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 Harvard 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 rigor 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, HMS 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 HMS may choose to amend the procedures set forth herein in such cases in order to expedite reviews, provided that the amended process is thorough, competent, objective and fair. With respect to federally-funded research, in any case of conflict between this Policy and applicable federal regulations, including 42 CFR Part 93, the applicable regulations will prevail.

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 directly or 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 HMS appointees conducting work through 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 subject to the Policy as described in the prior sentence or if the person was subject to the Policy at the time the research activities underlying the alleged misconduct were undertaken and the work in

[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.

question was conducted through, or by utilizing the resources of, HMS or an HMS affiliated institution.

This Policy does not apply to authorship or collaboration disputes or any other allegation that is not specifically covered by this Policy. This Policy applies only to allegations of research misconduct that occurred within six years of the date the University, the U.S. Department of Health and Human Services ("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 HMS or an HMS affiliated institution determines is not subject to the exception, the institution[2] 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 HHS Office of Research Integrity ("ORI"), HMS or an HMS affiliated institution determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.
- The six-year time limitation also does not apply if:
    - The matter is governed by regulation or other requirements issued by an agency that recognizes no statute of limitations;
    - The matter is subject to any other exception articulated in an HMS affiliated institution's policy; or if
    - HMS, in consultation with an HMS affiliated institution as applicable, determines in good faith that the interests of the institution warrant application of these procedures to the alleged research misconduct.

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

[2] If the work in question was conducted through, or by utilizing the resources of, an HMS affiliated institution, the HMS affiliated institution will be responsible for determining whether the subsequent use exception applies and for documenting its determination and making such documentation available to HMS and/or HHS upon request. HMS shall be responsible for such determination and documentation with regard to any work conducted through, or by utilizing the resources of HMS.

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

Accepted practices of the relevant research community: those practices established by applicable research misconduct regulation or by a sponsor's funding components (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 through 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.

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: an individual who in good faith makes an allegation of research misconduct.

Conflict of interest: an unresolved financial, personal, or professional relationship that reasonably could compromise a person's decisions under this Policy.

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: 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 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

As applied to an institutional or committee member: cooperating with the research misconduct proceeding by impartially carrying out the duties assigned for the purpose of helping an institution meet its responsibilities under the 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.

Institution: Institution means HMS and, as applicable, the relevant HMS affiliated institution.

Institutional Deciding Official (DO): the institutional official who makes final determinations on 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 same individual cannot serve as the Deciding Official and the Research Integrity Officer.

Institutional member: an individual who is employed by, is an agent of, or is affiliated by contract or agreement (including academic appointment) with HMS directly or through an HMS affiliated institution. Institutional members may include, but are not limited to, 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 (research coordinators, support staff, technicians), volunteers and agents conducting research funded through, or utilizing the resources of, HMS or HMS appointees conducting work through an HMS affiliated institution.

Institutional record. The institutional record comprises:

(a) The records that the Institution(s) compiled or generated during the research misconduct proceeding, except records the Institution(s) 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(s), 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(s);
4. Decision(s) by the Deciding Official(s), such as the written decision from the Deciding Official(s).

(b) A single index listing all the research records and evidence that the Institution(s) compiled during the research misconduct proceeding, except records the Institution(s) 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 about whether to recommend 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 (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. As used under this Policy:

(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.

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, such as 42 CFR Part 93. This includes at a minimum:

(a) Reviewing allegations of research misconduct to determine if they fall within the definition of research misconduct and warrant an inquiry; and
(b) Overseeing inquiries and investigations.

Research misconduct[3]: fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, research training, or other activities relating to research or research training, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

Research misconduct proceeding: any actions related to alleged research misconduct taken under this Policy or applicable regulation, including allegation assessments, inquiries, investigations and oversight reviews by ORI or other cognizant agencies.

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,

[3] For cases involving research supported by the National Science Foundation (NSF), the definition is as follows: fabrication, falsification, or plagiarism, whether committed by an individual directly or through the use or assistance of other persons, entities, or tools, including artificial intelligence (AI)-based tools, in proposing or performing research funded by NSF, reviewing research proposals submitted to NSF, or in reporting research results funded by NSF.

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, online content, lab meeting reports, journal articles, and correspondence.

Respondent: the individual 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) A good faith allegation of research misconduct; or
(b) Good faith cooperation with a research misconduct proceeding.

Standing Committee: the HMS Standing Committee on Faculty Conduct, charged with the responsibility to:

(a) Evaluate and affirm, remit or overturn any finding of an inquiry committee that no allegations proceed to investigation; and
(b) To evaluate and affirm, remit or overturn any 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 also may serve on an inquiry committee.

