Oregon Health Authority
Public Health Division

Policy & Procedures for Responding to Allegations of Research Misconduct

In conjunction with:
The Public Health Institutional Review Board

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I. INTRODUCTION

A. Purpose

The Oregon Health Authority (OHA, The Authority) – Public Health Division (PHD, The Division) is committed to maintaining an environment that promotes ethical standards in the conduct of research. The Division does not tolerate misconduct in any aspect of research and will promptly conduct inquiries and/or investigations of any allegation of research misconduct. The purpose of this document is to explain and outline the policy and procedures by which The Division will follow when alleged research misconduct has occurred.

B. General Policy

PHD employees engaged in research, regardless of their position or level of responsibility, are expected to maintain their scientific integrity, periodically re-examine their work to ensure it does not compromise the well-being of human subjects, report any suspected instances of unethical research behavior, and support investigations into alleged misconduct if they arise. This includes any research proposed, performed, reviewed, or reported, or any record generated from that research, regardless of the funding source. Research misconduct is defined as the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or honest differences in interpretation or judgment of data.

C. Scope

This policy and the associated procedures apply to all individuals at the PHD engaged in research regardless of funding source. The U.S. Public Health Service's (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 person paid by, under the control of, or affiliated with OHA's PHD, such as scientists, trainees, research analysts, technicians, and other staff members, students, interns, or collaborators.

When an allegation of possible research misconduct is received by a PHD official, this policy is to normally be followed. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of the PHD and the PHS. Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the State Public Health Officer.

II. DEFINITIONS

A. *Allegation* means any written or oral statement or other 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. *Data* means all forms of scientific information about the research at issue without regard to

the type of recording or storage media involved. Data includes, but is not limited to, raw numbers, filed notes, interviews, notebooks and folders, laboratory observations, computers and other equipment including parts therein (e.g. CD-ROMS, hard drives, flash drives, etc.), research interpretations and analyses, tables, slides, photographs, charts, gels, individual facts, statistics, tissue samples, reagents, and statements by individuals.

D. *Deciding Official* means the PHD official who makes final determinations on allegations of research misconduct and any responsive PHD action. The OHA, Director of Public Health will serve as the Deciding Official.
E. *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.
F. *Good faith allegation* 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.
G. *Inquiry* means information-gathering and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
H. *Investigation* means the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.
I. *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.
J. *PHS* means the U.S. Public Health Service, an operating division of the U.S. Department of Health and Human Services.
K. *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 C.F.R. Part 93 entitled, "Public Health Service Policies on Research Misconduct".
L. *PHS support* means Public Health Service grants, contracts, or cooperative agreements, or applications thereof.
M. *Preponderance of the evidence* means proof by information, compared with that opposing it, which leads to the conclusion that the fact at issue is more likely true than not.
N. *Prima facie showing* means evidence that on its face is sufficient to prove research misconduct in the absence of respondent's presentation of substantial contradictory evidence.
O. *Research* 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.
P. *Research Integrity Officer (RIO)* means the PHD official responsible for assessing allegations of research misconduct, determining when such allegations warrant inquiries and overseeing those inquiries and investigations. The State Public Health Officer will serve as the Research Integrity Officer.
Q. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or

honest differences in interpretation or judgment of data.

1. *Fabrication* is making up data or results and recording or reporting them.
2. *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.
3. *Plagiarism* is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

R. *Research record* means any data, document, computer file, or other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, 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; X-ray film; slides; biological materials; computer files, flash drives and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and subject research files.

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

T. *Retaliation* means any action that adversely affects the employment or other status of an individual that is taken by PHD or an employee because the individual has, in good faith, made an allegation of research misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

U. *Whistleblower* means a person who makes an allegation of research misconduct.

III. ROLES AND RESPONSIBILITIES

All employees or individuals associated with OHA–PHD shall report observed, suspected, or apparent misconduct in research to the RIO for appropriate action. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, arrangements will be made for the individual to discuss this issue with the RIO. The RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem, if he or she finds that the circumstance described does not meet the definition of research misconduct.

