

Standard Administrative Policy and Procedure

Subject: Responding to Allegations of Research Misconduct **Number:** UW SAP 9-3.6

I. PURPOSE

As a recipient of federal research funds, the University of Wyoming must have institutional policies and procedures in place to handle allegations of research misconduct.

II. POLICIES

The University of Wyoming (University) is committed to integrity in research and will address any allegation of misconduct in research through a thorough, competent, objective, and fair proceeding. These policies and procedures outline the actions to be taken when an allegation of research misconduct has been brought forward. These policies apply to all individuals paid by, under the control of, or affiliated with the University, such as scientists, affiliates, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the University, regardless of the funding source. Faculty, students, other trainees, staff, and all other members of the University of Wyoming research community are required to know and follow these policies.

III. DEFINITIONS

Allegation means a disclosure of possible research misconduct through any means of communication including but not limited to any written or oral statement or other form of communication to an institutional administrator, including department chairs, deans, the Vice President for research, the Associate Vice President for research, the Provost, or the research Integrity Officer.

Complainant is the person who in good faith makes an allegation of research misconduct.

Conflict of Interest is 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.

Deciding Official is the institutional administrator designated to make final determinations on allegations of research misconduct and any responsive institutional actions. Unless otherwise designated by the President of the University, the Vice President for Academic Affairs will serve as the deciding official. **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.

Good Faith as applied to an allegation means an allegation made with honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation. good faith as applied to a committee member means cooperating with the research misconduct proceedings by carrying out duties assigned impartially for the purpose of helping an institution meet its responsibility under this policy. A committee member does not act in good faith if her/his acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the research misconduct proceeding.

Inquiry means preliminary gathering of information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct falls within the definition of research misconduct and warrants an investigation.

Inquiry Official is an individual selected by the RIO to conduct the inquiry. The inquiry official shall not have unresolved personal, professional, or financial conflicts of interest in relation to the inquiry and should have appropriate professional expertise to evaluate the evidence and issues related to the allegation and conduct the inquiry.

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.

Notice means a written communication served in person, sent by mail or its equivalent to the last known street address, facsimile number, or email address of the addressee.

ORI is 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 PHS.

PHS means the Public Health Service, an operating component of the DHHS.

PHS Regulation means the PHS Regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR 93.

PHS Support means PHS grants, sub-grants, contracts, subcontracts, cooperative agreements, or applications under those PHS funding instruments; or salary or other payments under PHS grant, cooperative agreements, or contracts.

Preponderance of the Evidence means proof by information that, compared with that opposing it, lead to the conclusion that the fact at issue is more probably true than not.

Research Integrity Officer (RIO) is the institutional administrator responsible for assessing allegations of research misconduct, determining when such allegations warrant inquiries, and overseeing inquiries and investigations of research misconduct.

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) by establishing, discovering, developing, elucidating, or confirming information about, or the underlying mechanism relating to matters to be studied.

Research Record means the record of data or results that embody the facts resulting from scientific inquiry 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, the following: 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 and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

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

Retaliation means any action that adversely affects an individual affiliated with the University that is taken by the institution or a person affiliated with the University because the individual has, in good faith, made an allegation of research misconduct.

Research Misconduct or Misconduct in Research means fabrication, falsification, or plagiarism, in proposing, performing or reviewing research, or in reporting research results.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research Record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Finding of Research Misconduct made under this part 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 proved by a Preponderance of evidence.

University Affiliation or Affiliated with the University refers to anyone associated with the University in any capacity such as a student, faculty member, staff member, administrator, employee, visiting scholar, or visitor.

IV. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer (RIO)

The RIO has the primary responsibility for implementation of the procedures set forth in this document. The RIO will appoint committees when appropriate and ensure that necessary and proper expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will attempt to ensure that confidentiality is maintained. The RIO will limit the disclosure of the identity of the complainant and respondent to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. The RIO will assist inquiry and investigation committees and all institutional personnel (as necessary) in complying with these procedures and with applicable standards imposed by federal regulations including but not limited to 42 CFR 93 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. The RIO will report to external agencies as appropriate and ensure the matter is handled and closed with appropriate due diligence and as required, complies with federal oversight agencies.