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, competence, 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 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. The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records, but refuses to provide them upon request. It is expected that all institutional members shall comply with applicable institutional policies and regulation regarding retention and storage of research records.

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). Due consideration shall be given to admissible, credible evidence of honest error or difference of opinion presented by a respondent.

B. Responsibility to Report Misconduct

All individuals subject to this Policy will report observed, suspected, or apparent research misconduct to the RIO or Deputy 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 research misconduct proceedings. All individuals subject to this Policy, including respondents, have an obligation to provide information, research records or other 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 Institution (including without limitation the RIO, all Committee members (as defined in this Policy) and 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, complainants and witnesses while conducting the research misconduct proceedings to those who need to know; and
2. Except as may otherwise be prescribed by applicable law, maintain confidentiality for any records or evidence from which research subjects might be identified and limit disclosure to those who need to know in order to carry out a research misconduct proceeding. The Institution will determine those who need to know consistent with a

thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. 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 the Institution 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 the Institution, to make such disclosure.

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.[4] Inappropriate dissemination of information may result in sanctions up to and including termination.

Nothing herein shall prevent the Institution 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.

E. Rights and Responsibilities of 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 the Institution 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.

F. Rights and Responsibilities of 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 HMS 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 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

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

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.

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

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

The Institution(s) will take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not any unresolved conflict of interest with the complainant(s), the respondent(s) or any witness(es).

The University will take reasonable and practical steps to protect the positions and reputations of anyone participating in the research misconduct process (including without limitation complainants, witnesses, committee members, the RIO, or the DO) and to protect these individuals from retaliation by respondents and/or other institutional members. Any alleged or apparent retaliation should be reported immediately to the RIO or to the RIO's supervisor, as applicable.

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.

If these criteria are met, the RIO will promptly:

(a) Document the assessment;
(b) Sequester all research records and other evidence; and
(c) Initiate an inquiry as set forth in Section VII below. 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 federal or externally funded research.

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

activities in question through, or 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 following assessment that 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, a joint review will be conducted, administratively staffed and managed 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 Acting RIO with respect to reviewing the allegation and conducting any research misconduct proceeding.

Any assessment conducted by HMS should be completed 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. An assessment is intended to be a review of readily accessible information relevant to the allegation, and, where an inquiry is appropriate, to include specific allegation language suitable for notification to the respondent. The assessment shall be documented in sufficient detail to permit a later review by ORI or other federal agency of the reasons for proceeding or not proceeding to inquiry. All records pertaining to the review of allegations will be retained by HMS for a period of seven (7) years following the completion of the assessment or any related research misconduct 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, and other evidence needed to conduct research misconduct proceedings.[5] Those engaged in administering this Policy shall be deemed by HMS to have all rights necessary for purposes of carrying out their duties under this Policy to access research records created or maintained by institutional members.[6]

As to timing, before or at the time of notifying the respondent(s), the RIO of the institution where the research in question was conducted, which may be the RIO at an HMS affiliated institution, will take all reasonable and practical steps to obtain custody of all original or substantially equivalent copies of research records and evidence needed to conduct the research

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

[6] Harvard's Research Data Ownership Policy makes clear that "the University asserts ownership over research datafor all projects conducted at the University, under the auspices of the University, or with University resources," andfurther 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.

misconduct proceeding. The duty to obtain, inventory, and securely sequester evidence extends to whenever additional items become known or relevant to the inquiry or investigation. 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 and shall be exclusively responsible for carrying out the sequestration, creating the inventory of sequestered research records, and documenting the devices, platforms, and methodologies used (e.g., forensic imaging of electronic devices, capture from specific cloud-based platforms, etc.). The respondents and all other institutional members subject to this Policy must provide immediate assistance in response to any request by the RIO to identify and secure research records relevant to the research misconduct proceeding.

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 and device/methodological documentation, to HMS for access in connection with any joint process that may be conducted by HMS on behalf of both institutions. When appropriate, HMS is responsible for providing the respondent copies of, or reasonable supervised access to, the sequestered research records.

B. Notice to Respondent

At the time of or before beginning an inquiry, the RIO will make a good faith effort to notify the respondent(s), in writing, that an allegation of research misconduct has been raised against them, the relevant research records have been sequestered (if applicable), and an inquiry will be conducted to decide whether to proceed with an investigation. If additional allegations are raised, the institution will notify the respondent(s) in writing. If additional respondents are identified, they must be notified in writing. Only allegations specific to a particular respondent will be included in the notification to that respondent.