PHD employees will cooperate with the RIO and other PHD officials in the review of allegations and the conduct of inquiries and/or investigations. Employees have an obligation to provide relevant evidence to the RIO or other institutional officials on misconduct allegations. In addition, employees will cooperate with outside agencies assisting in its conduct and oversight of inquiries and investigations and with any follow-up actions.

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, regardless of what funding source may be involved.

A. Research Integrity Officer

The State Public Health Officer will serve as the RIO who will have primary responsibility for implementation of the procedures set forth in this document. The RIO will:

- Be a PHD 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 misconduct, and those who report apparent misconduct in good faith;
- 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. Every attempt will be made to ensure that confidentiality is maintained;
- Assist inquiry and investigation committees and all PHD 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;
- Report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest. This includes but is not limited to:
  - Notification of The Division's decision to initiate an investigation in writing to the Director of ORI on or before the date the investigation begins;
  - Notification if The Division plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation;
  - Notification if The Division determines that it will not be able to complete an investigation within 120 days

B. Whistleblower

The whistleblower is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation. The Division will undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

Employees who receive or learn of an allegation of research misconduct will treat the whistleblower with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the whistleblower and other individuals who cooperate with the Division against retaliation. Employees will immediately report any alleged or apparent retaliation to the RIO.

The PHD will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the whistleblower requests anonymity, The Division will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an

investigation committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed.

The whistleblower will have an opportunity to testify before the inquiry and investigation committees, review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, be informed of the results of the inquiry and investigation, and protected from retaliation. If the RIO has determined that the whistleblower may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower for comment.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determination and resulting actions. The respondent will have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, review the draft inquiry and investigation reports, and have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of research misconduct, he or she may request that the RIO undertake reasonable efforts, as appropriate, to restore his or her reputation.

PHD employees who receive or learn of an allegation of research misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 C.F.R. Part 93 and these procedures are followed. Employees will report significant deviations from these instructions to the RIO. The RIO will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Deciding Official

The OHA, Director of Public Health will serve as the Deciding Official and will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower on the draft report. The Deciding Official will consult with the RIO or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

IV. POLICY AND PRINCIPLES

A. Confidentiality

Institutional employees who make, receive, or learn of an allegation of research misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the whistleblower, the respondent, and all other affected individuals. The RIO may establish reasonable conditions to ensure the confidentiality of such information.

B. Responding to Allegations

In responding to allegations of research misconduct, the RIO and any other PHD official with an assigned responsibility for handling such allegations will make diligent efforts to ensure that the following functions are performed:

- Any allegation assessment or inquiry is conducted in an objective, thorough, and competent manner. If warranted, an investigation must begin within 30 days after determination;
- Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation;
- Immediate notification is provided to ORI if:
  - there is an immediate health hazard involved;
  - there is an immediate need to protect federal funds or equipment;
  - there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
  - it is probable that the alleged incident is going to be reported publicly;
  - the allegation involves a public health sensitive issue; or
  - there is a reasonable indication of a possible federal criminal violation. In this instance, The Division will inform ORI within 24 hours of obtaining that information.
- Investigation notifications are sent to ORI on or before the date the investigation begins. Inquiry reports will be provided along with notification. The inquiry report will contain:
  - name and position of respondent;
  - description of the allegations of research misconduct;
  - the PHS support, including grant numbers, grant applications, contracts, publications, etc., if applicable;
  - basis for recommending that the alleged actions warrant an investigation; and
  - comments on the report by the respondent, whistleblower, or a witness.

C. Evidentiary Standards

The Division must have the burden of proof for making a finding of research misconduct. A finding of research misconduct requires that:

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

The absence of, or the respondent's failure to provide, research records adequately documenting the questioned research establishes a rebuttable presumption of research misconduct that may be relied upon

by The Division in proving research misconduct. Credible evidence corroborating the research or providing a reasonable explanation for the absence of, or respondent's failure to provide, the research records may be used by the respondent to rebut this presumption.

