# Introduction

## ISUPP 7060 Policy Overview

Pursuant to the primary mission and goals of Idaho State University are the creation and dissemination of knowledge through research and scholarship. To this end, the University is committed to fostering an environment which allows academic freedom for its faculty, students, and staff while maintaining integrity and responsible ethical conduct. The policy, **ISUPP 7060, Misconduct in Research and Scholarship**, establishes the University’s position on this subject, and the institutional responsibility to respond to any allegations of such conduct, to take steps to resolve and address such infractions of conduct, should they occur.

Accordingly, this procedure restates the policy definition of misconduct in research and scholarship, and details the processes for the inquiry into and investigation of alleged misconduct. The application of ISUPP 7060 intends to protect innocent scholars from harassment and to protect the individual(s) who report such allegations from possible retribution.

Both ISUPP 7060 and these Implementing Procedures apply to all personnel at ISU engaged in scholarship and research activities, regardless of funding source or collaborating institution. The policy applies to any institutional member paid by, under the control of, or affiliated with the institution.

## Regulatory Basis –

To ensure ISU’s continued qualification for sponsored funds from federal and state sources, this procedure and ISUPP 7060 embrace the institutional requirements first issued in the Federal Research Misconduct Policy of December 6, 2000, 65 FR 76260-76264. ISU primarily mirrors the Public Health Service’s Policies on Research Misconduct, 42 CFR Part 93, because the majority of our sponsors require compliance with this agency’s rules (HHS, PHS, NSF). The ISU policy and procedure incorporates the NSF revisions of 2002 and the PHS revisions of 2005. This guidance includes the flexibility to meet differing requirements that may arise from specific research sponsors (ex: Department of Defense).

## Scope

This policy applies only to allegations of research misconduct that occurred within six years of the date either ISU or the research sponsor (ex: Health and Human Services) received the allegation, subject to the subsequent use, health or safety of the public, and grandfather exceptions in 42 CFR § 93.105(b).

Normally, the application of the policy and the procedures detailed here follow when an allegation of possible misconduct in research is received by the Research Integrity Officer (RIO). Under some circumstances, the sponsor (ex: Department of Defense) may require variations in this procedure. Any change from the procedures must also ensure fair treatment to the subject of the inquiry or investigation. Any significant variation in process should be approved in advance by the Vice President for Research (VPR).

# Definitions

## ***Allegation*** means any written or oral statement or other indication of possible research misconduct made to an institutional official.

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

## ***Conflict of interest (COI)*** 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.

## ***Deciding Official (DO)*** means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. At ISU the Deciding Official is the Executive Vice President and Provost.

## ***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.

## ***Good faith allegation*** means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

## ***Inquiry*** means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

## ***Institutional member*** includes any person who is employed by ISU regardless of payroll classification. This also includes collaborators who may be in non-paid positions (i.e., volunteer agreements, memoranda of understanding).

## ***Investigation*** means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

## ***Misconduct*** means *Research Misconduct* as defined in this section.

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

## ***Plagiarism*** is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. This includes appropriation of ideas obtained through confidential review of others’ research proposals and manuscripts.

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

## ***PHS regulation*** means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."

## ***PHS support*** means PHS grants, contracts, or cooperative agreements or the associated applications.

## ***Research Integrity Officer (RIO)*** means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. At ISU the RIO is the Assistant Vice President for Research Outreach and Compliance.

## ***Research misconduct*** means misconduct in research and scholarship, as defined in 42 CFR Part a3:

### Fabrication or falsification of data, plagiarism, or other practices which seriously deviates from those that are commonly accepted within the academic or scientific community for proposing, conducting, implementing, or reporting research.

### Failure to comply with federal, state, or University requirements for protecting researchers, human subjects, and the public during research and for insuring the welfare of laboratory animals.

### Use of research funds, facilities, or staff for unauthorized and/or illegal activities.

## Research misconduct also includes other practices that seriously deviate from those that are commonly accepted within the scientific community for the proposing, conducting or reporting research.