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 an allegation warrants an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

B. Inquiry Initiation

The inquiry ordinarily will be conducted by the RIO and/or their designee(s) and, as applicable, the RIO of the relevant HMS affiliated institution, provided they utilize one or more faculty subject matter experts as needed to assist them. Alternatively, the RIO(s) may appoint such faculty subject matter experts to be members of an ad hoc committee tasked to conduct the Inquiry along with or in lieu of the RIO(s). In all cases, individuals conducting the inquiry will not have personal, professional, or financial conflicts of interest with those involved with the research misconduct proceeding. When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO or their designee may appoint committee members from outside the institution. Any determination that an allegation(s) should proceed to investigation must be approved by the faculty Chair of the Standing Committee or another member of the Standing Committee designated by the Chair.

Prior to the initiation of the Inquiry, the respondent will be notified in writing of the identities of those who will conduct the inquiry and will be afforded five (5) calendar days to lodge objections based upon an individual's alleged personal, professional, or financial conflict of interest. The Chair of the Standing Committee or another designed member of the Standing Committee will make the final determination as to whether a conflict exists.

C. Inquiry Process

The RIO(s) or inquiry committee, as applicable, will conduct a preliminary review of the evidence. In the process of fact-finding, the RIO(s), or inquiry committee, as applicable, may interview the respondent and/or witnesses, which may include a complainant. Any interviews will be recorded or transcribed, with recordings or transcripts 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 the Institution deems appropriate to maintain confidentiality.

Subject to the final approval of the Chair of the Standing Committee (or designee), the RIO(s) or inquiry committee, as applicable, will evaluate the evidence and determine whether an investigation is warranted. An investigation is warranted if:

(a) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and
(b) Preliminary information-gathering and fact-finding from the inquiry indicates that the allegation may have substance. Any determination by the RIOs, or committee as applicable, that an allegation(s) should proceed to investigation must be approved by the faculty Chair of the Standing Committee or another member of the Standing Committee designated by the Chair following review of the final inquiry report, including respondent's comments on the draft inquiry report.

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,

HMS shall consult promptly with the relevant federal agency to determine the next steps that should be taken.

D. 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:

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

The Office of the 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 Chair of the Standing Committee or other designated member of the Standing Committee, the RIO and the inquiry committee.

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

The RIO or their designee will give the respondent a copy of the draft inquiry report for review and an opportunity to provide written comments within 10 business days.

Any comments that are submitted by the respondent will be attached to the final inquiry report. Based on the comments, the RIO(s), or inquiry committee as applicable, may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the Chair of the Standing Committee or other member of the Standing Committee designated by the Chair. If the inquiry determines that further investigation is warranted with respect to any allegation, the faculty Chair of the Standing Committee or another member of the Standing Committee designated by the Chair must approve the determination(s) following review of the final inquiry report. If approved, the RIO will notify the respondent of the final outcome with

a copy of the final inquiry report and include a copy of or link to this Policy and any applicable agency regulation, including 42 C.F.R. Part 93 (if applicable).

F. Institutional Decision and Notification

1. Standing Committee Review

   If the final inquiry report for any respondent recommends that no allegation proceed to investigation with respect to that respondent or if the Chair of the Standing Committee or their designee fails to approve an inquiry report's determination that an allegation(s) proceed to investigation with respect to a respondent, then the RIO will transmit the final inquiry report for that respondent and any comments to the full Standing Committee, which shall meet to consider the inquiry committee's recommendation.

   Following its meeting, the Standing Committee shall provide a letter to the Deciding Official(s), along with a copy of the final inquiry report, with a determination of whether the Standing Committee agrees with the inquiry committee's recommendation.

   Regardless of whether there is a recommendation for investigation, the Standing Committee's letter may recommend additional actions consistent with the principles and goals underlying this policy, including for example: 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

   For any matter where the inquiry determines that an investigation is not warranted with regard to any allegation against a respondent, the final inquiry report and any comments, along with the final Standing Committee letter, will be submitted to the Deciding Official(s). Such inquiry is completed when the DO(s) makes a determination that an investigation is not warranted.

3. Notification to Respondent(s) and to Federal Agencies (when appropriate)

   Within 30 calendar days of a determination that an investigation is warranted, the RIO will:
   1. 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
   2. Provide ORI with a copy of the final inquiry report along with the approval of the Chair of the Standing Committee or his or her designee of the final inquiry determination (or comply with any other notice obligation to a government agency or other funder).

   The RIO also will notify institutional officials who have a need to know of the decision.

4. Documentation of Decision Not to Investigate

If the inquiry determines that an investigation is not warranted, then 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 review and assessment of why the institution did not proceed to investigation. HMS must provide these records to ORI (or the relevant federal agency) upon request.

