Marcus Institute for Aging Research
Hebrew SeniorLife

HARVARD MEDICAL SCHOOL AFFILIATE

Principles and Procedures for Dealing with Allegation of Research Misconduct in PHS-funded Research

Title:	Principles and Procedures for Dealing with Allegation of Research Misconduct in PHS-funded Research
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Original Effective Date:	8/16/17
Revised Date:	
Renewal Date:	7/17/19
Approved By:	

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1 Purpose

The purpose of this policy is to inform Institutional Members (as defined below) of Hebrew SeniorLife of the Public Health Service (PHS) Policies on Research Misconduct Final Rule at 42 CFR Parts 50 and 93, and to set clear expectations and institutional guidance for personal and professional integrity in Research. The effects of Research casts a broad net, from human health to education and beyond, and thus it is imperative that Research is conducted with the utmost transparency and integrity. Research Misconduct occurs when Research integrity is breached (and as further defined below).[1]

2 Definitions

Allegation means a disclosure of possible Research Misconduct through any means of communication. The disclosure may be written or oral statement or other communication to an institutional official of US Department of Health and Human Services (HHS) or Hebrew SeniorLife.

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

Evidence means any document, tangible item, or testimony offered or obtained during a Research Misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Funding Component means any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, *e.g.*, agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS.

Good Faith as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have 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 knowing or reckless disregard for information that would negate the allegation or testimony. **Good faith as applied to a committee member** means cooperating with the Research Misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part. A committee member does not act in good faith if his/her 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.

[1] For guidance regarding misconduct in non-PHS-funded research, refer to the HSL Policy "Reporting Suspected Misconduct" and/or the HSL Code of Conduct (both available on the HSL Intranet).

Hearing means that part of the Research Misconduct proceeding from the time a respondent files a request for an administrative hearing to contest Office of Research Integrity (ORI) findings of Research Misconduct and HHS administrative actions until the time an Administrative Law Judge (ALJ) issues a recommended decision.

Inquiry means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of the Federal policy at §§ 93.307– 93.309.

Institution means any individual or person that applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, small research institutions, and independent researchers. Hebrew SeniorLife is considered an Institution.

Institutional member or members means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an Institution. Institutional members may include, but are not limited to, employees, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and sub-awardees, and their employees.

Investigation means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of Research Misconduct or to a recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Preponderance of the evidence means 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 Misconduct is defined as **fabrication**, **falsification**, or **plagiarism** in proposing, performing, or reviewing Research, or in reporting Research results. Research Misconduct does not include honest error or differences of opinion.

- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** is manipulating Research materials, equipment, or processes, or changing or omitting data or results such that the Research is not accurately represented in the Research record.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research, as defined under PHS regulations, means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to public health by establishing, discovering, developing, elucidating or confirming information about, or the underlying mechanism relating to, biological causes, functions or effects, diseases, treatments, or related matters to be studied. **Research**, as used herein, includes all PHS-funded basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

Research Integrity includes

- the use of honest and verifiable methods in proposing, performing and evaluating Research
- reporting Research results with particular attention to adherence to rules, regulations, guidelines, and
- following commonly accepted professional codes or norms

Research Integrity Officer means the official designated by Hebrew SeniorLife to be responsible for assessing allegations of Research Misconduct, determining when such allegations warrant inquiries, conducting inquiries and investigations or staffing any committees constituted to undertake inquiries and investigations, and overseeing inquiries and investigations.

Research Record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the Research Misconduct proceeding.

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

Retaliation for the purpose of this part means 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.

3 General Policies and Principles

In accordance with PHS policy at 42 CFR 93.104, the requirements for making a finding of Research Misconduct are as follows:

- There be a significant departure from accepted practices of the relevant research communities, and
- The misconduct be committed intentionally, knowingly or recklessly; and
- The allegation be proven by a preponderance of the evidence (also known as the 'standard of proof').

A response to an allegation usually involves several phases, including

- An inquiry – the assessment of whether the allegation has substance and if an investigation is warranted;
- An investigation (if necessary) – the formal development of a factual record and the examination of that record leading to dismissal of the case or to a recommendation for a finding of Research Misconduct or other appropriate remedies;
- Adjudication (if necessary, after an investigation) – recommendations are reviewed and appropriate corrective actions determined.