## Research misconduct does not include honest error or honest differences in interpretations or judgments of data.

## ***Research Record*** means any data, document, computer file, computer diskette, 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 that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; proposal documents, budgets; 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.

## ***Research Sponsor*** means the agency or organization, if any, that sponsored the research that is the subject of an inquiry or investigation. The research sponsor can be governmental, private, or non-profit in nature. If no research agency sponsored the work, then ISU is considered the Research Sponsor.

## ***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 the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

# Rights and Responsibilities

This section defines both the responsibilities and rights of the parties normally involved in the processes instigated by an allegation of misconduct as defined in ISUPP 7060.

## Notices and Communication

A primary responsibility of all parties involved in the research misconduct review processes is to actively engage in the notification and response process set forth in this procedure.

Notices of allegations, changes to schedules and responsive comments will be issued in email format whenever manageable. Notice of findings, or final results of an investigation, shall be issued in writing on paper under the signature of the Deciding Official, routed by certified mail or a private delivery service to the last known address of the respondent.

Any party to a research misconduct proceeding who requires specific accommodations of format or seeks a paper process throughout, must notify the Research Integrity Officer (RIO) during the inquiry phase, within 5 days of the initial notice of inquiry. Requests for accommodation or paper transmission must be made in writing with an explanation of the need.

## The parties with responsibilities under this policy and procedure include:

1. Research Integrity Officer

2. Complainant

3. Respondent

4. Deciding Official

### Research Integrity Officer (RIO)

The Assistant Vice President for Research Outreach and Compliance will serve as the Research Integrity Office (RIO) for ISU, and has primary responsibility for implementation of the institution’s policies and procedures on research misconduct. A detailed listing of the responsibilities of the RIO is set forth in Appendix A to these procedures.

These responsibilities include the following duties related to research misconduct review proceedings:

#### Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;

#### Receive allegations of research misconduct;

#### Assess each allegation of research misconduct in accordance with Section V., A. of this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

#### As necessary, take interim action and notify research sponsors of special circumstances, in accordance with Section IV., F. of this policy;

#### Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with Section V., C. of this policy and maintain it securely in accordance with this policy and applicable law and regulation;

#### Provide confidentiality to those involved in the research misconduct proceeding as required by 42 CFR § 93.108, other applicable law, and institutional policy;

#### Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with Section III., C. of this policy;

#### Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;

#### Appoint the chair and members of the investigation committee, ensure that the committee is properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;

#### Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;

#### In cooperation with other institutional officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;

#### Keep the DO and others who need to know apprised of the progress of the review of the allegation of research misconduct;

#### If applicable, notify and make reports to relevant research sponsor as required by 42 CFR Part 93;

#### Ensure that administrative actions taken by ISU and other research sponsors are enforced. Take appropriate action to notify other involved parties, such as research sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and

#### Maintain records of the research misconduct proceeding and make them available to the research sponsor in accordance with Section VIII., F of this policy.

#### The RIO can delegate any of these duties to his/her designee.

### Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant should be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during any resulting investigation, and be given the transcript or copy of the recording of their interview for correction.

### Respondent

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

#### A good faith effort by the RIO to notify the respondent in writing at the time of or before beginning an inquiry;

#### An opportunity to comment on the draft inquiry report and have his/her comments attached to the report if provided within 14 days of receipt;

#### Be notified of the outcome of the inquiry, and receive a copy of the final inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the ISU’s policies and procedures on research misconduct;

#### Be notified in writing of the allegations to be investigated, within 30 days of the DO decision to begin an investigation, but before the investigation starts. Be also notified in writing of any new allegations not addressed in the initial notice of investigation, within 14 days of ISU’s determination to pursue the additional allegations.

#### Be interviewed during the investigation, have the opportunity to correct the recording or transcript of any interviews, and have the corrected recording or transcript included in the record of the research misconduct investigation;

#### Have interviewed any witness who has been reasonably identified by the respondent as having information on relevant aspects of the proceedings, with the exception that the recording or transcript be provided to the witness for correction, and the corrected recording or transcript be included in the record of investigation; and

#### Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the investigation report is based. Be notified of the option to comment within 30 days of receipt of the draft investigation report. The comments will be considered by ISU and addressed in the final investigation report.

