Oregon Health Authority
Public Health Division

Policy & Procedures for Addressing 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 upholding the highest standards of scientific rigor in research and maintaining an environment that promotes research integrity, ethical standards, and the responsible conduct of such research. The Division does not tolerate misconduct in any aspect of research and will promptly conduct inquiries and/or investigations of any allegation or evidence of possible 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. As the Oregon Public Health Institutional Review Board (PH IRB) also serves the Oregon State Hospital (OSH) via our Interagency Agreement #186747-0 (IAA 186747-0), OSH is to also follow the policy and procedure outlined in this document when there are allegations or evidence of possible research misconduct within their hospital. Reference to the "institution," "institutional employees," or "institutional members," throughout this policy are applicable to whichever of these institutions has received the allegation of research misconduct. Although "PHD" or "The Division" may be used interchangeably with "institution," if OSH has received the allegation of research misconduct, this policy will apply. It is the responsibility of OSH to specify which institutional officials within their hospital will serve in the applicable roles discussed below.

B. General Policy

Institutional 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. They are to conduct research with honesty, rigor, and transparency. 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 differences of opinion.

The PHD strives to reduce the risk of research misconduct, support all good-faith efforts to report suspected misconduct, promptly and thoroughly address all allegations of research misconduct, and seek to rectify the scientific record and/or restore researchers' reputations, as appropriate. Research misconduct is contrary to the interests of the PHD, the health and safety of the public, the integrity of research, and the conservation of public funds. Both the PHD and its members have an affirmative duty to protect those funds from misuse by ensuring the integrity of all research conducted on behalf of the PHD. The Division is responsible for ensuring that these policies and procedures for addressing allegations of research misconduct meet the requirements of the PHS Policies on Research Misconduct (42 CFR Part 93, "the PHS regulation"). The PHD will establish and maintain these policies and procedures, inform all institutional members about these policies and procedures, and make these policies and procedures publicly available. The PHD is committed to following these policies and procedures when responding to allegations of research misconduct.

C. Scope

The revised U.S. Public Health Service (PHS) Policies on Research Misconduct (42 CFR 93 in the *Code of Federal Regulations)* took effect January 1, 2025 and must be applied to any allegations received on or after January 1, 2026. 42 CFR 93 applies to any research, research-training or research-related applications, proposals, grants, or cooperative agreements, or related records or activities with PHS. This policy and its procedures follow 42 CFR 93 and apply to all individuals paid by, under the control of, or affiliated with the PHD engaged in research regardless of funding source. This includes scientists, trainees, research analysts, technicians, and other staff members, students, interns, or collaborators. Although "PHS support" and "PHS-supported" are referenced throughout this policy, the Division elects to apply this policy and the regulations of 42 CFR 93 to all research it or its staff are engaged in, and all allegations of research misconduct, regardless of funding source. As stated above, all instances of "The Division" and "the PHD" stated in this policy should also be implicative of the OSH, due to the execution of the aforementioned IAA.

These policies and procedures apply only to research misconduct occurring within six years of the date HHS or the PHD receives an allegation of research misconduct, subject to the following exceptions:

- The six-year time limitation does not apply if the respondent continues or renews any incident of alleged research misconduct that occurred before the six-year period through the use of, republication of, or citation to the portion(s) of the research record alleged to have been fabricated, falsified, or plagiarized, for the potential benefit of the respondent ("subsequent use exception"). For alleged research misconduct that appears subject to this subsequent use exception, but the PHD determines is not subject to the exception, the PHD will document its determination that the subsequent use exception does not apply and will retain this documentation for the later of ten years after completion of the institutional proceeding or the completion of any HHS proceeding.
    - Although, the federal policy at 42 CFR 93 requires a documentation retention period of seven years, the Division elects to follow the *Oregon State Archives Record Retention Schedule* and will retain this documentation for 10 years after the research project is closed, or the research misconduct proceeding is complete, whichever is later.
- The six-year time limitation also does not apply if the Office of Research Integrity (ORI) or the PHD, following consultation with ORI, determines that the alleged research misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public.

When an allegation of possible research misconduct is received by an institutional 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 institution involved 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. This policy and its related procedures do not supersede or establish an alternative to the PHS regulation or any existing regulations for handling research misconduct involving non-PHS supported research. They do not replace the PHS regulation, and in case of any conflict between this document and 42 CFR Part 93, the PHS regulation will prevail. They are intended to enable the Division to comply with the requirements of the PHS regulation.