During an investigation, disclosure of the identity of the respondent is limited to those who need to know in order to conduct an investigation, and participate in an investigation, and this may include institutional personnel as well as personnel from federal agencies (e.g. HHS or The Office of Research Integrity (ORI)).

HSL, and in certain circumstances HHS, has the burden of proof in making a finding of Research Misconduct.

This policy and procedure documents HSL's commitment to Research integrity and outlines how it complies with federal policies and accepted research practices.

A. Scope

This document applies to allegations of Research Misconduct by an Institutional Member (as those terms are defined above). In addition to the language set forth in the Definitions section, examples of Research Misconduct include:

PHS support of biomedical or behavioral research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information, (2) applications or proposals for PHS support for biomedical or behavioral research, research training or activities related to that research or research training, or (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.[i]

This statement of policy and procedures does not apply to authorship or collaboration disputes and applies only to allegations of Research Misconduct that occurred within six years of the date the institution or HHS received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b)

B. Responsibility to Report

All Institutional Members will report observed, suspected or apparent Research Misconduct to the HSL Research Integrity Officer (RIO), the VP for Research Administration, the Director of IRB Operations, or the reporter's Department Head. If a report is made to anyone other than the HSL RIO, the person to whom a report is made must contact the HSL RIO. If an individual is unsure of whether misconduct occurred, that person may have an informal and confidential discussion with the HSL RIO. If the HSL RIO does not believe the circumstances described meet the definition of Research Misconduct, the HSL RIO will either refer the person to other offices or individuals with the responsibility to resolve the issue (e.g. Human Resources, a supervisor, etc.), or respond in accordance with the HSL Reporting Suspected Misconduct policy or HSL Code of Conduct, as appropriate.

C. Cooperation with Proceedings

All Institutional Members including respondents, will cooperate with the HSL RIO and other institutional officials in providing relevant materials and information to enable the review of allegations, and the conduct of inquiries and investigations.

D. Confidentiality

The RIO shall, as required by 42 CFR § 93.108: (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. The RIO may use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

E. Protection of Complainants, Witnesses and Committee Members

Institutional Members may not retaliate in any way against complainants, witnesses, or committee members. Any such retaliation or suspected retaliation should be immediately reported to the HSL RIO, 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.

F. Protection of Respondents

As requested and as appropriate, the HSL RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in Research Misconduct, but against whom no finding of Research Misconduct is made.[ii] During the Research Misconduct proceeding, the HSL RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings regarding the case.

G. Interim Administrative Actions and Notifying ORI of Special Circumstances

Throughout the Research Misconduct proceeding, the HSL 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 HSL RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.[iii] 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. The HSL RIO shall, at any time during a Research Misconduct proceeding, notify ORI immediately if he/she has 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;
- HHS 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 HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.[iv]

4 Conducting the Assessment and Inquiry

A. Assessing the Allegations

Ordinarily within one week of receiving an allegation of Research Misconduct, the HSL RIO will assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified, whether it is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103.[v] An inquiry must be conducted if these criteria are met.

In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or 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 HSL RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the Research Misconduct proceeding, as provided in the section below titled 'Notice to Respondent, Sequestration of Research Records'.

B. Initiation and Purpose of Inquiry

If the HSL RIO determines that the criteria for an inquiry are met, s/he will immediately initiate the inquiry process. 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.[vi]

C. Notice to Respondent, Sequestration of Research Records

At the time of or before beginning an inquiry, the HSL 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. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the HSL RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the Research Misconduct proceeding, inventory the records and evidence and sequester 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.[vii] The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The HSL RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.[viii]

E. Charge to the Committee and First Meeting

The HSL RIO will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, and not to determine whether Research Misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of Research Misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

At the committee's first meeting, the HSL 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 HSL RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence, including the testimony obtained during the inquiry.

