranted based on the criteria in this Policy.

The scope of the inquiry is not required to and does not include deciding whether misconduct definitely occurred, determining who committed the research misconduct, or conducting exhaustive interviews and analyses.[5] 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, HMS shall promptly consult with the relevant federal agency to determine the next steps that should be taken.

E. The Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the funding support, including, for example, grant numbers, grant applications, contracts and publications listing all support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent.

The Office of General Counsel shall be available to advise the inquiry committee and the RIO with respect to the report. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

F. Notification of the Results of the Inquiry; Opportunity to Comment

The RIO or their designee shall notify the respondent as to whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 business days, and include a copy of or link to this Policy and 42 C.F.R. Part 93 (if applicable).

Any comments that are submitted by the respondent will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

G. Institutional Decision and Notification

1. Standing Committee Review

If the final inquiry report for any given respondent recommends that no allegation proceed to investigation with respect to that respondent, the RIO will transmit the final inquiry report for that respondent and any comments to the Standing Committee, which shall meet to consider the inquiry committee's recommendation. Any Standing Committee member(s) who served as the inquiry committee shall be recused from discussion of the case.

[5] As noted above, an investigation is warranted if the committee determines, based on its review during the inquiry,that: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and (2) the preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

Following its meeting, the Standing Committee shall produce a letter to the Deciding Official(s). The letter will include a determination of whether the Committee agrees with the inquiry committee's recommendation.

As part of the Standing Committee letter, and regardless of whether there is a recommendation for investigation, the Committee may recommend additional actions consistent with the principles and goals underlying this policy. Such recommended actions include, without limitation: correcting the public research record; requiring additional training or mentorship of the respondent; and/or referring concerns raised during the inquiry process not germane to the inquiry committee's charge to other institutional processes.

2. *Decision by Deciding Official*

The final inquiry report and any comments, along with the final Standing Committee letter, will be submitted to the Deciding Official(s), who will make a written determination as to whether an investigation is warranted. The inquiry is completed when the DO(s) make this determination.

3. *Notification to Federal Agencies (when appropriate)*

Within 30 calendar days of the Deciding Official(s)' decision that an investigation is warranted, the RIO will provide ORI (or the relevant federal agency) with the Deciding Official(s)' written decision and a copy of the final inquiry report. The RIO also will notify institutional officials who have a need to know of the Deciding Official(s)' decision.

4. *Documentation of Decision Not to Investigate*

If the DO(s) decide that an investigation is not warranted, the RIO shall secure and maintain for 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.

5. *Time for Completion*

The inquiry, including preparation of the final inquiry report and the decision of the DO(s) on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If an extension is approved, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

IX. THE INVESTIGATION

A. Initiation and Purpose

The investigation ordinarily should begin shortly after completion of the inquiry and in the case of PHS funding, must begin within 30 calendar days after the determination by the DO(s) that an investigation is warranted. On or before the date on which the investigation begins, the RIO must: (1) if applicable, notify ORI of the decision to begin the investigation and provide ORI with a copy of the inquiry report (or comply with any other notice obligation to a government agency or other funder); and (2) notify the respondent in writing of the allegations to be investigated.

The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation committee shall pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. If new allegations are identified, the RIO must also 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 notice of the investigation.

B. Sequestration of Research Records

On or before the date on which the respondent is notified, or the investigation begins, whichever is earlier, the RIO at HMS or the HMS-affiliated institution where the research in question was conducted 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 the institution's decision to investigate additional allegations 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 procedures that apply during the inquiry, including the requirement that a RIO at a HMS-affiliated institution create an inventory of sequestered records and transfer all to HMS for access by the investigation committee.

C. Appointment of the Investigation Committee

The RIO or their designee, 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 the appropriate subject-matter expertise to: evaluate the evidence and issues related to the allegation; interview the respondent and complainant; and conduct the investigation. Individuals appointed to the investigation committee also may have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO or their designee may select investigation committee members from outside the institution.

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 or their designee will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. *Charge to the Committee*

   The RIO will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry; identifies the respondent; informs the committee that it must conduct the investigation as prescribed by this Policy; defines research misconduct; and instructs the investigation committee on the burden of proof. The charge shall state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and

key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. Finally, the charge shall inform the committee that a written investigation report that meets the requirements of this Policy must be prepared reflecting the committee's work.

2. *First Meeting*

At the committee's first meeting, the RIO will review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of this Policy, the applicable policies of any relevant HMS affiliated institutions and applicable federal regulations. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

- Use diligent efforts to ensure that the investigation 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; record or transcribe each interview; provide the recording or transcript to the interviewee for correction; and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. The Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

- Describes the nature of the allegation of research misconduct, including identification of the respondent.
- Describes and documents financial support for the research subject to the allegations, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing support;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence

taken into custody but not reviewed; and

- Includes a statement of findings for each allegation of research misconduct identified during the investigation.[6] Each statement of findings must: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that they did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific funding support (if any); (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with federal agencies or external funders.