#### Be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO and/or other institutional officials, the DO may terminate the institution’s review of an allegation, when it has been admitted, if the institution’s acceptance of the admission and any proposed settlement is approved by the research sponsor, if applicable.

### Deciding Official (DO)

The Deciding Official (DO) will receive the inquiry and investigation reports and, after consulting with the RIO, decide the extent to which ISU accepts the findings of the investigation and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. The DO shall ensure that the final investigation report, the findings of the DO and a description of any pending or completed administrative actions are provided to research sponsor, as required by 42 CFR § 93.315.

# General Policies and Principles

## Responsibility to Report Misconduct

All institutional members will 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 meet with or contact the RIO at the ISU Office for Research Outreach and Compliance to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically. 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 offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO and will be counseled about appropriate procedures for reporting allegations.

## Reporting Misconduct

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an obligation to provide evidence relevant to research misconduct allegations to the RIO, their delegates, or other institutional officials.

## Confidentiality

The RIO shall, as required by 42 CFR § 93.108:

### Limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and

### Limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding, except as otherwise prescribed by law.

### Use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

### ISU may provide confidentiality for witnesses when the circumstances indicate that the witnesses may be harassed or otherwise need protection. This will be determined by the DO.

## Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or inquiry/investigation committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

ISU will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, the institution 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. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

## Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the institution.

Respondents may consult with legal counsel or a non-lawyer personal advisor (who is not a principal or witness in the case) to seek advice and may bring the personal advisor to interviews or meetings on the case. Legal counsel will not be present at the interviews or meetings.

## Interim Administrative Actions and Notifying Research Sponsors of Special Circumstances

### Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, federal funds and equipment, or to the integrity of the research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and/or take appropriate interim action to protect against any 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 or delaying publication.

### The RIO shall, at any time during a research misconduct proceeding, notify the research sponsor immediately if he/she has reason to believe that any of the following conditions exist:

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

#### Research sponsor resources or interests are threatened;

#### Research activities should be suspended;

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

#### Federal action is required to protect the interests of those involved in the research misconduct proceeding;

#### The research misconduct proceeding may be made public prematurely and research sponsor action may be necessary to safeguard evidence and protect the rights of those involved; or

#### The research community or public should be informed.

# Conducting the Assessment and Inquiry

## Assessment of Allegations

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

The assessment period should be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

## Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation; it is not intended to reach a conclusion about whether misconduct definitely occurred or who was responsible. An inquiry does not require a full review of all the evidence related to the allegation.

## Notice to Respondent; Sequestration of Research Records

### At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if a respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

### On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

## Appointment of the Inquiry Committee

### The RIO will appoint an inquiry committee and committee chair within 10 calendar days of the initiation of the inquiry. The inquiry committee should consist of a minimum of 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 allegation, interview the principals and 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 ISU. The RIO will notify the respondent of the proposed committee membership within 10 calendar days.

### 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 5 business days, the RIO will determine whether to replace the challenged member or expert with a qualified substitute. Regardless of decision, the RIO shall notify the respondent of the inquiry committee member decision.

## Formal Instruction to the Inquiry Committee and the First Meeting

The RIO will prepare a formal instruction for the inquiry committee that:

### Describes the allegations and any related issues identified during the allegation assessment and

### States that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and by key witnesses

#### to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by the research sponsors.

#### The purpose is *not* to determine whether research misconduct definitely occurred or who was responsible.

At the committee's first meeting, the RIO will review the instructions with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the inquiry committee. The RIO and ISU counsel will be present or available throughout the inquiry to advise the committee as needed.