II. DEFINITIONS

A. *Accepted practices of the relevant research community* means those practices established by 42 CFR Part 93 and by PHS funding components, as well as commonly accepted professional codes or norms within the overarching community of researchers and institutions that apply for and receive PHS awards.

B. *Administrative record* comprises: the institutional record; any information provided by the respondent to the ORI, including but not limited to the transcript of any virtual or in-person meetings under § 93.403(b) between the respondent and ORI, and correspondence between the respondent and ORI; any additional information provided to ORI while the case is pending before ORI; and any analysis or additional information generated or obtained by ORI. Any analysis or additional information generated or obtained by ORI will also be made available to the respondent

C. *Allegation* means a disclosure of possible research misconduct through any means of communication and brought directly to the attention of an institutional or HHS official.

D. *Assessment* means a consideration of whether an allegation of research misconduct appears to fall within the definition of research misconduct; appears to involve PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training; and is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The assessment only involves the review of readily accessible information relevant to the allegation.

E. *Complainant* means an individual who in good faith makes an allegation of research misconduct.

F. *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.

G. *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.

H. *Evidence* means any document, whether in hard copy or electronic form, information, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

I. *Fabrication* means making up data or results and recording or reporting them.

J. *Falsification* means 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.

K. *Good faith* as applied to a complainant or witness, means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness's position could have based on the information known to the complainant or witness at the time. An allegation or cooperation with a research misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to an institutional or committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under 42 CFR Part 93. An

institutional or committee member does not act in good faith if his/her acts or omissions during the research misconduct proceedings are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

L. *Inquiry* means preliminary information-gathering and initial fact-finding that meets the criteria and follows the procedures of § 93.307 - §93.309.
M. *Institution* means any person who applies for or receives PHS support for any activity or program that involves the conduct of biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training. This includes, but is not limited to, colleges and universities, PHS intramural biomedical or behavioral research laboratories, research and development centers, national user facilities, industrial laboratories or other research institutes, research institutions, and independent researchers.
N. *Institutional Deciding Official (IDO)* means the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as the Institutional Deciding Official and the Research Integrity Officer. The OHA, Director of Public Health will serve as the PHD Deciding Official.
O. *Institutional member(s)* means an individual (or individuals) who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to, officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, technicians, postdoctoral and other fellows, students, volunteers, subject matter experts, consultants, or attorneys, or employees or agents of contractors, subcontractors, or sub-awardees.
P. *Institutional record* comprises: (a) The records that the institution compiled or generated during the research misconduct proceeding, except records the institution did not consider or rely on. These records include but are not limited to (1) documentation of the assessment as required by § 93.306(c); (2) if an inquiry is conducted, the inquiry report and all records (other than drafts of the report) considered or relied on during the inquiry, including, but not limited to, research records and the transcripts of any transcribed interviews conducted during the inquiry, information the respondent provided to the institution, and the documentation of any decision not to investigate as required by § 93.309(c); (3) if an investigation is conducted, the investigation report and all records (other than drafts of the report) considered or relied on during the investigation, including, but not limited to, research records, the transcripts of each interview conducted pursuant to § 93.310(g), and information the respondent provided to the institution; (4) decision(s) by the Institutional Deciding Official, such as the written decision from the IDO under § 93.314; (5) the complete record of any institutional appeal consistent with § 93.315; (b) a single index listing all the research records and evidence that the institution compiled during the research misconduct proceeding, except records the institution did not consider or rely on; and (c) a general description of the records that were sequestered but not considered or relied on.
Q. *Intentionally* means to act with the aim of carrying out the act.
R. *Investigation* means the formal development of a factual record and the examination of that record that meets the criteria and follows the procedures of §93.310 - §93.317
S. *Knowingly* means to act with awareness of the act.
T. *Office of Research Integrity or ORI* means the office established by Public Health Service Act section 493 (42 U.S.C. 289b) sitting within the U.S. Department of Health and Human Services (DHHS) to which the HHS Secretary has delegated responsibility for addressing

research integrity and misconduct issues related to U.S. Public Health Service (PHS) supported activities.

U. *Plagiarism* means the appropriation of another person's ideas, processes, results, or words, without giving appropriate credit. (a) Plagiarism includes the unattributed verbatim or nearly verbatim copying of sentences and paragraphs from another's work that materially misleads the reader regarding the contributions of the author. It does not include the limited use of identical or nearly identical phrases that describe a commonly used methodology. (b) Plagiarism does not include self-plagiarism or authorship or credit disputes, including disputes among former collaborators who participated jointly in the development or conduct of a research project. Self-plagiarism and authorship disputes do not meet the definition of research misconduct.

