Purpose: HSPH has developed this Policy to implement a process and procedure to respond to allegations of research misconduct and to coordinate the application of these with the requirements of Title 42 Code of Federal Regulations (CFR) Part 50, Subpart F, Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Part 93 Public Health Service Policies on Research Misconduct.

I. Introduction

A. General Policy

The overarching mission of Harvard School of Public Health ("HSPH") is to advance the public's health through learning, discovery, and communication with the specific objectives of providing the highest level of education to public health scientists, practitioners, and leaders; fostering new discoveries leading to improved health for the people of this country and all nations; strengthening health capacities and services for communities; and informing policy debate, disseminate health information, and increase awareness of health as a public good and fundamental right. In order to assist in maintaining these standards, to foster a research environment that supports a culture of integrity, to maintain the confidence of our employees, patients, peers, and to comply with regulatory requirements, HSPH is committed to addressing possible incidents of research misconduct. As a result, this Policy on Research Integrity (the "Policy") has been established to guide the process of assessment, inquiry, and investigation of such incidents.

B. Scope

This Policy and the associated procedures apply to all individuals at HSPH engaged in research, including but not limited to research that is supported by or for which support is requested from the Public Health Service ("PHS"). The PHS regulation at 42 CFR Part 93 applies to any research, research-training or research-related grant or cooperative agreement with PHS. This Policy applies to any agent affiliated with HSPH. Any employee or student at HSPH is considered an agent when that individual is on-duty in any capacity as an employee or student of HSPH. Specifically, an agent is an individual who, by agreement or otherwise, may act on behalf of the School and bind it by words or actions; a person who represents the School by its authority or delegated authority. An individual who is not an employee is considered an agent of HSPH for purposes of engagement in Human Research when that individual has been specifically authorized to conduct Human Research on behalf of HSPH.

The Policy and associated procedures will normally be followed when the *Research Integrity Officer (RIO)* of HSPH receives an allegation of possible research misconduct. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of HSPH and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Deciding Official of HSPH.

This policy and the associated procedures do not apply to authorship or collaboration disputes and apply only to allegations of research misconduct that occurred within six years of the date

HSPH or Health and Human Services received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions listed in 42 CFR Part 93.105 (b), as applicable.

II. Definitions

A. *Allegation* means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other credible and significant indication of possible research misconduct made to an institutional official.

B. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

C. *Deciding Official*, at the time of adoption of this Policy, means the Dean for Academic Affairs, who shall make final determinations on allegations of research misconduct and any responsive institutional actions.

D. *Good faith* as applied to a complainant or witness means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation. Good faith as applied to a committee member means cooperating with the purpose of helping the institution meet its responsibility under the regulations cited in this policy. 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 proceedings.[1]

E. *Inquiry* means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures of 42 CFR §§ 93.307-93.309[2] to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

F. *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.[3]

G. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.

H. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

I. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Part 93 entitled “Public Health Service Policies on Research Misconduct”

J. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefore, for biomedical or behavioral research, biomedical or behavioral research training, or

activities related to that research or training that may be provided through: PHS grants, cooperative agreements, or contracts or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements or contracts.[4]

K. *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.

L. *Research Integrity Officer (RIO)* means the Associate Dean for Regulatory Affairs & Research Compliance. The RIO is responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

M. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written, electronic or hard-copy account or object that reasonably may be expected to provide evidence or information regarding the proposed, performed, reviewed, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; voice recordings; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

N. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

O. *Retaliation* means an adverse action taken against a complainant, witness, or committee member by HSPH or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.[5]

P. *Research misconduct* means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. *Fabrication* is making up data or results and recording or reporting them. *Falsification* is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.[6]

Q. *Complainant* means a person who in good faith makes an allegation of research misconduct.

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The RIO has primary responsibility for implementation of the procedures set forth in this document. The RIO will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct

research, those who are accused of research misconduct, those who report apparent research misconduct in good faith, and those who may serve on inquiry and investigation committees.