B. Complainant

The complainant may be given an opportunity to testify during the inquiry and investigation phase, to review portions of the inquiry and investigation reports pertinent to their allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry and investigation.

C. Respondent

The RIO will provide notice to the respondent of the allegation(s) through a good faith effort in writing at the time of or before beginning an inquiry. The respondent will be notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed and present evidence during the inquiry and investigation, to review the draft inquiry and investigation reports, and to have the advice of independent outside counsel at the respondent's expense. The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is cleared of allegation(s) of research misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. General Counsel

The General Counsel for the University is responsible for ensuring the legal protection of the University in the adherence of all activities conducted per this policy. In addition, the General Counsel is responsible for reviewing the inquiry report and the investigation report for legal sufficiency.

E. Inquiry Official

The RIO may choose to conduct the inquiry directly or designate another qualified individual, referred to as the inquiry Official, to do so. The inquiry Official shall not have unresolved personal, professional, or financial conflicts of interest in relation to the inquiry and should have appropriate professional expertise to evaluate the evidence and issues related to the allegation and conduct the inquiry.

F. Inquiry Committee

When appropriate, the RIO may delegate the inquiry portion of the research misconduct process to an inquiry committee. The inquiry committee is responsible for examining the research Record for evidence in support of any alleged research misconduct; for interviewing the complainant, respondent, and other possible witnesses; and for writing a report that recommends whether or not an investigation should be conducted.

G. Investigation Committee

The investigation committee is responsible for examining the research record for evidence in support of any alleged research misconduct; for interviewing the complainant, respondent, and other possible witnesses; and for writing a report that presents and justifies its findings in regard to all allegations of research misconduct considered by the investigation committee.

H. Inquiry/Investigation Committee Chair

The Chair of either committee is selected from among the committee members, by the committee, and serves as the individual who takes the lead in drafting the committee report based on the committee's findings. Working with the RIO, the committee chair handles the compilation of comments from the other committee members into the final committee report and ensures the report is distributed to the committee members for final signatures. The elements of the committee report must be in accordance with the required elements outlined in this policy. The committee chair ensures that the respondent is afforded the opportunity to comment, that the respondent's comments are considered by the committee, and that the respondent's comments are reflected in and/or attached to the final committee report.

I. Deciding Official

The Vice President for Academic Affairs will serve as the deciding official, unless otherwise designated by the President of the University. The deciding official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The deciding official will consult with the RIO and other appropriate officials and will make final decisions based on recommendations from inquiries and investigations, determine whether research misconduct occurred, impose University sanctions, and determine whether to take other appropriate administrative actions [*see* Section VII].

V. GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct

Everyone affiliated with the University must report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may contact the RIO for a confidential informal discussion. If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other appropriate offices or officials to assist with resolving the problem.

B. Cooperation with Research Misconduct Proceedings

Everyone affiliated with the University must cooperate with the RIO, inquiry committee, investigation committee, and University Officials in the review of research misconduct allegations.

C. Confidentiality

The RIO shall, as required by 42 CFR § 93.108: (1) limit disclosure of the identities of all respondents and complainants to those who need to know in order to carry out a through, competent, objective, and fair research misconduct proceeding: and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO must discuss confidentiality and may obtain written confidentiality agreements from all individuals with whom any aspect of an allegation of research misconduct is disclosed. If the complainant to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. The RIO will attempt to honor the request during the inquiry or investigation of the allegation(s) in accordance with applicable policies and regulations and state and local laws, if any.

D. Protecting the Complainant, Witnesses, and Committee Members

The RIO will monitor the treatment of individuals who bring allegations of research misconduct and those who cooperate in inquiries or investigations. The RIO will ensure that these persons will not be retaliated against and will review instances of alleged retaliation for appropriate action. Everyone affiliated with the University is expected to immediately report any alleged or apparent retaliation to the RIO. The University will protect the privacy of those who report misconduct in good faith to the maximum extent possible.

E. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. As with the complainant, the RIO will limit the disclosure of the identity of the respondent to those who need to know, consistent with a thorough, competent, objective, and fair research misconduct proceeding. Anyone affiliated with the University accused of research misconduct may consult with independent outside legal counsel to seek advice. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided in 42 CFR 93 and this policy.

F. Interim Administrative Actions and Notifying ROI of Special Circumstances

Throughout the research misconduct proceedings, the RIO will review each allegation to determine if there is any threat of harm to public health and safety, federal funds and/or equipment, or the integrity of the PHS-supported research process. In the event of such a threat, the RIO will, in consultation with other institutional administrators and ORI, take appropriate interim action to protect against such threat. Interim action might include additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of the responsibility for the handling of federal funds and equipment, additional review of research data and results, suspension of research with animals or humans, or delaying publication. The RIO shall, at any time during a research misconduct proceeding, notify ORI immediately if they have reason to believe that any of the following conditions exist:

- 1. Health or safety of public is at risk, including an immediate need to protect human or animal subjects;
- 2. HHS resources or interests are threatened;
- **3.** Research activities should be suspended;
- 4. There is reasonable indication of possible violations of civil or criminal law;

- 5. Federal action is required to protect the interests of those involved in the research misconduct proceedings;
- 6. The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; OR
- 7. The research community or public should be informed.

VI. PRELIMINARY ASSESSMENT OF ALLEGATIONS (PRE-INQUIRY REVIEW)

Upon receiving an allegation of research misconduct, the RIO will immediately assess the allegation to determine whether there is sufficiently credible and specific evidence to warrant an inquiry, whether federal support or federal applications for funding are involved, and whether the allegation falls under the definition of research misconduct. The assessment should be completed in a timely manner. If the RIO determines that the allegations are sufficiently credible so that evidence of research misconduct may be identified and that an inquiry should be conducted, then the RIO shall, on or before the date and time the respondent is notified of the allegation, obtain custody of, inventory, and sequester research Records and evidence needed to conduct the research misconduct proceedings.

VII. CONDUCTING THE INQUIRY

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the RIO determines that the allegation provides sufficient information to allow specific follow-up and falls under the definition of research misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the RIO should identify clearly the original allegation and any additional allegations that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether research misconduct occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Notice to Respondent

On or before the date on which the inquiry begins, the RIO must make a good faith effort to notify in writing the presumed respondent of the research misconduct allegation and provide the respondent with a copy of this University policy. If the inquiry further identifies additional respondents, the RIO must notify them as well. The notification to the respondent should include:

1. The specific allegation(s);

- 2. The rights and responsibilities of the respondent;
- **3.** The purpose of the inquiry;
- 4. The role of an inquiry committee (if utilized);
- 5. A description of the inquiry process; and
- 6. Copy of the UW policy on research misconduct

The Dean and Department Chair, or equivalent in the respondent's department, are also notified in writing of the determination to convene an inquiry.

C. Sequestration of the Research Records

After determining that an allegation falls within the definition of research misconduct, the RIO must take prompt measures to ensure that all original research Records, evidence, and other materials relevant to the allegation are immediately secured and inventoried. research Records include any data, document, email, computer file, computer hard drive, or any 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. research Records include, but are not limited to: grant or contract applications whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; laboratory records, both physical and electronic; theses; abstracts; oral presentations; internal reports; manuscripts and publications; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; clinical records directly related to research; research subject files; and any documents provided to any institutional administrator by a respondent in the course of the research misconduct proceeding. Where the research Records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instrument. The RIO will provide the respondent with an inventory of items sequestered and will generally provide copies of most sequestered items within 5 business days after sequestration, although specialty copies such as gels and films may require a longer period of time to duplicate. If PHS funding is involved, the RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Official and/or Inquiry Committee