V. *Preponderance of the evidence* means proof by evidence that, compared with evidence opposing it, leads to the conclusion that the fact at issue is more likely true than not.

W. *Public Health Service or PHS* means the unit within the U.S. Department of Health and Human Services that consists of the following components: the Office of the Assistant Secretary for Health, the Office of Global Affairs, the Administration for Strategic Preparedness and Response, the Advanced Research Projects Agency for Health, the Agency for Healthcare Research and Quality, the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the Substance Abuse and Mental Health Services Administration, and any other components of HHS designated or established as components of the Public Health Service.

X. *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".

Y. *PHS support* means PHS funding, or applications or proposals for PHS funding, for biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or training, that may be provided through funding for PHS intramural research; PHS grants, cooperative agreements, or contracts; subawards, contracts, or subcontracts under those PHS funding instruments; or salary or other payments under PHS grants, cooperative agreements, or contracts.

Z. *Recklessly* means to propose, perform, or review research, or report research results, with indifference to a known risk of fabrication, falsification, or plagiarism.

AA. *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.

BB. *Research Integrity Officer (RIO)* means the institutional official responsible for administering the institution's written policies and procedures for addressing allegations of research misconduct in compliance with 42 CFR Part 93 to assess allegations of research misconduct, determine when such allegations warrant inquiries, and oversee those inquiries and investigations. The State Public Health Officer will serve as the PHD's Research Integrity Officer.

CC. *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 differences of opinion.

DD. *Research misconduct proceeding* means any actions related to alleged research misconduct taken under 42 CFR Part 93, including allegation assessments, inquiries, investigations, ORI oversight reviews, and appeals under subpart E of 42 CFR Part 93

EE. *Research record* means the record of data or results that embody the facts resulting from scientific inquiry. Data or results may be in physical or electronic form. Examples include, but are not limited to, research proposals, raw data, processed data, clinical research records, laboratory records, study records, laboratory notebooks, progress reports, manuscripts, abstracts, theses, records of oral presentations, online content, lab meeting reports, and journal articles.

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

GG. *Retaliation* means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members in response to (a) a good faith allegation of research misconduct or (b) good faith cooperation with a research misconduct proceeding.

HH. *Small institution* means an institution that may be too small to conduct an inquiry or investigation into an allegation of research misconduct as required by 42 CFR Part 93 without actual or apparent conflicts of interest.

II. *Suspension and Debarment Official or SDO* means the HHS official authorized to impose suspension and debarment, which are the actions that Federal agencies take to disqualify persons deemed not presently responsible from doing business with the Federal Government.

III. ROLES AND RESPONSIBILITIES

A. The Division

The PHD will respond to each allegation of research misconduct under 42 CFR Part 93 in a thorough, competent, objective, and fair manner. To the extent possible, the PHD will limit disclosure of the identity of respondents, complainants, and witnesses while conducting the research misconduct proceedings to those who need to know. Those who need to know may include Institutional Review Boards, the PH IRB Administrator, journals, editors, publishers, co-authors, and collaborating institutions. This limitation on disclosure no longer applies once the PHD has made a final determination of research misconduct findings. The PHD will take all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records, and other evidence. The PHD agrees to cooperate with ORI during any research misconduct proceeding or compliance review, including addressing deficiencies or additional allegations in the institutional record if directed by ORI and to assist in administering and enforcing any HHS administrative actions imposed on institutional members. The PHD may also take steps to manage published data or acknowledge that data may be unreliable.

Before or at the time of notifying the respondent of the allegation(s) and whenever additional items become known or relevant, the PHD will promptly take all reasonable and practical steps to obtain all

research records and other evidence and sequester them securely. The PHD will ensure that the institutional record contains all required elements. Upon completion of the inquiry, the PHD will provide ORI with the complete inquiry report and add it to the institutional record. The PHD will maintain the institutional record and all sequestered research records and other evidence in a secure manner for ten years after completion of the institutional and/or HHS proceeding, whichever is later.

The PHD will provide information related to the alleged research misconduct and proceedings to ORI upon request and transfer custody or provide copies of the institutional record or any component of it and any sequestered evidence to HHS, regardless of whether the evidence is included in the institutional record. Additionally, the PHD will promptly notify ORI of any special circumstances that may arise. – The Division will promptly notify ORI in advance if at any point during the proceedings (including the assessment, inquiry, investigation, or appeal stage) it would like to close a research misconduct case because the respondent has admitted to committing research misconduct or a settlement with the respondent has been reached.