## Inquiry Process

The inquiry committee will normally interview the complainant and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the RIO and ISU counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. These findings will be provided to the RIO as the draft Inquiry Report per Section VI. The scope of the inquiry committee does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

## Time for Completion

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

# The Inquiry Report

## Elements of the Inquiry Report

A written inquiry report must include the following information:

### the name and position of the respondent;

### a description of the allegations of research misconduct;

### if applicable, the identification of associated funding agency support, by listing numbers for grant, grant applications, contracts and publications listing research support;

### the basis for recommending or not recommending that the allegations warrant an investigation;

### any comments on the draft report provided by the respondent or complainant.

ISU counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee. The inquiry report should include:

#### a summary of the inquiry process used;

#### a list of the research records reviewed;

#### summaries of any interviews; and

#### statement of any other actions to be taken if an investigation is not recommended.

## Comments on the Draft Inquiry Report by the Respondent and the Complainant

The RIO will provide the respondent with a copy of the draft inquiry report for comment and rebuttal. The RIO may provide the complainant, if he or she is identifiable, with those portions of the draft inquiry report (or with a summary of the inquiry findings for comment instead of portions of the draft report) that address the complainant’s role in the inquiry.

### Confidentiality:

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

### Receipt of Comments on Draft Inquiry Report:

The complainant and respondent may provide their comments on the draft inquiry report, if any, within 14 business days of their receipt of the draft report. Their responses should be submitted to the RIO. The RIO will provide the comments, if any are received, to the inquiry committee. Any comments received within this time limit will become part of the final inquiry report and record, maintained by the RIO. The inquiry committee may revise the report in response to comments, as appropriate.

## Institutional Decision and Notification

### Decision by Deciding Official:

The RIO will transmit the final report and any comments to the DO no later than 50 days from the start of the inquiry, providing 10 days for DO consideration. The DO will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry stage is complete when the DO expresses this determination, in writing, to the RIO. The DO determination shall be made within 60 calendar days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

### Notification:

The RIO will notify both the respondent and the complainant in writing of the DO'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 institutional officials and research sponsors of the DO's decision.

### Documentation of Decision Not to Investigate:

If the DO 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 research sponsor of those reasons why an investigation was not conducted. These documents must be provided to research sponsor personnel upon request.

## Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the RIO no more than 60 calendar days following its first meeting, unless the RIO approves an extension for good cause. If the RIO approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

# Conducting the Investigation

## Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent.

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

## Notifying Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must:

### If appropriate, notify the director of the research funding source of the decision to begin the investigation and provide them a copy of the inquiry report; and

### Obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry, while maintaining those records and evidence from the inquiry process. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry. Neither the respondent nor other parties to the allegations should be notified of the intent to investigate until records are sequestered.

### Notify the respondent in writing of the allegations to be investigated.

## Appointment of the Investigation Committee

An investigation committee will be appointed by the RIO after consulting with the VPR as soon after the beginning of the investigation as is practical, within 14 days

The investigation committee must consist of at least three individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from ISU or outside the institution.

Individuals appointed to the investigation committee may also have served on the inquiry committee. The RIO will notify the respondent of the proposed committee membership within five (5) business days.

The respondent may submit a written objection within 5 days of receipt of committee member list. They may submit their objection to the RIO. The RIO will determine whether to replace the challenged member or expert with a qualified substitute and will notify the respondent of the decision

## Formal Instructions to the Committee and the First Meeting

### Instructing the Committee

The RIO will define the subject matter of the investigation in a written instructions to the committee that:

#### Describe the allegations and related issues identified during the inquiry;

#### Identifies the respondent;

#### Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;

#### Defines research misconduct;

#### Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;

#### Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that:

##### research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion);

##### the research misconduct is a significant departure from accepted practices of the relevant research community; and

##### the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

#### Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and 42 CFR § 93.313.

### First Meeting

The RIO, with the assistance of ISU counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of the investigation instructions and, where research sponsor funding is involved, that sponsor’s regulation. The RIO will be present or available throughout the investigation to advise the committee as needed.

## 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 relevant to reaching a decision on the merits of each allegation;

### Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

### Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant

#### aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to

#### the interviewee for correction, and include the recording or transcript in the record of the investigation; and

### Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

## Time for Completion

The investigation is to be completed within 120 days of its start, including: conducting the investigation, preparing the report of findings, providing the draft report for comment to the RIO, the DO decision-making, with routing the final report to a research sponsor, if applicable. If the RIO determines that the investigation will not be completed within this 120-day period, he/she will notify the respondent, the complainant and the DO. The RIO will also notify any research sponsor as necessary.