The RIO will receive allegations of research misconduct and assess each allegation in accordance with section IV of this document to determine whether it falls within the definition of research misconduct and warrants an inquiry. He/she will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will attempt to ensure that confidentiality is maintained. The RIO will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The RIO is also responsible for maintaining files of all documents and evidence, and for the confidentiality and the security of the files.

In all cases, the RIO will be responsible for informing the Deciding Official of the status of the allegations when the RIO decides to move into the inquiry phase. The RIO will also be responsible for informing the respondent's supervisor (which, in the case of faculty members, shall be the Chair of the Department) of the status of the allegations at appropriate times, and for coordinating assessments, inquiries and investigations with such supervisor as appropriate.

The RIO will notify and make reports to ORI as required by 42 CFR Part 93, and described further in section IX of this document. The RIO will also ensure that administrative actions taken by HSPH or ORI are enforced and other involved parties are notified of those actions, such as sponsors, law enforcement agencies, professional societies, and licensing boards, as applicable.

B. Complainant

The complainant may have an opportunity to testify before the inquiry and investigation committees, to review transcripts or summaries of his or her testimony, and to have reasonable steps taken by HSPH to be protected from retaliation. If the RIO has determined that the complainant may be able to provide pertinent information on any portions of the inquiry report or draft investigation report, these portions may be given to the complainant for comment.

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will receive a copy of this policy and be notified in writing of the initial and any subsequent allegations when an inquiry is opened, and notified in writing of the final determinations and resulting actions. The respondent will have an opportunity to comment on the inquiry report and have his/her comments attached to the report.[7] The respondent will also have the opportunity to be interviewed by and present evidence to the investigation committee and shall have the opportunity to request during the investigation that any witness reasonably identified by the respondent as having information on relevant aspects of the investigation be interviewed.[8] Any resulting recordings or transcripts shall be included as part of the investigation record, provided the witness has the opportunity to review and correct the

recordings or transcripts of his or her testimony prior to submission. The respondent is entitled to review transcripts or summaries of his or her testimony, the draft inquiry report, and investigation reports.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation.

D. Deciding Official

The Deciding Official will be responsible for issuing the final institutional determination in all cases, whether concluded after an inquiry or investigation, including making a final determination on whether misconduct occurred, the nature of any sanctions, and whether to take other appropriate administrative actions. The Deciding Official shall, as he or she deems appropriate, consult with the RIO, any inquiry or investigation committees constituted by the RIO, and any other relevant bodies or officials, to the extent applicable, or any subsequent committees, which assume their responsibilities with respect to research conduct.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with HSPH should report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, or whether there are reasonable grounds to suspect misconduct, he or she may call the RIO at 617-432-2148 to discuss the situation informally. If the circumstances described by the individual do not meet the definition of research misconduct, or there are not reasonable grounds to suspect misconduct, the RIO may refer the individual or allegation to other offices or officials with responsibility for resolving the problem.
At any time, an employee or individual associated with HSPH may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations. The RIO shall endeavor to maintain the confidentiality of such discussions and consultations to the maximum extent consistent with legal requirements, other institutional policies, or other appropriate limitations.

B. Protecting the Complainants, Witnesses, and Committee Members

The RIO will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The RIO will attempt to protect these persons against retaliation in the terms and conditions of their employment or other status at HSPH and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the 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.

Also, HSPH will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, HSPH will make an effort to honor the request during the allegation assessment or inquiry to the extent permitted by applicable policies and regulations and state and local laws, if any. The complainant will be advised that anonymity may not be possible in a number of situations, including if the matter progresses to the inquiry or investigation stage and the complainant's testimony is required.

The RIO shall: (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. Except as may otherwise be prescribed by applicable law, confidentiality must be maintained for any records or evidence from which research subjects might be identified.[9] The RIO may use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation, and confidentiality to the extent possible without compromising public health and safety or thoroughness of the inquiry or investigation.