If the alleged research misconduct involves multiple institutions, the PHD may work closely with the other affected institutions to determine whether a joint research misconduct proceeding will be conducted. If so, the cooperating institutions will choose an institution to serve as the lead. In a joint research misconduct proceeding, the lead institution will obtain research records and other evidence pertinent to the proceeding, including witness testimony, from the other relevant institutions. By mutual agreement, the joint research misconduct proceeding may include committee members from the institutions involved. The determination of whether further inquiry and/or investigation is warranted, whether research misconduct occurred, and the institutional actions to be taken may be made by the institutions jointly or tasked to the lead institution.

B. Research Integrity Officer

The State Public Health Officer will serve as the PHD Research Integrity Officer (RIO) who will have primary responsibility for implementation of the procedures set forth in this policy. All employees or individuals associated with The Division 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. The RIO will report any allegation not made in good faith to the PHD Deciding Official for appropriate action.

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.

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.
- Upon receiving an allegation of research misconduct, regardless of what funding source may be involved, immediately assess the allegation to determine whether it (a) is within the definition of research misconduct under the PHS regulation, (b) is within the applicability criteria of the regulation at § 93.102, and (c) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. This assessment should be documented.
- Promptly sequester all research records and other evidence per the PHS regulation and initiate the inquiry, if it is determined that the requirements for an inquiry are met.
- Keep detailed documentation of the assessment to permit a later review by ORI, if the PHD determined that requirements for an inquiry are not met.
- 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 PHD may choose to have the RIO or another designated institutional official conduct the inquiry in lieu of a committee, and, if needed, this individual may utilize one or more subject matter experts to assist them in the inquiry.;
- 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; and
  - Notification if The Division determines that it will not be able to complete an investigation within 180 days

C. Complainant

The complainant is the person(s) who in good faith makes an allegation of research misconduct. Allegations are to be brought directly to the attention of an institutional or HHS official through any means of communication. Complainants are responsible for maintaining confidentiality and cooperating with an inquiry or investigation. If the complainant 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 complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.

The PHD will provide confidentiality consistent with 42 CFR Part 93 for all complainants in a research misconduct proceeding and take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved potential, perceived, or actual personal, professional, or financial conflicts of interest with the complainant(s). Any alleged or apparent retaliation by respondents and/or other institutional members, should immediately be reported to the RIO.
The complainant(s) will have an opportunity to testify before the inquiry and investigation committees and may be permitted to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony. If the PHD chooses to notify one complainant of the inquiry results in a case, all complainants will be notified to the extent possible.

D. Respondent

The respondent is the individual against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding. In writing, the respondent will be informed of the allegations when an inquiry is opened and notified of the final determination and resulting actions. The PHD will take precautions to ensure that individuals responsible for carrying out any part of the research misconduct proceeding do not have unresolved potential, perceived, or actual personal, professional, or financial conflicts of interest with the respondent. The respondent will not be present during the witnesses' interviews but will be provided with a transcript of the interview after it takes place. The respondent will have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, view and comment on the draft inquiry and investigation reports, and have the advice of counsel. The respondent has the burden of going forward with and proving, by a preponderance of evidence, affirmative defenses raised. If no finding of research misconduct is made, the respondent may request that the RIO undertake reasonable efforts, as appropriate, to restore his or her reputation.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. The respondent's destruction of research records documenting the questioned research is evidence of research misconduct where a preponderance of evidence establishes that the respondent intentionally or knowingly destroyed records after being informed of the research misconduct allegations. The respondent's failure to provide research records documenting the questioned research is evidence of research misconduct where the respondent claims to possess the records but refuses to provide them upon request. 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 admitting to research misconduct, the respondent will sign a written statement specifying the affected research records and confirming the misconduct was falsification, fabrication, and/or plagiarism; committed intentionally, knowingly, or recklessly; and a significant departure from accepted practices of the relevant research community.

If the alleged research misconduct involves multiple respondents, the PHD may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings.

