

UNIVERSITY OF SAN FRANCISCO

POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

I. Introduction

A. General Policy

In accordance with its Vision, Mission and Values, the University of San Francisco expects students, faculty and staff to adhere to the strongest levels of scientific integrity while conducting research and to responsibly carry out all types of scholarly activities.

The University of San Francisco takes the strongest possible position on preventing misconduct in research and in supporting good faith complainants. All reports or concerns received will be investigated thoroughly according to this document with every effort being taken to protect the person(s) filing the report as well as others involved in the process.

B. Scope

This statement of policy and procedures apply to all individuals at the University of San Francisco (USF) engaged in research or scholarly activities and is intended to carry out USF's responsibilities under the Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93. This document applies to allegations of research misconduct (fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results) by any person who at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at the University of San Francisco.

This policy also encompasses (1) biomedical or behavioral research, research training or activities related to that research or research training that are supported by or for which support is requested from PHS; (2) applications or proposals for biomedical or behavioral research, research training or activities related to that research or research training; (3) plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training. This includes any research proposed, performed, reviewed, or reported, or any research record generated from that research, regardless of whether an application or proposal for PHS funds resulted in a grant, contract, cooperative agreement, or other form of PHS support.

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

This document may also be used by the University of San Francisco when an allegation of misconduct or irresponsible conduct of research has been made against a student, faculty or staff member. Misconduct or irresponsible conduct of research includes but is not limited to fabrication, falsification or plagiarism, inappropriate or insufficient protection of human subjects or of animals used in research, conflict of interest in all facets of scholarly activities, personal and financial misconduct and inappropriate research practices.

II. Definitions

Terms used in the Policy and Procedures statement have the same meaning as given them in the Public Health Service Policies on Research Misconduct, 42 CFR Part 93 and those definitions take precedence in any discrepancies with those definitions included in this statement.

- A. *Allegation* means any written or oral statement or other indication of possible research misconduct made to an institutional official.
- B. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- C. *Deciding Official (DO)* means the institutional official who makes final determinations on allegations of research misconduct and any institutional administrative actions. The DO 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. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement. The Provost shall serve as the DO unless she or he is unable to serve according to this definition.
- D. *Evidence* means any document, tangible item, or testimony offered or obtained during a research misconduct proceedings that tends to prove or disprove the existence of an alleged fact.
- E. *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.

- F. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.
- G. *Institutional member* means a person who is employed by, is an agent of, or is affiliated by contract or agreement with an institution. Institutional members may include, but are not limited to officials, tenured and untenured faculty, teaching and support staff, researchers, research coordinators, clinical technicians, postdoctoral and other fellows, students, volunteers, agents, and contractors, subcontractors, and sub-awardees, and their employees.
- H. *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.
- I. *ORI* means the Office of Research Integrity, the office to which the Health and Human Services (DHHS) Secretary has delegated responsibility for addressing research integrity and misconduct issues related to activities supported by the U.S. Public Health Service.
- J. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.
- K. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 93.
- L. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefore.
- M. *Research Integrity Officer (RIO)* means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; and (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. The Vice Provost will serve as the RIO unless she or he is unable to serve according to the provisions of this document including the possibility of real or perceived conflict of interest or being the subject of the allegation.

- N. *Research record* means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.
- O. *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.
- P. *Retaliation* means an adverse action taken against a complainant, witness, or committee member by this institution or one of its institutional members in response to (1) a good faith allegation of research misconduct; or (2) good faith cooperation with a research misconduct proceeding.
- Q. *Research misconduct* 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. Research misconduct does not include honest error or differences of opinion.
- R. *Whistleblower or complainant* means a person who makes an allegation of research misconduct.

III. Rights and Responsibilities

A. Research Integrity Officer

The Vice Provost will serve as the Research Integrity Officer who will have primary responsibility for implementation of the procedures and policies set forth in this document. The Research Integrity Officer is an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of research misconduct, those who make good faith allegations of research misconduct, and those who may serve on inquiry and investigation committees.