As requested and as appropriate, the 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.[10]

D. Cooperation with Inquiries and Investigations

HSPH employees/agents will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of research misconduct. If, on the basis of this preliminary assessment, the RIO determines that the allegation is not sufficiently supported to warrant further inquiry, the RIO may submit a written summary of the basis for this determination to the Deciding Official, along with a recommendation that no further action should be taken.

In some cases it may be unclear initially whether a dispute or other situation should properly be characterized as an "allegation of research misconduct" at all. The RIO will have the authority

to assess these situations and to determine that such a situation should not be so characterized, and to close the matter on that basis or refer it to a different administrative process. In these situations, the RIO will make a determination whether it is necessary to inform the Deciding Official.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to indicate specific follow-up, and falls under the definition of research misconduct, then he or she will initiate the inquiry process. In initiating the inquiry, the RIO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and in some cases to take testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation, and not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. An inquiry does not require a full review of all the evidence related to the allegation.[11] The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

On or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, the RIO will promptly 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.[12] If PHS funding is involved, the RIO may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The RIO will appoint an Inquiry Committee to consider the allegation as promptly as reasonably possible. 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.[13] These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

D. Charge to the Committee and the First Meeting

The RIO may prepare a charge for the Inquiry Committee that sets the time for completion of the inquiry, describes the allegations and any related issues identified during the allegation assessment, and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine

whether there is sufficient evidence of possible research misconduct to warrant an investigation, not to determine whether research misconduct definitely occurred or who was responsible. If applicable, they may be told of the possibility that the members of the Inquiry Committee may later be asked to assume the responsibilities of an Investigation Committee.

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

E. 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 and testimony obtained during the inquiry. The Committee members will consult with the RIO and, as appropriate, with a member of the OGC, and decide whether there is sufficient evidence of possible research misconduct to recommend further investigation.

F. Inquiry Decision and Notification

1. Decision Whether to Conduct Investigation or Close Case

Based on the report and recommendation of the Inquiry Committee, the RIO will determine whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation.

If the RIO determines that there is insufficient evidence of possible misconduct to warrant an investigation he or she will submit a determination to the Deciding Official for final decision. If the Deciding Official concurs, the matter will be closed.

If the RIO determines that there is sufficient evidence of possible misconduct to warrant an investigation, the RIO shall inform and/or consult with the Deciding Official as the RIO deems necessary, and the matter will proceed to the investigation stage.

2. Finding of Misconduct During Inquiry Process

In some situations, where the RIO in consultation with the Inquiry Committee determines that it has become clear during the inquiry process that research misconduct occurred, the Inquiry Committee may be converted into an Investigation Committee by the RIO. The RIO may alternatively determine that it is unnecessary and would be inefficient and wasteful for all involved to go through the procedures of an investigation before concluding the matter. The latter may occur, for example, if the respondent makes a legally sufficient admission of research misconduct and all other relevant issues are resolved, or where the evidence presented during the inquiry stage is otherwise particularly compelling. In the case of an admission by the respondent, the RIO shall promptly consult with the ORI to determine the

next steps that should be taken. In such situations, in consultation with the ORI, it may be appropriate to come to a conclusion of research misconduct without proceeding through a formal investigation phase.

In such cases where no PHS funding is involved, the RIO may recommend that the Deciding Official make a final determination in the case based on the inquiry report. The RIO shall state in writing the reasons why he/she believes that an investigation is not necessary. If the Deciding Official concurs, he/she may make a final determination in the case based on the inquiry report. In such circumstances, the final Inquiry Committee report shall be deemed the equivalent of the final Investigation Committee report for the remainder of this Policy.