In cases where the allegations and apparent evidence are straightforward, the RIO may choose to conduct the inquiry directly or designate another qualified individual, referred to as the inquiry Official, to do so. The inquiry Official shall not have unresolved personal, professional, or financial conflicts of interest in

relation to the inquiry and should have appropriate professional expertise to evaluate the evidence and issues related to the allegation and conduct the inquiry. In complex cases, the research Integrity Officer, in consultation with other institutional administrators as appropriate, will propose an inquiry committee within 15 calendar days of the initiation of the inquiry. The inquiry committee should consist of 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 the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may include scientists, subject matter experts, or other qualified persons, and they may be from inside or outside the University. The RIO will notify the respondent of the proposed committee membership within 15 calendar days of the initiation of the inquiry. If the respondent has an objection to any of the committee members, the respondent must submit a written objection of any appointed member of the inquiry committee to the RIO, based on bias or conflict of interest within 7 calendar days. The RIO will determine whether to replace the challenged member with a qualified substitute. In cases where either the RIO or an inquiry Official conduct the inquiry process, the respondent will be informed of the person serving in that role and also be given the same opportunity to object to that posting, using the same timeline described above.

E. Charge to the Committee and the First Meeting

The RIO will prepare a charge for the inquiry Official or inquiry committee that sets forth the time for completion of the inquiry, describes the allegations and any related issues identified during the allegation assessment. The charge will state the purpose of the inquiry, which is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible. At the first meeting, the RIO will review the charge with the inquiry Official/committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry. The inquiry committee will select its chair at this first meeting. The necessity for confidentiality will be discussed, and the RIO and General Counsel will be present to answer any questions and to advise the Official/committee as needed. The date of this first meeting is the start of the 60-calendar day timetable for the completion of the inquiry process.

F. Inquiry Process

The individual(s) executing the inquiry process (the RIO, inquiry Official, or inquiry committee) will provide an opportunity to the complainant, the respondent(s), and key witnesses to be interviewed and to examine relevant research Records and materials. Evidence and testimony obtained during the inquiry will be evaluated. After consultation with the RIO and institutional counsel, the Official/committee 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 research misconduct occurred or conducting exhaustive interviews and analyses. The inquiry personnel should expect to complete its inquiry and to draft its report within 28 calendar days from its first meeting.

VIII. THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and position of the individual(s) involved with the inquiry; the allegations; the PHS (or other funding) Support, if any; a list of the research records reviewed; transcripts of interviews conducted; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and a determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended.

B. Comments on the Draft Report

The RIO will provide the General Counsel with the draft of the inquiry report to conduct a review for legal sufficiency. The General Counsel will have 7 calendar days to complete this review. The comments from the General Counsel should be incorporated into the draft inquiry report. After completion of the legal review, the RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft inquiry report or a summary of the inquiry findings that pertain to the complainant's allegations in the inquiry. These reviews will be conducted simultaneously, and the respondent and complainant will be provided to the RIO, inquiry Official, or inquiry committee to amend the report should they choose to do so. However, the comments must be appended to the report in their entirety. The inquiry report must be finalized within 7 calendar days.

C. Inquiry Decision and Notification

The RIO will transmit the final report 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 deciding official will have 7 calendar days to complete the review and make a decision whether to proceed with the investigation. The RIO will notify both the respondent and the complainant in writing of the deciding official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The RIO will also notify all appropriate University officials of the deciding official's decision.

D. Time Limit for Completing the Inquiry and the Injury Report

The inquiry is completed when the deciding official makes a determination, which will be made within 60 calendar days of the first meeting of the inquiry Official/committee, unless circumstances clearly warrant a longer period. If the RIO approves an extension, the reason for the extension and the RIO's decision to grant the extension will be entered into the records of the case and the report and federal agencies will be notified as appropriate. The respondent also will be notified of the extension.