A detailed list of the responsibilities of the Research Integrity Officer is available from the Provost Office. These responsibilities include the following duties

related to research misconduct 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 this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;
- As necessary, take interim action and notify ORI of special circumstances, in accordance with this policy;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with 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 this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, ensure that those committees are 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 Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42 CFR Part 93;
- Ensure that administrative actions taken by the institution and ORI are enforced and take appropriate action to notify other involved parties, such as 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 ORI in accordance with this policy.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or 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 an investigation, and be given a transcript or recording of the interview for correction.

C. Respondent

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

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;
- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that included a copy of, or refers to 42 CFR Part 93 and the institution's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the institution decides to begin an investigation), and be notified in writing of any new allegations, not addressed in the inquiry or in the initial notice of investigation, within a reasonable time after the determination to pursue those allegations;
- Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of the investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the institution and addressed in the final report.

The respondent should be given the opportunity to admit that research misconduct occurred and that she or he committed the research misconduct. With the advice of the RIO and institutional legal counsel, the Deciding Official may terminate the institution's review of an allegation that has been admitted. In cases where allegations are admitted that involve PHS grants, contracts, cooperative agreements or proposals, the DO may terminate the procedures if it is approved by ORI.

D. Deciding Official

The Provost will serve as the Deciding Official. She or he will receive the inquiry and after consulting with the RIO and/or other institutional officials, decide whether an investigation is warranted under the criteria in 42 CFR § 93.307(d). Any finding that an investigation is warranted must be made in writing by the DO and must be provided to ORI, together with a copy of the inquiry report meeting the requirements of 42 CFR § 93.309, within 30 days of the finding. If it is found that an investigation is not warranted, the DO and the RIO will ensure that detailed documentation of the inquiry is retained for at least seven (7) years after termination of the inquiry, so that ORI may assess the reasons why the institution decided not to conduct an investigation.

The DO will receive the investigation report and, after consulting with the RIO and/or other institutional officials, decide the extent to which this institution 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 ORI, as required by 42 CFR § 93.315.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members or individuals associated with the University of San Francisco will report observed, suspected, or apparent research misconduct to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Research Integrity Officer at (415) 422-6136 to discuss the suspected 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 Research Integrity Officer 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 Research Integrity Officer or their executive officer (i.e., vice president or dean) and will be counseled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

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 or other institutional officials.

C. Confidentiality

The RIO shall, as required by 42 CFR §93.108: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects may be identified to those who need to know in order to carry out a research misconduct proceeding. The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make further disclosure of identifying information.

D. Protecting the complainants, witnesses and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or 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.

E. 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 notices and opportunities provided for in 42 CFR Par

93 and the policies and procedures of USF. Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. If counsel is brought to interviews or meetings, the role of the lawyer is limited to advising (as opposed to representing) the respondent.

F. Interim administrative actions

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 the integrity of the PHS supported research process. In the event of such a threat, the RIO will, in consultation with other institutional officials and ORI, take appropriate interim action to protect against any such threat. 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 ORI immediately if he/she has reason to believe that any of the follow conditions exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS 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 HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. 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 is within the jurisdictional criteria of 42 CFR § 93.102(b), and whether the allegation falls within the definition of research misconduct in this policy and 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. The RIO shall, on or before the date on which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in this document.

B. 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. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of the 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 the 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. The RIO may consult with ORI for advice and assistance in this regard.

D. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within ten (10) days of the initiation of the inquiry or as soon thereafter as practical. The inquiry committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and should include individuals with the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

The Research Integrity Officer will notify the respondent of the proposed committee membership within ten (10) days of the establishment of the committee. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within five (5) days of notification, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

E. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- States that an investigation is warranted if the committee determines: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct and is within the jurisdictional criteria of 42 CFR § 93.102(b); and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy and 42 CFR § 93.309(a).