If the PHD determines that prima facie showing of research misconduct, the respondent has the burden of proving any affirmative defenses raised, including any honest error or differences of opinion and of proving any mitigating factors that the respondent wants the institution to consider in imposing administrative actions following research misconduct proceedings.

V. CONDUCTING THE INQUIRY

A. Initiation and Purpose of the Inquiry

Following a preliminary assessment, if the RIO determines that the allegation provides sufficiently credible and specific information so that potential evidence of research misconduct may be identified, and falls under the PHS definition of research misconduct, he or she will immediately initiate the inquiry process. Through initiating the inquiry, the RIO should clearly identify the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to gather information and facts informally to determine whether an allegation or apparent instance of misconduct warrants an investigation. This may include testimony of the respondent, whistleblower, and/or key witnesses. The inquiry's purpose is not to reach a final conclusion about whether misconduct occurred or who was responsible, and as such, it does not require a full review of all evidence related to the allegation. The findings of the inquiry, however, must be set forth in a formal inquiry report.

B. First Steps

As soon as practicable after the RIO determines that an inquiry is required, he or she will:

- Ensure that all original research records and materials relevant to the allegation are immediately secured. The RIO may consult with ORI for advice and assistance in this regard;
- Notify in writing the presumed respondent(s), at the time of or before beginning an inquiry and invite a response to the allegation. If the inquiry subsequently identifies additional respondents, they must be notified;
- At his or her discretion, seek the advice of one or more individuals who are professionally familiar with the nature of the area of alleged misconduct;
- In writing, notify the OHA, Director of Public Health, Assistant Attorney General, and ORI (if the request to open the inquiry originated from ORI) prior to conducting the inquiry;
- Appoint and charge the inquiry committee within ten business days of determining an inquiry is required;
- Ensure that the inquiry is completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period; and
- Ensure that the inquiry process and investigation, if applicable, is completed even in the event where the respondent leaves the PHD after allegations are made.

The RIO or Assistant Attorney General may consult with ORI at any time regarding appropriate procedures to be followed.

C. Records

Research records produced under PHS grants and cooperative agreements are the property of the PHD, and employees cannot interfere with the Division's right of access to them. Under contracts, certain research records may belong to PHS, but the PHD will be provided access to contract records in their custody for purposes of reviewing misconduct allegations.

The documents and materials to be sequestered will include all the original items (or copies, if originals cannot be located) that may be relevant to the allegations. These include, but are not limited to, research records as defined in section II.R of this document.

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. Disclosure is limited to those who have a need to know in order to carry out a research misconduct proceeding. The RIO should notify the respondent that an inquiry is being initiated simultaneously with the sequestration of records or evidence so that the respondent can assist with location and identification of the research records. The RIO should obtain the assistance of the respondent's supervisor and Assistant Attorney General in this process, as necessary. If the respondent is not available, sequestration may begin in the respondents' absence. To prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification, the respondent should not be notified in advance of the sequestration. In addition to securing records under the control of the respondent, the RIO may need to sequester records from other individuals, such as co-authors, collaborators, or the whistleblower(s). As soon as practicable, a copy of each sequestered record will be provided to the individual from whom the record is taken if requested.

A dated receipt should be signed by both the person assigned to sequester material and the person from whom an item is collected; a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

The RIO will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of a PHD official assigned by the RIO. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the Assistant Attorney General.

D. Notification of the Respondent

The RIO will notify the respondent in writing of the opening of the inquiry. The notification will identify

the research project in question and the specific allegations, define alleged research misconduct, identify the funding involved, list the names of the inquiry committee members (if appointed) and experts (if any). It should be explained that the respondent has an opportunity to challenge the appointment of a member of the committee or expert for bias or conflict of interest, to be interviewed, to present evidence to the committee, and to comment on the inquiry report. They will be notified of their obligation as an employee of The Division to cooperate and told The Divisions' policy on protecting the whistleblower against retaliation and the need to maintain the whistleblower's confidentiality during the inquiry and any subsequent proceedings.

E. Appointment of the Inquiry Committee

In complex cases, the RIO, in consultation with other PHD officials as appropriate, will appoint a committee and committee chair within ten business days of the initiation of the inquiry. The inquiry committee will consist of at least three individuals who do not have real or apparent conflicts of interest in the case and are unbiased. They must have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of the PHD.