IX. CONDUCTING THE INVESTIGATION

A. Evidentiary Standards

The burden is on the University to prove (reasonably conclude) research misconduct by a preponderance of the evidence. The destruction of, absence of, or respondent's failure to provide research Records adequately documenting the questioned research is evidence of research misconduct when the University has established by a Preponderance of the evidence that the respondent intentionally, knowingly, or recklessly destroyed research Records, failed to maintain them, or failed to produce them in a timely manner. The University must also show that the respondent's conduct constitutes significant departure from accepted practices of the relevant research community. The respondent may provide evidence of all affirmative defenses and/or any mitigating factors that are relevant to the finder of fact. The finder of fact shall give due consideration to admissible, credible evidence of honest error or differences of opinion presented by the respondent.

B. Initiation and Purpose of the Investigation

The initiation of the investigation must begin within 30 calendar days after the determination by the deciding official that an investigation is warranted. The investigation is initiated at the time of the first meeting of the investigation committee. The purpose of the investigation is to explore in detail the allegations, to examine the evidence, and to determine whether research 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 of the investigation beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public, or if it affects research that forms the basis for public policy, clinical practice, and/or public health practice. The findings of the investigation will be set forth in an investigation report.

C. Notifying ORI and respondent; Sequestration of the Research Records

If PHS funding is involved refer to Section VI of this policy. On or before the date on which the investigation begins, the RIO must make a good faith effort to notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of the decision to pursue new allegations. The RIO should also notify the complainant at this time.

The RIO, with assistance from institutional administrators, will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur 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 University's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

D. Appointment of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will propose an investigation committee within 15 calendar days of the deciding official's decision that an investigation must be conducted. 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 the allegations, interview witnesses, and conduct the investigation. These individuals may include scientists, subject matter experts, or other qualified persons, and they may be from inside or outside the University. Individuals appointed to the investigation committee may also have served on the inquiry committee. Reasonable steps will be taken to ensure an impartial and unbiased investigation to the maximum extent practicable. The RIO will notify the respondent of the proposed committee membership within 15 calendar days of the deciding official's decision that an investigation must be conducted. If the respondent has an objection to any of the committee members based on bias or conflict of interest, the respondent must submit a written objection of any committee member of the investigation committee within 7 calendar days. The RIO will determine whether to replace the challenged member with a qualified substitute.

E. Charge of the Committee and the First Meeting

The RIO will prepare a charge for the investigation committee that sets forth the time for completion of the investigation and describe the allegations and related issues identified during the inquiry. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key

witnesses and to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional allegations and/or respondents, the committee will notify the RIO, who will determine whether it is necessary to notify the respondent of the new subject matter or allegations or to provide notice to additional respondents. The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, the deciding official's decision, and this policy. The necessity for confidentiality will be discussed, and the RIO and General Counsel will be present to answer any questions and to advise the committee as needed. The investigation committee will select its chair at this first meeting. The dates of this first meeting is the start of the 120-calendar day timetable for the completion of the investigation process. This timetable is in agreement with that specified by ORI in 42 CFR 93.

F. Investigation Process

The investigation committee and the RIO must use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence considered in reaching a decision on the merits of each allegation. Also, reasonable steps should be taken to ensure an impartial and unbiased investigation to the maximum extent practical. The investigation committee will provide an opportunity to the complainant, the respondent(s), and/or any other available person who has been reasonably identified as having information regarding any relevant aspect of the investigation, including witnesses identified by the respondent, to be interviewed. The record or transcript of the witness interviews (including complainant/s and respondent/s) will be provided to each interviewee for correction. All of the interviewee records and/or transcripts will be included in the record of the investigation. Finally, the investigation committee and the RIO shall diligently pursue all significant issues and leads discovered that are determined relevant to the investigation, including evidence of any additional instances of possible research misconduct. The investigation committee should expect to complete its investigation and draft report within 77 calendar days from its first meeting.

X. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

A written investigation report must include the name and position of the committee members; the allegations; the PHS (or other funding) Support, if any; a list of the research Records reviewed; transcripts of interviews conducted; state the findings; and explain the basis for the findings. The report will include a description of any disciplinary action and administrative actions taken by the institution. If PHS funding is involved, a final report must be submitted to ORI (*See* Section VI Requirements for Reporting to ORI When PHS Funding is involved below). If work

was funded by other agencies the report shall be shared with the agency per the relevant regulation or policy.