In such cases where PHS funding is involved, it may be appropriate to come to a conclusion of research misconduct without the proceeding through a formal investigation phase, provided that:

a. The RIO consults with ORI; and

b. The Inquiry Committee report is provided to the respondent with a clear statement that normally in cases involving PHS funding, the Institution does not come to a finding of research misconduct without conducting a formal Investigation, but that in the present case it intends to come to such a finding based on the specific, described facts that have come to light during the inquiry phase; and

c. The respondent makes no objection to this process within fourteen (14) calendar days of receipt of the draft inquiry report.

If the respondent objects on the basis of reasonable written grounds to this process, or if ORI determines that further action is necessary to examine the evidence or resolve the outstanding issues, the matter shall proceed to the investigation stage.

If no such objection is received, the RIO may recommend that the Deciding Official make a final determination in the case based on the inquiry report. The RIO shall state in writing the reasons why an investigation is not necessary. If the Deciding Official concurs, he/she may make a final determination in the case based on the inquiry report. In such circumstances, the final Inquiry Committee report shall be deemed the equivalent of the final Investigation Committee report for the remainder of this Policy.

3. Completion of Inquiry

The inquiry is completed either when the Deciding Official concurs that an investigation is not warranted, or when the RIO determines that an investigation is warranted, or when the RIO makes the determination described in the first sentence of section F. (2) immediately above. In cases where PHS funding is involved, if the inquiry takes longer than sixty (60) days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period.[14]

4. Notification

   The RIO will notify both the respondent and the complainant in writing of the outcome of the inquiry process and will remind them of their obligation to cooperate in the event that an investigation is opened. The RIO will also notify all appropriate HSPH officials of the Deciding Official's decision.

   If it is determined that an investigation is warranted and PHS funding is involved, the RIO will notify the Director, ORI, as required by PHS regulations.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states (1) the name and title of the respondent, committee members and experts, if any; (2) a description of the allegations of research misconduct; (3) the PHS support, including grant numbers, grant applications, contracts and publications listing PHS support; (4) a summary of the inquiry process used; (5) a list of the research records reviewed; (6) summaries of any interviews; (7) a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; (8) any comments on the report by the respondent or the complainant; and (9) the Inquiry Committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. As appropriate, a member of the OGC will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and Others

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal. The RIO may also determine that the complainant, or other people involved, may be able to provide pertinent information on portions of the draft reports, in which case those portions, or a summary, may be provided to such individuals for comment.

1. Confidentiality

   The RIO may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

   Within a reasonable period of time, generally no less than fourteen (14) calendar days from their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the Inquiry Committee. Any comments regarding the draft report submitted by the complainant or respondent will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Time Limit for Completing the Inquiry Report in Cases Involving PHS Funding

If PHS funding is involved, 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 sixty (60) calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the sixty (60) day period.[15]

VII. Conducting the Investigation

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged 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. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

To the extent not already done so at the preliminary assessment or inquiry stage, the RIO will take all reasonable and practical steps to obtain custody of any additional pertinent research records and evidence needed to conduct the research misconduct proceedings, inventory the records and evidence, and sequester them in a secure manner.[16] The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage, or the identification of records during the inquiry process that had not been previously secured. 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. Whenever possible, this sequestration will occur before or at the time the respondent is notified; and whenever additional items become known or relevant to the investigation.[17] The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.[18]

C. Notification of the Respondent

The RIO will notify the respondent in writing as soon as reasonably possible after the determination is made to open an investigation, but before the investigation begins. The notification should include: a copy of the inquiry report; the specific allegations; the sources of PHS funding, if any; the definition of research misconduct; the procedures to be followed in the investigation, including the appointment of the Investigation Committee and experts; the opportunity of the respondent to be interviewed, to provide information, to challenge the

membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report; the fact that ORI will perform an oversight review of the report regarding PHS issues to the extent applicable; and an explanation of the respondent's right to request a hearing before the DHHS Department Appeals Board if there is an ORI finding of misconduct under the PHS definition. The 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.[19]

D. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials, will appoint an Investigation Committee as soon as reasonably practical after notification to the respondent that an investigation is planned. 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. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee.