In the event that the allegations and apparent evidence are straightforward the RIO may choose to conduct the inquiry directly or designate another qualified individual to do so. Examples of such consist of an allegation of plagiarism, falsification, or an admission of misconduct by the respondent. In such cases, the inquiry official will still obtain the necessary expert and technical advice to properly consider all scientific issues.

The RIO, in consultation with the committee, will determine whether additional experts other than those appointed to the committee need to be consulted during the inquiry to provide special expertise regarding the analysis of specific evidence. These experts may be chosen from inside or outside of the PHD but will strictly provide an advisory function to the committee; they will not vote nor will they generally interview witnesses.

The RIO will take reasonable steps to ensure that the members of the committee and other experts have no bias or personal or professional conflict of interest with the respondent, whistleblower, or the case in question. In making this determination, the RIO will consider whether the individual:

- Has any financial involvement with the respondent or whistleblower;
- Has been a coauthor on a publication with the respondent or whistleblower;
- Has been a collaborator or coinvestigator with the respondent or whistleblower;
- Has been a party to a scientific controversy with the respondent or whistleblower;
- Has a supervisory or mentor relationship with the respondent or whistleblower;
- Has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or whistleblower; or
- Falls within any other circumstance that might appear to compromise the individual's objectivity in

reviewing the allegations.

The respondent will be notified of the proposed committee membership within five business days of its establishment. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within five business days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute.

F. Inquiry Process

The RIO will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment. It will be explained that the purpose of the inquiry is to hold a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. No determination on whether research misconduct definitely occurred or who was responsible will be made. Criteria warranting an investigation include, but are not limited to:

- A reasonable basis for concluding that the allegation involves PHS supported research and falls within the definition of research misconduct; and
- Preliminary information-gathering and preliminary fact finding from the inquiry indicates that the allegation may have substance.

At the committee's first meeting, the RIO will review the charge with the committee. Allegations, related issues, and the appropriate procedures for conducting the inquiry will be discussed. The RIO will assist the committee with for the organization of the inquiry and will be available to answer any questions. Throughout the inquiry, both the RIO and Assistant Attorney General will be available as needed.

Members of the committee and experts will agree in writing to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, whistleblower, witnesses, or anyone not authorized by the RIO to have knowledge of the inquiry.

G. General Approaches to Conducting an Interview

Purpose of the Interview – At the inquiry stage, the purpose is to allow each respondent, whistleblower, or witness to tell his or her side of the story. The committee will not speculate about what happened or put words in the interviewees' mouths. Information obtained from others interviewed will not be disclosed unless necessary and done without identifying the source of the information.

Issues to Cover - Before an interview, the committee should provide each interviewee with a summary of the intended matter to be discussed. If additional issues are raised, the interviewee will be given an opportunity to supplement the record in writing or in an additional interview. It will be reiterated that his or her cooperation and truthful answers are expected.

Confrontation - At this stage, interviewees will not be told whether other testimony conflicts with theirs,

although questions may be asked for purposes of clarifying the testimony. Avoid leading questions such as, "You must have made a mistake and thought it was actually this way, right?"

Using Experts - Although generally not involved in interviews, the committee may request that experts attend or participate in them to assist in the evaluation of the allegations. If the committee determines that such participation is not appropriate, it may ask an expert to prepare questions for the committee to use at the interview. Any expert retained to assist the committee may be provided a copy of the resulting transcripts or summaries of the interviews.

Transcription - Interviews will be transcribed or recorded. A transcript or summary of the interview will be provided to each interviewee for review and correction of errors. Changes to the transcript or summary will be made only to correct factual errors.

Confidentiality - Interviewees should be advised that the proceedings are confidential and that they should not discuss the inquiry or their interview with anyone else other than their counsel or adviser.

Access to Counsel - Interviewees may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or witness in the case. However, the counsel or adviser may only advise the subject and may not participate directly in the interview. Interviewees will respond directly to the interview questions.