B. Comments on the Draft Report

The RIO will provide the General Counsel with the draft of the investigation report for review for legal sufficiency. The General Counsel will have 7 calendar days to complete this review. The comments from the General Counsel should be incorporated into the draft investigation report. After completion of the legal review, the RIO will provide the respondent with a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based, for comment and rebuttal. Additionally, the RIO will provide the complainant, if he or she is identifiable, with portions of the draft investigation report or a summary of the investigation findings that pertain to the complainant's allegations in the investigation. These reviews will be conducted simultaneously, and the respondent and complainant will be provided with 30 calendar days to submit their comments, in accordance with 42 CFR § 93.312. These comments will be provided to the investigation committee to amend their report should they choose to do so. The comments must be appended to the report in their entirety. The investigation committee will have 7 calendar days from the date it receives the comments and the respondent's rebuttal, if any, to finalize its report.

C. Investigation Decision and Notification

The RIO will transmit the final report to the deciding official, who will make the determination, based on a preponderance of the evidence, of whether the findings from the investigation report are supported by sufficient evidence. The deciding official will also determine what institutional sanctions should be imposed. If this determination varies from that of the investigation committee, the deciding official will explain in detail the basis for rendering a decision different from that of the investigation committee. If PHS funding is involved, such explanation shall be included in the University of Wyoming's letter transmitting the report to ORI. The deciding official's explanation should be consistent with the definition of research misconduct as set forth in this policy, and with the evidence reviewed and analyzed by the investigation committee. The deciding official may also return the report to the investigation committee with a request for further fact-finding or analysis. The deciding official's determination, together with the investigation committee's report, as well as any comments made by the respondent or complainant on the draft investigation report, constitutes the final investigation report for purposes of ORI review (42 CFR § 93.313(g)). The deciding official will have 14 calendar days to complete her/his review and make her/his decision. When a final decision on the case has been reached, the RIO will notify both the respondent and the complainant In addition, the deciding official will determine, in addition to in writing. institutional sanctions, whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant

parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI When PHS Funding is Involved

The investigation committee should transmit the final report with attachments, including the respondent's and complainant's comments to the ORI, through the RIO. [See Section VI]

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 calendar days of its initiation. The initiation is defined as the first meeting of the investigation committee. This timeframe includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the deciding official for approval, and finalizing the report. If the investigation cannot be completed within the original 120-day time limit, an extension may be sought and approved by the RIO. If PHS funding is involved, any extension must be submitted to ORI prior to the deadline. The respondent must be notified if the investigation phase is extended.

XI. REQUIREMENTS FOR REPORTING TO ORI WHEN PHS FUNDING IS INVOLVED

A. If the ORI is involved, after the completion of an inquiry, the University will notify the ORI in writing within 30 calendar days that it has completed its inquiry. At that time, it will provide the ORI with the final inquiry report. The final inquiry report must include complete information as to the funding support involved.

The following must be provided to ORI on request:

- 1. The University's policies and procedures under which the inquiry was conducted (this policy);
- 2. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- **3.** The allegations the investigation is to consider.

If the deciding official decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request. If the inquiry committee and the deciding official determine that an investigation is warranted,

the institution must provide ORI with the written finding by the deciding official and a copy of the inquiry report within 30 days (CFR § 93.309).

If the ORI is involved, after the completion of an investigation, the University must notify the ORI within 120 days from the first meeting of the investigation committee that the investigation has been completed and must provide the ORI with a copy of the final investigation report.

- **B.** In accordance with CFR § 93.313, the University's final investigation report must be in writing and include:
 - 1. Allegations. Describe the nature of the allegations of research misconduct.
 - 2. PHS Support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
 - **3.** Institutional Charge. Describe the specific allegations of research misconduct for consideration in the investigation.
 - 4. **Policies and Procedures.** If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
 - 5. **Research Records and Evidence**. Identify and summarized the research Records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
 - 6. Statement of Findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, If the allegation(s) of research misconduct is substantiated, the following must be included:
 - **a.** Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or reckless;
 - **b.** Summarize the facts and the analysis which support the findings and consider the merits of any reasonable explanation by the respondent;
 - c. Identify the specific PHS support;
 - d. Identify whether any publications need correction or retraction;
 - e. Identify the person(s) responsible for the misconduct; and
 - **f.** List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.