E. Committee Members

Committee members are experts who act in good faith to cooperate with the research misconduct proceedings by impartially carrying out their assigned duties for the purpose of helping The Division meet its responsibilities under 42 CFR Part 93. Committee members will have relevant scientific expertise and be free of real or perceived conflicts of interest with any of the involved parties. Committee members or anyone acting on behalf of the PHD will conduct research misconduct proceedings consistent with the PHS regulation. They will determine whether an investigation is warranted, documenting the decision in an inquiry report. During an investigation, committee members participate in recorded interviews of 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(s). They will also determine whether or not the respondent engaged in research misconduct and document the decision in the investigation report. They consider respondent and/or complainant comments on the inquiry/investigation report(s) and document that consideration in the investigation report.

An investigation into multiple respondents may convene with the same investigation committee members or anyone acting on behalf of the Division, but there will be separate investigation reports and separate research misconduct determinations for each respondent. Committee members may serve for more than one investigation, in cases with multiple respondents. Committee members may also serve for both the inquiry and the investigation.

F. Witnesses

Witnesses are people whom the Division has reasonably identified as having information regarding any relevant aspects of the investigation. Witnesses provide information for review during research misconduct proceedings. Witnesses will cooperate with the research misconduct proceedings in good faith and have a reasonable belief in the truth of their testimony, based on the information known to them at the time.

G. Institutional Deciding Official

The Institutional Deciding Official (IDO) is the institutional official who makes final determinations on allegations of research misconduct and any institutional actions. The same individual cannot serve as both the IDO and the RIO, thus the OHA, Director of Public Health will serve as the PHD Deciding Official and will receive the inquiry and/or investigation report and any written comments made by the respondent and/or the complainant on the draft report. The PHD Deciding Official will consult with the RIO or other appropriate officials and will determine in a written decision whether to conduct an investigation, whether misconduct occurred, and if so, what kind and who committed it, whether to impose sanctions, or whether to take other appropriate administrative actions.

IV. POLICY AND PRINCIPLES

A. Confidentiality

PHD 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 complainant(s), the respondent(s), witnesses, and all other affected individuals consistent with 42 CFR Part 93. 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 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:
  - Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
  - HHS or other federal funds, resources, equipment, or interests are threatened;
  - Research activities should be suspended;
  - Federal action is required to protect the interests of those involved in the research misconduct proceeding;
  - HHS may need to take appropriate steps to safeguard evidence and protect the rights of those involved;
  - the allegation involves a public health sensitive issue; or
  - there is a reasonable indication of a possible violation of civil or criminal law. 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(s);
  - 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(s), complainant(s), and/or witnesses, if applicable.

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 is 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.

If the PHD determines a 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 Division to consider in imposing administrative actions following research misconduct proceedings.

V. CONDUCTING THE INQUIRY

A. Assessment

An assessment's purpose is to determine whether an allegation warrants an inquiry. An assessment is intended to be a review of readily accessible information relevant to the allegation. Upon receiving an allegation of research misconduct, the RIO or another designated institutional official will promptly determine whether the allegation (a) falls within the definition of research misconduct, (b) is within the applicability criteria of 42 CFR Part 93 § 93.102, and (c) is credible and specific enough to identify and sequester potential evidence.

If the RIO or another institutional official determines that the allegation meets these criteria, they will promptly: (a) document the assessment and (b) initiate an inquiry and sequester all research records and other evidence. Per federal requirements, the RIO or other institutional official must document the assessment and retain the assessment documentation securely for seven years after completion of the misconduct proceedings. However, the PHD elects to retain such documentation for ten years, per the Oregon State Archives Record Retention Schedule. If the RIO or another institutional official determines that the alleged misconduct does not meet the criteria to proceed to an inquiry, they will write sufficiently detailed documentation to permit a later review by ORI of why the Division did not proceed to an inquiry. This documentation will also be securely retained for ten years post study-closure, or the closure of the misconduct case, whichever is later.

B. Initiation and Purpose of the Inquiry

Following the assessment, if the RIO determines that the allegation provides sufficiently credible and specific information so that potential evidence of research misconduct may be identified, falls under the PHS definition of research misconduct, and is within the applicability criteria § 93.102, 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 conduct an initial review of the evidence to determine whether an allegation or apparent instance of misconduct warrants an investigation. This may include testimony of the respondent(s), complainant(s), and/or key witnesses but it does not require a full review of all related evidence. The findings of the inquiry must be set forth in a formal inquiry report within 90 days of initiating it unless circumstances warrant a longer period, in which the Division will sufficiently document the reasons for exceeding the time limit in the inquiry report.

C. 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 90 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.

D. 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. 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 to carry out a research misconduct proceeding.