After consultation with the HSL RIO, the committee members will decide whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d). The scope of the inquiry is not required to and does not normally include deciding whether Misconduct definitely occurred, determining definitely who committed the Research Misconduct or conducting exhaustive interviews and analyses. 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, the institution shall promptly consult with ORI to determine the next steps that should be taken. See Section on Completion of Cases; Reporting Premature Closures or ORI.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the deciding official on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the HSL RIO determines that circumstances clearly warrant a longer period. If the HSL RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.[ix] Notification of an extension will ordinarily be given to the respondent.

5 Inquiry Report

A. Elements of 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 PHS support, including, for example, grant numbers, grant applications, contracts and publications listing PHS 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 or complainant;[x] (6) the names and titles of the committee members and experts who conducted the inquiry; (7) a summary of the inquiry process used; (8) a list of the research records reviewed; (9) summaries of any interviews; and (10) whether any other actions should be taken if an investigation is not recommended. The HSL RIO should ensure that the report is reviewed for legal sufficiency and modifications should be made as appropriate in consultation with the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The HSL RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.[xi] A confidentiality agreement or other written commitment to confidentiality shall be a condition for access to the report.

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 HSL RIO.

C. Institutional Decision and Notification

- Decision by Deciding Official – The HSL President & Chief Executive Officer (CEO) is the HSL deciding official (DO). The HSL RIO will provide the HSL DO with a copy of the Inquiry Report. The HSL DO will determine in writing whether an investigation is warranted. The inquiry is complete when the HSL DO makes this determination and communicates the written decision to the HSL RIO.

- Notification to ORI – Within 30 calendar days of the HSL DO's decision that an investigation is warranted, the HSL RIO will provide ORI with a copy of the decision and a copy of the inquiry report. The HSL RIO will also notify institutional officials (at HSL and any other institution that may be involved) who need to know of the decision. The HSL RIO must provide the following to ORI, upon request: (1) the policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any of the interviews, and copies of all relevant documents; and (3) the charges to be considered under the investigation.

- Documentation of Decision Not to Investigate – If the HSL DO decides that an investigation is not warranted, the HSL RIO will secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

Complainant will receive notification of the DO's decision.

6 Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the HSL DO that an investigation is warranted.[xii]

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 will also determine whether there are additional instances of possible Research Misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged Research Misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the HSL RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The HSL RIO must also give the respondent written notice of any new allegations of Research Misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.[xiii]

The HSL RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all 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 for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the 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.[xiv]

C. Appointment of the Investigation Committee

The HSL RIO, in consultation with other institutional officials as appropriate, may appoint an investigation committee and the committee chair as soon after the beginning of the investigation as is practical. 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 scientific 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 may also have served on the inquiry committee. When necessary to secure the necessary expertise or to avoid conflicts of interest, the HSL RIO may select committee members from outside the institution.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee - The HSL 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 in the following section of this policy entitled "Investigation Process";
   - Defines Research Misconduct;
   - Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, Research Misconduct occurred and, if so, the type and extent of it and who was responsible;
   - Informs the committee that in order to determine that the respondent committed Research Misconduct it must find that a preponderance of the evidence establishes that: (1) Research Misconduct, as defined in this Policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the Research Misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the Research Misconduct intentionally, knowingly, or recklessly; and
   - Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

2. First Meeting - The HSL RIO will convene the first meeting of the investigation committee to 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 statement of policy and procedures and 42 CFR Part 93. The HSL RIO will be present or available throughout the investigation to advise the committee as needed, and may or may not be a member of the committee.

E. Investigation Process

The investigation committee and the HSL 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;[xv]

- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;[xvi]
- Interview 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, and 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;[xvii] 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.[xviii]

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the HSL RIO determines that the investigation will not be completed within this 120-day period, s/he will submit to ORI a written request for an extension, setting forth the reasons for the delay. The HSL RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.[xix]

7 The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the HSL 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 the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing PHS support;
- Describes the specific allegations of Research Misconduct considered in the investigation;
- Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- 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.[xx] 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 he or she did not engage in Research Misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (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 non-PHS federal agencies.[xxi]

B. Comments on the Draft Report and Access to Evidence

1. Respondent - The HSL RIO must give the respondent a copy of the draft investigation report 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 the date he/she received the draft report to submit comments to the HSL RIO. The respondent's comments must be included and considered in the final report.[xxii]

3. Confidentiality - In distributing the draft report, or portions thereof, to the respondent, the HSL RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