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 General Counsel shall be available to advise the investigation committee and the RIO with respect to the report. Modifications should be made as appropriate in consultation with the RIO and the investigation committee.

G. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO will give the respondent a copy of the draft investigation report and exhibits for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from receipt of the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Confidentiality

In distributing the draft report to the respondent for comment, the RIO will remind the respondent of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

H. Decision by Deciding Official

The RIO will transmit the final investigation report to the Standing Committee, which shall meet to consider the investigation committee's recommendation. The respondent will be offered an opportunity to attend the meeting and address the Standing Committee. Any Standing Committee member(s) who served as the inquiry committee shall be recused from discussion of the case.

[6]As noted above, a finding of research misconduct requires that: there be a significant departure from accepted practices of the relevant research community; the respondent committed the research misconduct intentionally, knowingly, or recklessly; and the allegation be proven by preponderance of the evidence.

Following its meeting, the Standing Committee shall produce a letter to the Deciding Official. The letter will include a determination of whether the Standing Committee agrees with the investigation committee's recommendation. If the Standing Committee letter includes a finding and/or recommendations regarding sanctions against the respondent, then the RIO or their designee shall provide the respondent with a copy of the draft Standing Committee letter for comment. In such cases, the respondent will be allowed no less than seven (7) calendar days from receipt of the draft letter to submit comments. Based on the comments, the Standing Committee may revise the draft letter as appropriate. Any comments that are submitted by the respondent prior to the deadline will be attached to the final Standing Committee letter, which will be submitted to the Deciding Official.

The Standing Committee letter may recommend institutional administrative actions, including without limitation: correcting the public research record; requiring additional training or mentorship of the respondent; and/or referring concerns raised during the investigation process not germane to the investigation committee's charge to other institutional processes.

The final investigation report and the final Standing Committee letter will be submitted to the DO(s), who will make a written determination as to (1) whether the institution accepts their findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee and/or the Standing Committee, the DO(s) will explain in detail the basis for rendering a different decision. Alternatively, the DO(s) may return the investigation report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the respondent will be notified in writing. HMS and any HMS-affiliated institution involved in the matter are responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. In consultation with institutional officials, the DO(s) also will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

I. Institutional Actions

After a determination of research misconduct is made, the DO(s) may decide on appropriate actions to be taken, after consultation with others at the University as appropriate. Sanctions for research misconduct shall be based on the seriousness of the misconduct, including but not limited to, the degree to which the misconduct: a) was intentional, knowing or reckless; b) was an isolated event or part of a pattern; and c) had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare. 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 employment; restitution of funds as appropriate; suspension or termination of an active award, letters of reprimand; and other action appropriate to the research misconduct. For cases involving research misconduct by students conducting research at HMS, sanctions shall be determined by the HMS Promotions and Review Board, or, for Harvard students from different Harvard Schools, by the relevant disciplinary board, for example, the Harvard School of Dental Medicine student

disciplinary board, or the Harvard Kenneth C. Griffin Graduate School of Arts and Sciences Administrative Board.

J. Notice to Federal Agencies of Institutional Findings and Actions

When the DO(s) reach a final decision on the case, the investigation is complete, and the RIO will transmit to the applicable funding agency: (1) a copy of the final investigation report with all attachments, along with a copy of the final Standing Committee letter; (2) a statement of whether the institution accepts the findings of the investigation report; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed institutional actions against the respondent.

K. Time for Completion

The investigation ordinarily shall be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment, finalizing the report and making necessary notifications. However, if the RIO determines that the investigation will not be completed within this 120-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. The RIO will ensure that periodic progress reports are filed with federal agencies and in accordance with federal regulations.

X. Interim Institutional Actions and Notifying Federal Agencies of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or the integrity of the 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, the University 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:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- Federal resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and federal action may be

necessary to safeguard evidence and protect the rights of those involved; or

- The research community or public should be informed.

XI. Completion of Cases

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. For allegations that include PHS funded research, HMS must notify ORI in advance if there are plans to close a case at the inquiry or investigation stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this Policy and 42 CFR § 93.315. For allegations that include non-PHS funded research, HMS must comply with any other notice obligation to a government agency or other funder.

XII. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

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 HMS' responsibilities to pursue allegations.

If the respondent, without admitting to the misconduct, elects to resign the respondent's position after HMS 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.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including ORI concurrence where required by 42 CFR Part 93 (or, for non-PHS funded research, other applicable federal agency requirements), the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.

C. Allegations Not Made in Good Faith

If relevant, the DO(s) will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO(s) determines that there was an absence of good faith, the DO(s) will determine whether any administrative action should be taken against the person who failed to act in good faith.

D. Maintaining Records

Unless HMS has transferred custody of the records of research misconduct proceedings (as defined by 42 C.F.R. § 93.317) to the funding agency in accordance with applicable law, the University shall maintain the records of a research misconduct proceeding in a secure manner during its pendency and for seven (7) years

after completion of the proceeding or completion of any agency oversight proceeding, or as required by any applicable record retention provision, whichever is later.