Before or at the time of notifying the respondent(s) that an inquiry is being initiated, the Division will obtain the original or substantially equivalent copies of all research records and other evidence that are pertinent to the proceeding, inventory these materials, and sequester them in a secure manner. The respondent is notified of the inquiry simultaneously with the sequestration of research records and other evidence so that the respondent can assist with location and identification of the records and evidence. 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 complainant(s). 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.EE of this document.

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. 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. The PHD has a duty to obtain, inventory, and securely sequester evidence that extends to whenever additional items become known or relevant to the inquiry or investigation. The RIO will lock records and materials in a secure place.

E. Notification of the Respondent

At the time of or before beginning the inquiry, the RIO will make a good-faith effort to notify the presumed respondent in writing that an allegation of research misconduct has been raised against them and an inquiry will be conducted to decide whether to proceed with an investigation. 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 complainant(s) against retaliation and the need to maintain the complainants' confidentiality during the inquiry and any subsequent proceedings.

The PHD is responsible for giving the respondent(s) copies of or supervised access to the sequestered research records. The respondent(s) will be notified whether the inquiry found that an investigation is warranted and will be provided with the opportunity to review and comment on the inquiry report and attach their comments to it. If additional allegations are raised, the Division will notify the respondent(s) in writing.

If the alleged research misconduct involves multiple respondents, the PHD may either conduct a separate inquiry for each new respondent or add them to the ongoing proceedings. The Division must give additional respondents written notice of the allegation(s) and the same rights and opportunities as the initial respondent. Only allegations specific to a particular respondent will be included in the notification to that respondent.

F. 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. The Division will ensure that a committee member or person acting on the PHD's behalf understands their commission, keeps the identities of respondents, complainants, and witnesses confidential, and conducts research misconduct proceedings in compliance with the PHS regulation. The PHD will take all reasonable and practical steps to protect the positions and reputations of good-faith committee members and to protect these individuals from retaliation.

In the event that the allegations and apparent evidence are straightforward the RIO may choose to conduct the inquiry directly or designate another qualified institutional official 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 subject matter expert and technical advice to properly consider all scientific issues and assist in the inquiry.

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, complainant, witnesses, or the case in question. In making this determination, the RIO will consider whether the individual:

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

The respondent(s) 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.

G. Inquiry Process

The inquiry committee, RIO, or other designated institutional official will conduct a preliminary review of the allegations, evidence, and any related issues identified during the allegation assessment. In the process of fact-finding, the respondent(s) and/or witnesses may be interviewed. It will be explained that the purpose of the inquiry is to hold a preliminary evaluation of the evidence and testimony of the respondent(s), complainant(s), and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. Criteria warranting an investigation include, but are not limited to:

- A reasonable basis for concluding that the allegation falls within the definition of research misconduct under 42 CFR 93 and involves PHS-supported biomedical or behavioral research, biomedical or behavioral research training, or activities related to that research or research training, as provided in § 93.102-; and
- Preliminary information-gathering and 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 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. No determination on whether research misconduct occurred or who was responsible will be made. Further, the inquiry committee will not assess whether the alleged misconduct was intentional, knowing, or reckless; such a determination is not made until the case proceeds with an investigation.

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(s), complainant(s), witnesses, or anyone not authorized by the RIO to have knowledge of the inquiry.

H. General Approaches to Conducting an Interview

Purpose of the Interview – At the inquiry stage, the purpose is to allow each respondent, complainant, or witness 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 with a copy of the resulting transcripts or summaries of the interviews.

Transcription - Interviews will be transcribed and 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 complainant(s), key witnesses, and the respondent(s), 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.

Complainant Interview - In interviewing the complainant, the inquiry committee should attempt to obtain as much additional evidence regarding the substance of the allegation as possible. A determination of the complainant's view of the significance and impact of the alleged misconduct should too be made. However, it is not the complainant'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 opinion 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 written statement attesting to the occurrence and extent of the misconduct. The admission must state the specific fabrication, falsification, or plagiarism that occurred, which research records were affected, and that it constituted a significant departure from accepted practices of the relevant research community. The written statement should confirm the respondent’s culpability and explain how the PHD determined that the respondent’s admission fully addresses the scope of misconduct. That signed, written statement should then immediately be provided to the ORI, by the PHD.