Order of Interviews - The inquiry committee should interview, if possible, the whistleblower, key witnesses, and the respondent, in that order. Interviewees should be asked to provide, in advance if possible, any relevant evidence including their own notes, manuscripts, research records, or other documents that were not sequestered previously but are relevant to the allegation.

Whistleblower Interview - In interviewing the whistleblower, the inquiry committee should attempt to obtain as much additional evidence regarding the substance of the allegation as possible. A determination of the whistleblower's view of the significance and impact of the alleged misconduct should too be made. However, it is not the whistleblower's responsibility to prove his or her allegations.

Respondent Interview- The respondent should be asked to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of scientific judgement occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

Recording Admissions - If the respondent admits to the misconduct, the respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is sufficient basis to proceed directly to an investigation. However, the admission may not prove sufficient enough to close a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made, the RIO or Division counsel may seek advice from ORI in determining whether there is a sufficient basis to close a case, after the admission is fully documented and all appropriate procedural steps are taken. If the case is closed, the report should be forwarded to the Deciding Official with recommendations for appropriate institutional sanctions and then submitted to ORI for review.

Committee Deliberations - The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct actually occurred. Committee deliberations should never be held in the presence of the interviewee. During the interview, the committee members should not debate among themselves or with interviewees over possible scientific interpretations. These questions should be reserved for private discussion among the inquiry committee members and expert consultants.

VI. THE INQUIRY REPORT

A. Elements for the Inquiry Report

A written inquiry report must be prepared that states:

- The name and title of the committee members and experts, if any;
- The allegations;
- The PHS support, if applicable;
- A summary of the inquiry process used;
- A list of the research records reviewed;
- Summaries of any interviews;
- A description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and
- The committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended.

The Assistant Attorney General may review the report for legal sufficiency.

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

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation.

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

Within 10 business days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submit will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as needed.

C. Inquiry Decision and Notification

The RIO will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 calendar days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and the reason for the extension will be entered into the records of the case and the report. The respondent will also be notified of the extension.

In writing, the RIO will notify both the respondent and the whistleblower of the Deciding Official's decision on whether to proceed to an investigation. They again will be reminded of their obligation to cooperate in the event an investigation is opened. The RIO will also notify all appropriate PHD officials of the Deciding Official's decision.

If the inquiry identifies non-research misconduct issues, the RIO shall refer these matters to the appropriate PHD Official and/or federal office for action. Issues requiring referral include:

- HHS Criminal Violations – Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General. If the possible criminal violation is identical to the alleged research misconduct (e.g. alleged false statements in a grant application), the criminal charge should be reported to ORI.
- Violation of Human Subject Regulations – Potential violations of human subject regulations should be referred to the Office on Human Research Protections and the local Public Health Institutional Review Board.
- Violation of FDA Regulations - Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA, Office of Regulatory Affairs.

Any questions regarding the proper referral of non-research misconduct issues may be referred to ORI.

If the decision is made to initiate an investigation, ORI must be informed by writing a letter to the Director, on or before the date the investigation begins. The notification must include:

- Name of the person(s) against whom the allegations have been made;
- The general nature of the allegation as it relates to the PHS definition of research misconduct, and if applicable, the PHS application(s) or grant number(s) involved.

VII. THE INVESTIGATION

A. Purpose

The purpose of the investigation is to explore in detail the allegations, examine the evidence in depth, and 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 when the alleged misconduct involves clinical trials and/or potential harm to human subjects or occurred with research that forms the basis for public policy, clinical practice, or public health practice, subsequently affecting the general public at large.

B. Sequestration of the Research Records

The RIO will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. Records should be sequestered before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the Division's decision to investigate additional allegations not considered during the inquiry. The procedures to be followed for sequestering records during the investigation are the same procedures that apply during the inquiry.