The RIO will notify the respondent of the proposed committee membership promptly. If the respondent submits a prompt written objection to any appointed member of the Investigation Committee or expert, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a charge to the committee that describes the allegations and related issues identified during the inquiry, define research misconduct, and identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.[*] The charge will also inform 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.

During the investigation, if additional information becomes available that substantially

[*]For cases involving PHS funding, the applicable standard of proof shall be "the preponderance of the evidence," as defined in 42 CFR Part 93.219, as amended from time to time.

changes the subject matter of the investigation or would suggest additional respondents, the Investigation Committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The RIO, with the assistance of a member of the OGC, will convene the first meeting of the Investigation Committee. At this meeting, the Investigation Committee will review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan.

F. Investigation Process

If PHS funding is involved the investigation must begin within thirty (30) calendar days after the determination by the Deciding Official that an investigation is warranted.[20]

The investigation will 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.[21] The Investigation Committee must take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical.[22] The Investigation Committee will 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; 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.[23] The Investigation Committee must also 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.[24]

Upon completion of all interviews, the Investigation Committee shall meet to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

VIII. The Investigation Report

A. Elements of the Investigation Report

The final report submitted to ORI must describe the nature of the allegation of research misconduct, including identification of the respondent; describe and document the PHS support, including, for example, the numbers of any grants that are involved, grant application, contracts, and publications listing PHS support; describe the specific allegations of research misconduct considered in the investigation; include the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provide to ORI previously; identify and summarize the research records and evidence reviewed and identify

any evidence taken into custody but not reviewed; and include a statement of findings for each allegation of research misconduct identified during the investigation.[25] Each statement of finding 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 had pending with non-PHS federal agencies.[26]

B. Comments on the Draft Report

1. Respondent

   The 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 thirty (30) days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.[27]

2. Complainant

   If the RIO determines that the complainant, or any other people involved, may be able to provide pertinent information on portions of the draft report, those portions, or a summary, may be provided to such individuals for comment. The complainant or other relevant individuals' comments must be submitted within thirty (30) days of the date on which he/she received the draft report and the comments must be included and considered in the final report.[28]

3. Office of General Counsel

   The draft investigation report will be transmitted to the Office of General Counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

   In distributing the draft report, or portions thereof, to the respondent and complainant, the 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. For example, the RIO may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

The investigation report shall be submitted to the Deciding Official. Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the Investigation Committee, and PHS funding is involved, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigation Committee in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, HSPH's policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee. The Deciding Official may also return the report to the Investigation Committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the Investigation Committee's, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant in writing. In addition, the Deciding Official 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 RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the Investigation Committee should transmit the final report with attachments, including the respondent's and complainant's comments, to the Deciding Official, through the RIO. The RIO will also submit the following to ORI: (1) a copy of the final investigation report with all attachments; (2) a statement of whether HSPH 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.[29]

E. Time Limit for Completing the Investigation Report

If PHS funding is involved, the investigation is to be completed within one hundred twenty (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 RIO determines that the investigation will not be completed within this one hundred and twenty (120) day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The 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. [30]

IX. Requirements for Reporting to ORI

A. As stated above, the decision of HSPH to initiate an investigation involving PHS funds must be reported in writing to the Director, ORI, on or before the date the investigation begins. The notification should include a copy of the inquiry report and the PHS applications or grant number(s) involved. If PHS funding is involved, ORI must also be notified of the final outcome of

the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

Additionally, HSPH will file an annual report with ORI certifying that it has complied with this Policy and indicating if HSPH has received any allegations or conducted any inquiries or investigations related to research misconduct involving PHS supported research. ORI may seek other aggregated information concerning any research misconduct proceedings initiated by HSPH.[31]

B. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry, investigation, or appeal 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 PHS regulations.[32]

C. For investigations involving PHS funds, if HSPH determines that it will not be able to complete the investigation in one hundred twenty (120) days, the RIO will submit to ORI a written request for an extension. The request will explain the reason for the delay, report on the progress to date, estimate the date of completion of the report, and describe other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.[33]

D. The respondent should be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and HSPH legal counsel, the Deciding Official may terminate HSPH's review of an allegation that has been admitted if the institution's acceptance of the admission and any proposed settlement is approved by ORI,[34] if applicable.