Normally, admission is sufficient to proceed directly to an investigation, however, the admission may not prove sufficient to close a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. The ORI can assist 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 PHD 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

At the conclusion of the inquiry, regardless of whether an investigation is warranted, the inquiry committee, RIO, or other designated institutional official will prepare a written inquiry report. The contents will include:

- The names, professional aliases, and positions of the respondent(s) and complainant(s).
- The allegations.
- The PHS support, if applicable, including any grant numbers, grant applications, contracts, and publications listing PHS support.;
- The composition of the inquiry committee, if used, including name(s), position(s), and subject matter expertise.
- Inquiry timeline and procedural history.
- An inventory of sequestered research records and other evidence and description of how sequestration was conducted.
- Any scientific or forensic analyses conducted.
- Summaries of any interviews and/or transcripts of interviews.
- The basis for recommending that the allegation(s) warrant an investigation or not.
- Any comments on the inquiry report by the respondent(s) or complainant(s).
- Any institutional actions implemented, including internal communications or external communications with journals or funding agencies.
- Documentation of potential evidence of honest error or difference of opinion. .

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

B. Comments on the Draft Inquiry Report

The RIO will provide the respondent(s) with a copy of the draft inquiry report for review and comment. The relevant portions of the draft inquiry report, those that address the complainant's role and opinions in the investigation, may be provided to the complainant, but the RIO is not required to do so.

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 complainant(s) and respondent(s) will provide their comments, if any, to the inquiry committee. Any comments that the complainant(s) or respondent(s) 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 PHD 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 PHD Deciding Official makes this determination, which will be made within 90 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(s) will also be notified of the extension.

Within a reasonable amount of time after the decision is made, the RIO will provide written notice to the respondent(s) of the decision on whether to proceed to an investigation, along with copies of the final inquiry report, the PHS regulation, and this policy and procedure. The written notice will include mention of any additional allegations raised against them not previously addressed by the inquiry report and allow the respondent(s) an opportunity to review the witness transcripts. They again will be reminded of their obligation to cooperate. The PHD may, but is not required to, notify a complainant whether the inquiry found that an investigation is warranted. If the PHD provides notice to one complainant in a case, it must provide notice, to the extent possible, to all complainants in the case.

The RIO will also notify all appropriate PHD officials of The Division’s 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 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, it must begin within 30 days after determination. Additionally, ORI must be informed by the Division within 30 days of that determination, by writing a letter to the ORI Director and including a copy of the inquiry report. 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.

If the inquiry committee, RIO, or other designated institutional official determines that an investigation is not warranted, the PHD will keep sufficiently detailed documentation to permit a later review by ORI of why the PHD did not proceed to an investigation, store these records in a secure manner for at least ten years after the termination of the inquiry, and provide them to ORI upon request.

VII. THE INVESTIGATION

A. Purpose

The purpose of the investigation is to develop a factual record, pursue leads, examine the record, and recommend finding(s) to the Institutional Deciding Official, who will make the final decision, based on a preponderance of evidence, on each allegation and any institutional actions. 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(s) of the allegation(s) within 30 days of determining that an investigation is warranted and before the investigation begins. If any additional respondent(s) are identified during the investigation, the PHD will notify them of the allegation(s) and provide them with an opportunity to respond, consistent with the PHS regulation. The PHD may choose to either conduct a separate inquiry or add the new respondent(s) to the ongoing investigation. The notification will include:

- A copy of the inquiry report;
- The specific allegations;

- A copy of or reference to 42 CFR 93 and this policy and procedures document;
- 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(s) 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(s), complainant(s), witnesses, or the case in question. The RIO will notify the respondent(s) of the proposed committee members within five business days of establishment. If a 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 conduct the research misconduct proceedings in compliance with the PHS regulation and 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 any respondent, complainant, witness, or other individual 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(s). The charge will explain that the committee is to evaluate the evidence and testimony of the respondent(s), complainant(s), 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, the process initiated, and ORI notified 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 individuals need to be interviewed, including the complainant(s), respondent(s), 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, complainant, 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 recorded and transcribed and the transcripts will be made available to the interviewee

for correction. The respondent(s) will not be present during the witnesses' interviews, but the PHD will provide the respondent(s) with a transcript of each interview, with redactions as appropriate to maintain confidentiality. The PHD will include the transcripts of the interviews with any corrections and exhibits in the institutional record of the investigation.

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(s) 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 180 calendar days of its initiation. This includes conducting the investigation, preparing the draft investigation report for each respondent, and providing the opportunity for respondent(s) to comment. The PHD will document the Deciding Official's final decision and transmit the institutional record (including the final investigation report and Deciding Official's decision) to ORI. If the PHD is unable to complete the investigation within 180 days, an extension from ORI must be requested in writing, documenting the reasons for exceeding the allotted time period in the investigation report. If an extension is granted, periodic progress reports shall be sent to ORI.