C. Notification of the Respondent

The RIO will notify the respondent as soon as reasonably possible after the determination is made to open an investigation. The notification will include:

- A copy of the inquiry report;
- The specific allegations;
- The sources of PHS funding, if applicable;
- The definition of research misconduct;
- The procedures to be followed in the investigation, including the appointment of the investigation committee and experts;
- Notification of their opportunity to be interviewed, to provide information, to be assisted by counsel, 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; and
- An explanation of the respondents' right to request a hearing before the DHHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition.

D. Appointment of the Investigation Committee

In consultation with other appropriate institutional officials, the RIO will appoint an investigation committee and its Chair within ten calendar days, or as soon thereafter as practicable, of notifying the respondent that an investigation is planned. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside The Division. Individuals appointed to the investigation committee may also have

served on the inquiry committee. Experts may be appointed to advise the committee on scientific or other issues.

The RIO will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflict of interest with the respondent, whistleblower, or the case in question. The RIO will notify the respondent of the proposed committee members within five business days of being established. If the respondent submits a 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.

Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, whistleblower, witnesses, or anyone not authorized by the RIO to have knowledge of the investigation.

E. Charge to the Committee and the First Meeting

The RIO will state the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines research misconduct, and identifies the name of the respondent. The charge will explain that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses and based on a preponderance of the evidence, discern whether or not research misconduct did occur. If so, it is then their duty to determine to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject and/or suggests additional respondents, the committee will notify the RIO. A determination will be made by the RIO on whether it is necessary to notify the respondent of the new subject matter and/or provide notice to additional respondents.

Diligent efforts will be made to ensure that the investigation is thorough and sufficiently documented, including an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations. In addition, reasonable steps will be taken to ensure an impartial and unbiased investigation occurs, to the maximum extent practicable. This will include assuring participation of persons with appropriate scientific expertise whom do not hold unresolved personal, professional, or financial conflicts of interest with those involved with the investigation.

With the support of the Assistant Attorney General, the 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. The necessity for confidentiality and for developing a specific investigation plan will be explained. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

F. Investigation Process

The investigation committee will be appointed and the process initiated within 30 calendar days of the

completed inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include:

- An inventory of all previously secured evidence and testimony;
- A determination of whether additional evidence needs to be secured;
- Which witnesses need to be interviewed, including the whistleblower, respondent, and other key witnesses whom have knowledge of the research or events in question;
- A proposed schedule of meetings, briefing of experts, and interviews;
- Anticipated analyses of evidence; and
- A plan for the investigation report.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Interviews will be conducted with each respondent, whistleblower, and any other available person who may have substantive information regarding any relevant aspects of the investigation, including witnesses identified by the respondent. Interviews will be tape recorded and/or transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

All leads and significant issues discovered shall be pursued diligently including any evidence of additional instances of possible research misconduct.

G. Committee Deliberations

The committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific community at the time the actions were committed. The committee will consider whether there is sufficient evidence of intent or if the respondent has presented substantial evidence of honest error and/or honest difference in interpretation or judgement of data, such that research misconduct cannot be proven. In reaching a conclusion, the burden of proof is on The Division to support its conclusions and findings by the preponderance of the evidence.

H. Time Limits

All aspects of the investigation must be completed within 120 calendar days of its initiation. This includes conducting the investigation, preparing the report of findings, giving the draft report to the respondent for comment, and sending the final report to ORI. If the PHD is unable to complete the investigation within 120 days, The Division must ask for an extension from ORI in writing. If an extension is granted, periodic progress reports shall be sent to ORI. The PHD will give the respondent

and whistleblower a copy of the draft investigation report for review and comment within 30 calendar days of the draft being prepared. Comments must be received from the respondent and/or whistleblower within 14 calendar days of receipt of the draft report.

VIII. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The final investigation report must be in writing and include:

- A description of the nature of the allegation of research misconduct;
- A description and documentation of the PHS support, if applicable. This includes any grant numbers, grant applications, contracts, and publications listing support;
- A description of the specific allegations of research misconduct for consideration in the investigation;
- A copy of the PHD policies and procedures under which the investigation was conducted, if not already sent to ORI;
- Identification and summary of the research records and evidence reviewed. This includes the identification of any evidence taken into custody but not reviewed;
- Comments made by the respondent and whistleblower on the draft investigation report; and
- A statement of finding as to whether research misconduct did or did not occur for each separate allegation of research misconduct identified during the investigation. If research misconduct is found:
  - Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
  - Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
  - Identify the specific PHS support, if applicable;
  - Identify whether any publications need correction or retraction;
  - Identify the person(s) responsible for the misconduct; and
  - List any current support or known applications or proposals for support that the respondent has pending with any other agency.