C. Decision by Deciding Official

The HSL RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered. The HSL RIO will provide the HSL DO with the final investigation report. The HSL DO will determine in writing: (1) whether the institution accepts the investigation report, its 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, the HSL DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the HSL DO may return the 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 HSL RIO will normally notify both the respondent and the complainant in writing. After informing ORI, the HSL DO 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. The HSL RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Notice to ORI of Institutional Findings and Actions

Unless an extension has been granted, the HSL RIO must, within the 120-day period for completing the investigation, submit the following to ORI: (1) a copy of the final investigation report with all attachments; (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 administrative actions against the respondent.[xxiii]

E. Maintaining Records for Review by ORI

The HSL RIO must maintain and provide to ORI upon request "records of research misconduct proceedings" as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of Research Misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the Research Misconduct allegation.[xxiv] The HSL RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of Research Misconduct or of the institution's handling of such an allegation.[xxv]

8 Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The HSL RIO 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.[xxvi]

9 Institutional Administrative Actions

If the HSL DO determines that Research Misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the HSL RIO. The administrative actions may include:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the Research Misconduct.

10 Other Considerations

- Termination or Resignation Prior to Completing Inquiry or Investigation

  The termination of the respondent's institutional 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 the institution's responsibilities under 42 CFR Part 93.

  If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution 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 HSL 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.

- Restoration of the Respondent's Reputation

  Following a final finding of no Research Misconduct, including ORI concurrence where required by 42 CFR Part 93, the HSL RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[xxvii] Depending on the particular circumstances and the views of the respondent, the HSL RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of Research Misconduct was previously publicized, and expunging all reference to the Research Misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the HSL DO.

- Protection of the Complainant, Witnesses and Committee Members
  During the Research Misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that Research Misconduct occurred, the HSL RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of Research Misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the Research Misconduct proceeding.[xxviii] The HSL DO will determine, after consulting with the HSL RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The HSL RIO is responsible for implementing any of the steps the HSL DO approves.

- Allegations Not Made in Good Faith
  If relevant, the HSL DO 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 HSL DO determines that there was an absence of good faith s/he will determine whether any administrative action should be taken against the person who failed to act in good faith.

11 Reference Materials

https://grants.nih.gov/grants/research_integrity/whatis.htm

https://grants.nih.gov/grants/research_integrity/research_misconduct.htm

https://ori.hhs.gov/front_misconduct

https://ori.hhs.gov/statutes-regulations

https://ori.hhs.gov/FR_Doc_05-9643

12 Appendix

Appendix A – RIO Responsibilities (separate document)

[ii] 42 CFR § 93.304(k)
[iii] 42 CFR § 93.304(h)
[iv] 42 CFR § 93.318
[v] 42 CFR § 93.307(a)
[vi] 42 CFR § 93.307(c)
[vii] 42 CFR §§ 93.305, 93.307(b)
[viii] 42 CFR § 93.304(b)
[ix] 42 CFR § 93.307(g)
[x] 42 CFR § 93.309(a)
[xi] 42 CFR § 93.308(a)
[xii] 42 CFR § 93.310(a)
[xiii] 42 CFR § 93.310(b) and (c)
[xiv] 42 CFR § 93.310(d)
[xv] 42 CFR § 93.310(e)
[xvi] 42 CFR § 93.310(f)
[xvii] 42 CFR § 93.310(g)
[xviii] 42 CFR § 93.310(h)
[xix] 42 CFR § 93.311
[xx] 42 CFR § 93.313
[xxi] 42 CFR § 93.313(f)
[xxii] 42 CFR §§ 93.312(a), 93.313(g)
[xxiii] 42 CFR § 93.315
[xxiv] 42 CFR § 93.317(b)
[xxv] 42 CFR §§ 93.300(g), 93.403(b) and (d)
[xxvi] 42 CFR § 93.316(a)
[xxvii] 42 CFR § 93.304(k)
[xxviii] 42 CFR § 93.304(l)

Personal Statement:

I understand that Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

I acknowledge receipt of the "Principles and Procedures for Dealing with Allegations of Research Misconduct in PHS-funded Research":

_____ _____

Name Date