The PHD will give the respondent(s) a copy of the draft investigation report and concurrently, a copy of, or supervised access to, the research records and other evidence that the investigation committee considered or relied on. The respondent(s) will submit any comments on the draft report within 30 calendar days of receipt. If the PHD chooses to share a copy of the draft investigation report or relevant portions of it with the complainant(s) for comment, the complainant's comments will be submitted within 30 days of the date on which they received the report. The PHD will add any comments received from either the respondent(s) or complainant(s) to the investigation 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, including any additional allegation(s) addressed during the research misconduct proceeding
- 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 allegation(s) of research misconduct for consideration in the investigation.
- Composition of investigation committee, including names, positions, and subject matter expertise.
- Any scientific or forensic analyses conducted.
- A copy of these policies and procedures under which the investigation was conducted, if not already sent to ORI.
- Inventory of sequestered research records and evidence reviewed, except records the PHD did not consider or rely on. Transcripts of all interviews conducted.
- Identification of the specific published papers, manuscripts submitted but not accepted for publication (including online publication), PHS funding applications, progress reports, presentations, posters, or other research records that contain the allegedly falsified, fabricated, or plagiarized material.
- Comments, if any, made by the respondent(s) and complainant(s) on the draft investigation report and the committee's consideration of these comments.
- A statement for each separate allegation of whether the committee recommends a finding of research misconduct. If research misconduct is found, the investigation report will present a finding for each allegation. These findings will:
  - Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was committed intentionally, knowingly, or recklessly;
  - Identify any significant departure from the accepted practices of the relevant research community and that the allegation was proven by a preponderance of the evidence;
  - Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent(s);
  - 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 PHS and non-PHS Federal agencies.

If the investigation committee does not recommend a finding of research misconduct for an allegation, the investigation report will provide a detailed rationale for its conclusion.

B. Comments on Draft Report

The RIO must provide the respondent(s) with a copy of the draft investigation report and any information or allegations added to the institutional record, allowing them 30 calendar days to review for comment and possible rebuttal. The PHD will give due consideration to admissible, credible evidence of

honest error or difference of opinion presented by the respondent(s). The respondents' comments will be attached to the final report which will take into account these comments in addition to all the other evidence.

The RIO may also provide the complainant(s) with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant'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(s) and complainant(s), 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 PHD Deciding Official will make the final written 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 PHD Deciding Official will explain in detail the basis for rendering a different decision in the PHD letter accompanying the report to ORI. The PHD 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 PHD Deciding Official is allowed to return the report to the investigation committee with a request for further fact-finding or analysis. The PHD Deciding Official's written determination, together with the investigation committee's report, constitutes the final institutional record that will be sent for purposes of ORI review.

When a final decision on the case has been reached, the RIO will notify both the respondent(s) and the complainant(s) in writing. In addition, the PHD's 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(s) 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. Creating and Transmitting the Institutional Record

After the Deciding Official has made a final determination of research misconduct findings, PHD will add their written decision to the investigation report so that it becomes part of the institutional record in a logical manner. The institutional record consists of the records that were compiled or generated during the research misconduct proceeding, except records the PHD did not rely on. These records include documentation of the assessment, a single index listing all research records and evidence, the inquiry report and investigation report, and all records considered or relied on during the investigation. The institutional record also includes the Deciding Official's final decision and any information the respondent provided to the PHD. The institutional record must also include a general description of the

records that were sequestered but not considered or relied on. If the respondent filed an appeal, the complete record of any institutional appeal also becomes part of the institutional record. If an internal appeals process is initiated by the respondent(s), the PHD will wait until the appeal is concluded to transmit the institutional record to ORI. After the Deciding Official has made a final written determination, and any institutional appeal is complete, the institution must transmit the institutional record to ORI.

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 PHD 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 PHD Deciding Official.

C. Protection of the Complainant and Others

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

D. Allegations Not Made in Good Faith

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

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. Per federal regulations at 42 CFR 93, the RIO will keep the file for seven 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. The Division elects, however, to follow the Oregon State Archives Record Retention Schedule and will retain this documentation for 10 years after the research project is closed, or the research misconduct proceeding is complete, whichever is later.

XII. APPEAL AND FINAL ACTIONS

Following the receipt of the report from the investigation committee, the respondent(s) and the complainant(s) 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.

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.