The PHD will maintain and provide to ORI upon request all relevant research records, including results of all interviews and the transcripts or recordings of such interviews.

B. Comments on Draft Report

The RIO will provide the respondent with a copy of the draft investigation report, allowing them 14 calendar days to review for comment and possible rebuttal. The respondent's comments will be attached

to the final report which will take into account these comments in addition to all the other evidence.

The RIO will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

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

In distributing the draft report, or portions thereof, to the respondent and whistleblower, 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. The RIO may request the recipient to sign a confidentiality statement or come to his or her office in order to review the report.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination on whether to accept the investigation report, its findings, and the recommended PHD actions. If their determination differs from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a different decision in the PHD letter accompanying the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, the PHD policies and procedures, and the evidence reviewed and analyzed by the investigation committee. However, prior to submission to ORI, the Deciding Official is allowed to 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 report, 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 whistleblower 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. Notice to ORI of Findings and Actions

The following information will be given to ORI upon finalization of the investigation:

- A copy of the investigation report, all attachments, and any appeals;
- A description of the final actions taken by PHD, including whether The Division found research misconduct, and if so, the identity of who committed the act ;
- A statement of whether The Division’s Deciding Official accepts the investigation’s finding; and
- A description of any pending or completed administrative actions against the respondent.

E. Completing the Research Misconduct Process

The Division will diligently pursue all significant issues and carry inquiries and investigations through to completion. If the PHD plans to end an inquiry or investigation before completion for any reason, including an admission of misconduct by the respondent, it will contact ORI before closing the case and submitting its final report. ORI may direct The Division to complete the process or refer the matter for further investigation.

IX. PUBLIC HEALTH DIVISION 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:

- Withdrawal or correction of all pending or published abstracts and papers derived 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; and/or
- Restitution of funds as appropriate.

X. OTHER CONSIDERATIONS

A. Termination of PHD 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.

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, the committee 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

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the RIO will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome. It may be necessary to publicize the final outcome in forums in which the allegation of research misconduct had previously been publicized or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Whistleblower and Others

Regardless of whether the institution or ORI determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect whistleblowers who made allegations of research misconduct in good faith and all others who cooperated in good faith with the inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will consult with the whistleblower to determine what steps, if any, are needed to restore their position and/or reputation. In addition to implementing any steps the Deciding Official approves, the RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the whistleblower's allegations of research misconduct were not made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the whistleblower.

E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

XI. RECORD RETENTION

After completion of a case and all ensuing related actions, the RIO will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the RIO or committees. The RIO will keep the file for three years after the case is completed to permit later assessment of the case if needed. ORI or other authorized DHHS personnel will be given access to the records upon request.

XII. APPEAL

Following the receipt of the report from the investigation committee, the respondent and the whistleblower have 14 calendar days to challenge the committee's report. They must submit a written argument to the RIO, which presents substantial evidence challenging the report. The RIO has the responsibility of evaluating the information provided in the written appeal.

XIII. FINAL ACTIONS

A. Agreement with the Appeal:

a. It is the duty of the RIO to determine the appeal's merit. If after reviewing the document, the RIO believes there is substantial new evidence, the investigation committee will be asked to re-open the case and provide a new evaluation of data outlined in the appeal.

b. If the investigation committee finds the appeal to be justified they will make a recommendation to the RIO and the original findings of the investigation committee may be overturned.

B. Reject the Appeal:

   a. If upon receipt of the appeal, the RIO does not believe substantial evidence has been presented to overturn the final report, a re-review of the evidence by the investigation committee will not occur.

C. Notice of Final Determination

   a. Written notice of the RIO's decision will be given to both the appellate and ORI.