5. Time for Completion

An inquiry will be completed within 90 days of initiation unless circumstances warrant a longer period, in which case HMS will document the reasons for the extension in the inquiry report.

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 that an investigation is warranted.

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. As part of its investigation, the institution will pursue diligently all significant issues and relevant leads, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion. If new allegations are identified during an investigation, the RIO also 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 notice 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 unless HMS and the HMS affiliated institution, as applicable, in their sole discretion, determine that circumstances warrant the conduct of 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 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 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, including the requirement that a RIO at an 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 appropriate scientific expertise. 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 appoint investigation committee members from outside the Harvard/affiliate community.

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 as to whether a conflict exists.

D. Committee Orientation

The RIO will provide an orientation to the committee, 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 is 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 also will inform the committee that a written investigation report that meets the requirements of this Policy must be prepared reflecting the committee's work.

The RIO or their designee will review with the committee the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality. 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 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 RIO or their designee 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;
- 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. HMS will refer to any exhibits with sufficient clarity that a reader of the transcript can readily identify the materials under examination; 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 the Institution deems appropriate to maintain confidentiality;
- 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 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.[7]

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:

(a) Identify the individual(s) who committed the research misconduct;
(b) Indicate whether the misconduct was falsification, fabrication, and/or plagiarism;
(c) Indicate whether the misconduct was committed intentionally, knowingly, or recklessly;
(d) 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;
(e) Summarize the facts and analysis supporting the conclusion and consider the merits of any reasonable explanation by the respondent;
(f) Identify the specific funding support (if any); and
(g) State whether any publications need correction or retraction. Where findings of research misconduct have been made, the investigation committee may recommend institutional action(s) to the Standing Committee.

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 as specified herein, 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.

G. Comments on the Draft Report and Access to Evidence

1. Respondent

[7] 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.

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 that the investigation committee considered or relied on. The respondent will be allowed 30 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.

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 recommendations. In any case where the investigation report makes a determination of research misconduct by a respondent, that respondent shall be offered an opportunity to attend the meeting and address the Standing Committee.

Following its meeting, the Standing Committee shall produce a letter to the Deciding Official (DO) for HMS or, if appropriate, to the DOs for HMS and the relevant responsible HMS affiliate institution(s). The letter will include a determination of whether the Standing Committee agrees with the investigation committee's recommendation. If the Standing Committee letter recommends a finding and/or 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 it deems appropriate. Any comments 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; notification of a current employer or other third party who may be depending on the reliability of respondent's research results; 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 review them and make a final written determination as to:

1. Whether the institution accepts the recommended findings of the investigation committee as to whether there was research misconduct and if so, who committed the misconduct; and
2. The appropriate institutional actions in response to any findings of research misconduct or, if no findings of misconduct are made, on the basis of other conduct detailed in the final investigation report warranting corrective action (if any). If this determination varies from the recommended 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 organizing the institutional record and ensuring compliance with all notification requirements of funding or sponsoring agencies. In consultation with institutional officials, the DO(s) also will 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.

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.

Sanctions will also consider the degree to which the respondent may continue to conduct or contribute to research. 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; initiation of Third Statute proceedings to revoke tenure; 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. 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.

As indicated above, the DO(s) may also determine that corrective action involving the respondent is warranted on the basis of the conduct detailed in the investigation report, even if no findings of misconduct have been made.

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 or agencies:

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

HMS should seek to complete the investigation within 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.

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, HMS 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; or
- Federal action may be necessary to safeguard evidence and protect the rights of those involved.

Pursuant to a recommendation of the Chair of the Faculty Conduct Committee, an Inquiry Committee or an Investigation Committee, HMS, through the RIO, 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 HMS finds there are no research records available to support the published or submitted research.

XI. RESPONDENT ADMISSIONS

For allegations that include PHS funded research, HMS will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it plans to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached. If the respondent admits to research misconduct, the institution will not close the case until providing ORI with the respondent's signed, written admission. The admission must state the specific fabrication, falsification or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from the accepted practices of the relevant research community. The institution must not close the case until giving ORI a written statement confirming the respondent's culpability and explaining how the institution determined that the respondent's admission fully addresses the scope of the misconduct. For allegations that include non-PHS funded research, HMS must comply with any other obligations to a government agency or other funder with regard to respondent admissions.

XII. OTHER CONSIDERATIONS

A. Multiple Institutions

If the alleged research misconduct involves multiple institutions, HMS and the HMS affiliated institution, as applicable, may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead institution. 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.

B. 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.

C. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, the RIO will, at the request of the respondent and as appropriate, undertake all reasonable and practical efforts to restore the respondent's reputation.

D. 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 or whether other steps are necessary to correct the research misconduct process.

E. 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, HMS 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.