# The Investigation Report

## Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

### Describes the nature of the allegation of research misconduct, including identification of the respondent;

### If applicable, describes and documents the research sponsor support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing research sponsor support;

### Describes the specific allegations of research misconduct considered in the investigation;

### Includes the institutional policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;

### Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and

### Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings must:

### Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;

#### summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;

#### identify the specific research sponsor 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 federal agencies.

## Comments on the Draft Report and Access to Evidence

### Respondent

The RIO must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit written comments to the RIO. The respondent's comments must be included and considered in the final report.

### Complainant

The RIO may provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The complainant will be allowed up to the same deadline as the respondent to provide written comments. The report should be modified, as appropriate, based on the complainant's comments.

### ISU General Counsel

The draft investigation report will be transmitted to ISU counsel for a review of its legal sufficiency and allowed 30 days to comment. Counsel’s Comments should be incorporated into the report as appropriate. Should either respondent or complainant provide comments on the draft investigation report, these should also be provided to Counsel for consideration, with time for review agreed to upon receipt by Counsel. Additional comments on the report may be a consideration in the overall timeline of the conclusion of the investigation.

### Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the RIO may require that the recipient sign a confidentiality agreement.

### RIO and Finalizing the Draft Investigation Report

### The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent’s and complainant’s comments are included and considered, with any observations by other officials. The RIO will transmit the final investigation report to the DO for decision-making.

## Decision by Deciding Official

The DO will receive the draft investigation report from the RIO and considering its findings, will determine, or state, in writing:

### whether ISU accepts the investigation report, its findings, and the recommended institutional actions; and

### the appropriate institutional actions in response to the accepted findings of research misconduct.

### If the DO’s determination varies from the findings of the investigation committee, the DO’s written determination will explain in detail the basis for rendering a decision different from the findings of the investigation committee;

### OR,

### the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

After any research sponsor has been informed of the final decision, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the investigation.

## Notice to ORI of Institutional Findings and Actions (if applicable)

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to ORI or other research sponsor:

### A copy of the final investigation report with all attachments;

### A statement of whether the institution accepts the findings of the investigation report;

### A statement of whether the institution found misconduct and, if so, who committed the misconduct; and

### A description of any pending or completed administrative actions against the respondent.

## Maintaining Records

The RIO must maintain and provide to research sponsor upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Records all of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any research sponsor-specific proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by the research sponsor to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.

# Completion of Cases; Reporting Premature Closures to ORI (if applicable)

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI or other research sponsor in advance if there are plans to close a case at the inquiry, or investigation stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except:

### 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 or other research sponsor, as prescribed in this policy and 42 CFR § 93.315.

# Institutional Administrative Actions [Optional]

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

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

## Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

## Restitution of funds to the grantor agency as appropriate; and

## Other action appropriate to the research misconduct.

# Other Considerations

## Termination or Resignation Prior to Completing Inquiry or Investigation

### The termination of the respondent's institutional employment, by resigning or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution’s responsibilities under 42 CFR Part 93.

### If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps.

### If the respondent refuses to participate in the process after resignation, the RIO and any investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

## Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, including appropriate research sponsor concurrence where required by 42 CFR Part 93, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation

### of the final outcome,

### publicize the final outcome in any forum in which the allegation of research misconduct was previously publicized, and

### expunge all reference to the research misconduct allegation from the respondent's personnel file.

Any institutional actions to restore the respondent's reputation should first be approved by the DO.

## Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion,

regardless of whether the institution, ORI or other research sponsor determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO will determine, after consulting with the RIO, and with the complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them. The RIO is responsible for implementing any steps the DO approves. The RIO will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

## Allegations Not Made in Good Faith

If relevant, the DO will determine whether the complainant’s allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the DO determines that there was an absence of good faith, he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

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