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

F. Inquiry Process

The inquiry committee will normally interview the complainant, the respondent, and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage.

G. 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 and extension, the inquiry record must include documentation of the reason for exceeding the 60-day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the PHS support (if any) including for example, grant numbers, grant applications, contracts and publications listing PHS support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant. Institutional counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

C. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within ten (10) days, and include a copy of or refer to 42 CFR Part 93 and the institution's policies and procedures on research misconduct.

C. Institutional Decision and Notification

1. Decision by Deciding Official

The Research Integrity Officer will transmit the final inquiry report and any comments to the Deciding Official, who will make the determination in writing of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination.

2. Notification

The Research Integrity Officer 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 Research Integrity Officer will also notify all appropriate institutional officials and ORI of the Deciding Official's decision.

3. 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 ORI of the reasons why an investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

VII. Conducting the Investigation

A. 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 misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. Under 42 CFR § 93.313 the findings of the investigation must be set forth in an investigation report.

B. Notifying ORI and Respondent; Sequestration of the Research Records

On or before the date on which the investigation begins, the RIO must: (1) notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report; and (2) 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 deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The Research Integrity Officer will prior to notifying respondent of the allegations, take all reasonable and practical steps to 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. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within ten (10) days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee must consist of individuals who do not have real or apparent 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 principals and key witnesses, and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the respondent of the proposed

committee membership within five (5) days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that

- Describes the allegations and related issues identified during the inquiry;
- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed in this document;
- 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: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving 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); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; 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.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional 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 these instructions and, where PHS funding is involved, the PHS regulation.

E. 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.

F. Time for completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to ORI a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VIII. The Investigation Report

A. 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;
- Describes and documents the PHS support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and

- publications listing PHS 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: (1) identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific PHS support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-PHS federal agencies.

C. Comments on the Draft Report and Access to Evidence

1. Respondent

The Research Integrity Officer 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. The respondent will be allowed thirty (30) days to review and comment on the draft report. The respondent's comments will be included and considered in the final report.

2. Complainant

The Research Integrity Officer will 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 must provide comments to the RIO within thirty (30) days of the date in which the draft report is received by her/him.

3. Institutional Counsel

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

4. Confidentiality

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

C. Decision by Deciding Official

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, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and (2) the appropriate institutional actions in response to the accepted findings of research misconduct. If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for the further fact-finding or analysis.

When a final decision on the case has been reached, the Research Integrity Officer will normally notify both the respondent and the complainant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI

In cases involving allegations of research misconduct involving current or potential PHS funding, the Research Integrity Officer shall submit within 120 days a final report with attachments, including the respondent's and complainant's comments, the Deciding Official's explanation (if this determination differs from the recommendations of the investigative report) to the ORI.

E. Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. Unless custody has been transferred to HHS or ORI has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding or the completion of any PHS proceeding involving the research misconduct allegation. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or the institution’s handling of such an allegation.

IX. Completion of Cases; Reporting Closure to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify ORI in advance if there are plans to close a case at the inquiry 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 (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

X. Institutional Administrative Actions

The University of San Francisco 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, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The 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 or 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 as appropriate, and
- Other action appropriate to the research misconduct.

XI. Other Considerations

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

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

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

B. Restoration of the Respondent's Reputation

If the institution finds no research misconduct, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. ORI must concur with this decision in cases involving allegations of research misconduct involving current or potential PHS funding. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others

During the research misconduct proceedings and upon its completion, regardless of whether the institution or ORI 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 in good faith and of any witnesses and committee member 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.

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

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

XII. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven (7) years after completion of the case to permit later assessment of the case. ORI or other authorized PHS personnel will be given access to the records upon request in cases involving allegations of research misconduct involving current or potential PHS funding.

NOTE: This document is based on and incorporates much of the wording of the "Sample Policy and Procedures" developed by the Office of Research Integrity, DHHS.