- 7. **Comments.** Include and consider any comments made by the respondent and complainant on the draft investigation report.
- 8. Maintain and provide records. Maintain and provide to ORI upon request all relevant research Records and records of the University's research misconduct proceeding, including but not limited to transcripts, summary, or recordings of all witness interviews.
- **C.** If the University plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the RIO will submit a report of the planned termination to ORI, including the reasons for the proposed termination.
- **D.** If the University determines that it will not be able to complete the investigation in 120 calendar days, the RIO will submit to ORI a written request for an extension that explains the reasons for the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the RIO will file periodic progress reports as requested by the ORI.
- **E.** When PHS funding or applications for funding are involved and an admission of research misconduct is made, the RIO will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of research misconduct. When the case involves PHS support, the University cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.
- **F.** The RIO will notify ORI at any stage of the inquiry or investigation if:
 - 1. There is an immediate health hazard involved;
 - 2. There is an immediate need to protect Federal funds or equipment;
 - **3.** 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 their co-investigators and associates, if any;
 - 4. It is probable that the alleged incident is going to be reported publicly; or
 - 5. The allegation involves a public health sensitive issue, e.g., a clinical trial; or

6. There is a reasonable indication of possible criminal violation. In this instance, the University must inform ORI within 24 hours of obtaining that information.

ORI expects the University to carry inquiries and investigations to completion and to pursue diligently all allegations of research misconduct. The University must notify ORI in advance if the University plans to close a case at the inquiry or investigation, stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except the closing of a case at the inquiry stage on the basis that an investigation is not warranted or a finding of no misconduct at the investigation stage which must be reported to ORI.

XII. THE UNIVERSITY'S ADMINISTRATIVE ACTIONS

The University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated. If the deciding official determines that the alleged misconduct is substantiated by the findings, they will decide on the appropriate actions, after consulting with the RIO. The actions may include:

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

Additionally, the deciding official, after consultation with the RIO and other institutional officials, may decide on the appropriate actions for a respondent after a non-Finding of research misconduct. The deciding official may determine that the respondent engaged in detrimental research practices that, despite being unsubstantiated as research misconduct, are serious research or professional concerns and warrant remedial actions. This may include (but not limited to) all of the actions stated above in this Section.

XIII. OTHER CONSIDERATIONS

A. Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's employment with the University, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct process. 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 that the respondent did not cooperate in the process.

B. Restoration of the Respondent's Reputation

If the University finds no misconduct and, after consulting with the respondent, the RIO will undertake reasonable efforts to restore the respondent's reputation. If PHS funding is involved, the ORI must be consulted prior to any attempt made to restore the respondent's reputation. Depending on the particular circumstances, the RIO should consider notifying individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct allegation from the respondent's personnel file. Any action by the University to restore the respondent's reputation must first be approved by the deciding official.

C. Protection of the Complainant and Others

Regardless of whether the University or ORI determines that research misconduct occurred, the RIO will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the deciding official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The RIO is responsible, to the best of their ability, for 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 complainant.

D. Allegations not Made in Good Faith

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

E. Interim Administrative Actions

University 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.

XIV. 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. Unless custody has been transferred to another institution or federal agency or an agency has advised the University in writing that it no longer needs to retain the records, the Research Integrity Officer will keep the file for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation under subparts D and E of 42 CFR 93.317(a), whichever is later. ORI or other authorized DHHS personnel or federal agencies with the need to know will be given access to the records upon request.

Responsible Division/Unit: Office of Research and Economic Development Source: None Links: <u>http://www.uwyo.edu/regs-policies</u> Associated Regulations, Policies, and Forms: None Approved: 3/20/2023