E. Throughout the research misconduct proceedings, 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 PHS supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat.[35] The RIO will notify ORI at any stage of the inquiry or investigation if:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

2. HHS resources or interests are threatened;

3. Research activities should be suspended;

4. There is a reasonable indication of possible violations of civil or criminal law;

5. Federal action is required to protect the interests of those involved in the research misconduct proceedings;

6. 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

7. The research community or public should be informed.[36]

X. Institutional Administrative Actions

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the RIO. The actions may include:

A. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.

B. 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;

C. Other action as appropriate to the misconduct.

XI. Other Considerations

A. Termination of Institutional Employment 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 misconduct procedures or otherwise limit any of HSPH's responsibilities under PHS regulations.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, any committees constituted to inquire into or investigate the allegation will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

Following a finding of no research misconduct, including ORI concurrence where required by PHS regulations, the RIO will, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation.[37] Depending on the particular circumstances, the RIO may consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. These actions should be taken in

consultation with the Deciding Official where appropriate.

C. Protection of the Complainant, Witnesses, and Committee Members

Regardless of whether HSPH or ORI determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainants 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.[38] These actions shall be taken in consultation with the Deciding Official, where appropriate.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official 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 Deciding Official determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

E. Interim Administrative or Other Actions

Officials of the HSPH will take interim administrative actions, as appropriate, to protect Federal funds and to ensure that the purposes of the Federal financial assistance are carried out and to otherwise protect the interests of the institution and its patients. They, as well as the Committees involved in Inquires and Investigations, may also take or recommend actions to address conduct by respondents or others involved that is deemed inappropriate or otherwise in need of correction whether or not it amounts to research misconduct.

XII. Record Retention

Where PHS funding is involved, 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 proceedings or the completion of any PHS proceedings involving the research misconduct allegation.[39] The 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.[40]

[1] 42 CFR §93.210
[2] 42 CFR §93.212
[3] 42 CFR §93.215
[4] 42 CFR §93.221
[5] 42 CFR §93.226
[6] 42 CFR §93.103
[7] 42 CFR §§93.304(e), 93.307(f)
[8] 42 CFR §93.310(g)
[9] 42 CFR §93.108(b)

[10] 42 CFR §93.304(k)
[11] 42 CFR §93.307(c)
[12] 42 CFR §93.307(b)
[13] 42 CFR §93.304(b)
[14] 42 CFR §93.307(g)
[15] 42 CFR §93.307(g)
[16] 42 CFR §93.310(d)
[17] 42 CFR § 93.310(d)(1)-(2)
[18] 42 CFR §93.310(d)
[19] 42 CFR §93.310(b) and (c)
[20] 42 CFR §93.310(a)
[21] 42 CFR §93.310(e)
[22] 42 CFR §93.310 (f)
[23] 42 CFR §93.310 (g)
[24] 42 CFR §93.310 (h)
[25] 42 CFR §93.313
[26] 42 CFR §93.313(f)
[27] 42 CFR §93.312(a), 313(g)
[28] 42 CFR §93.312(b), 313(g)
[29] 42 CFR §93.315
[30] 42 CFR §93.311
[31] 42 CFR §93.302(b) and (c)
[32] 42 CFR §93.316(a)
[33] 42 CFR §93.311
[34] 42 CFR §93.316
[35] 42 CFR §93.304(h)
[36] 42 CFR §93.318
[37] 42 CFR §93.304(k)
[38] 42 CFR §93.304(l)
[39] 42 CFR §93.317(b)
[40] 42 CFR §§93.300(g), 93.403(b) and (d)