POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF MISCONDUCT IN RESEARCH, SCHOLARLY, AND CREATIVE ACTIVITIES

(This policy supersedes PS 91-02)

This policy statement was recommended by the Academic Senate in its meeting December 5, 2015, and approved by the President on February 1, 2016.

1.0 PURPOSE

1.1 Statement of Values. California State University, Long Beach (University) is committed to ethical principles and procedures upholding integrity in all forms of research, scholarly, and creative activity. Engagement in both sponsored and non-sponsored research activities shall be conducted with the highest level of integrity and intellectual honesty. Members of the University community engaged in funded research shall act responsibly with respect to the use of funds and ensure that all persons associated with the funded research for which the University is responsible comply with all policies of the University, CSU, and funding agencies and all applicable laws.

Members of the University community engaged in research, scholarly and creative activities shall not: fabricate data or results; change or knowingly omit data or results to misrepresent results in the research record; or intentionally misappropriate the ideas, writings, research, or findings of others. All those engaged in research shall pursue the advancement of knowledge while meeting the highest standards of honesty, accuracy, and objectivity in their work in general and as authors. This standard applies to all publications. Those engaged in research are also expected to demonstrate accountability for sponsors' funds and to comply with specific terms and conditions of contracts and grants.

Complainants shall act in good faith.

1.2 Legal Framework. This policy and the procedures therein are intended to conform to the requirements of the United States Department of Health and Human Services (HHS), the U.S. Public Health Service (PHS), the National Science Foundation (NSF), and federal regulations including, but not limited to, the "Public Health Service Policies on Research Misconduct" [42 Code of Federal Regulations (CFR) 93] and the policies of the National Science Foundation [45 CFR, Part 689], and thus are referenced where applicable.

2.0 SCOPE

This policy applies to: research conducted under an externally funded sponsored project that is awarded to the University or University Research Foundation; internally funded research; and unfunded research conducted by faculty, staff, or students working under the supervision of faculty and/or staff. Any individual working on or contributing to such a project, whether for monetary compensation or not, is covered by this policy.

The scope of this policy includes any research proposed, performed, reviewed or reported, or any research record generated from that research, regardless of whether an application or proposal for external or internal funds resulted in an award. The scope of this policy does not extend to authorship or collaboration disputes. It applies only to Allegations of Research Misconduct occurring within six (6) years of the date the University or the sponsor received the Allegation, subject to the subsequent use, health and safety of the public, and grandfather exceptions in 42 CFR 93.105(b).

3.0 DEFINITIONS

Allegation: A disclosure of possible Research Misconduct through any means of communication. The disclosure may be by written or oral statement or other communications to the University, University Research Foundation, or HHS official.

Complainant: A person who in good faith makes an Allegation of Research Misconduct.

Conflict of Interest: The actual or apparent interference of one person's interests with the interests of another person or entity, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official (DO): The person responsible for making the final decision regarding allegations of Research Misconduct. The Deciding Official will be the Provost and Senior Vice President of Academic Affairs or designee and should have no direct prior involvement in the University's Inquiry, Investigation, or Allegation assessment. A Deciding Official's appointment of an individual to assess Allegations of Research Misconduct, or to serve on an Inquiry or Investigation Committee, shall not be considered direct prior involvement.

Evidence: Any document, tangible item, or testimony offered or obtained during a Research Misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

Fabrication: Making up data or results and recording or reporting them.

Falsification: 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 as applied to a Complainant or witness: Having a belief in the truth of one's Allegation or testimony that a reasonable person in the Complainant's or witness's position could have, based on the information known to the Complainant or witness at the time. An Allegation or cooperation with a Research Misconduct proceeding is not in good faith if it is made with knowing or reckless disregard for information that would negate the Allegation or testimony. Good faith as applied to a committee member means cooperating with the purpose of helping the University meet its responsibilities under any applicable federal regulations and this policy. A committee member does not act in good faith if his/her acts or omissions on the committee are dishonest or influenced by personal, professional, or financial conflicts of interest with those involved in the Research Misconduct proceedings.

Inquiry: Preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures set forth in federal regulations.

Investigation: The formal development of a factual record and the examination of that record leading to a decision to make no finding of Research Misconduct or to a recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions, including administrative actions.

Office of Research Integrity (ORI): The federal office to which the HHS Secretary has delegated responsibility for addressing research integrity and misconduct issues related to PHS supported activities.

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

Preponderance of the evidence: Proof by information which, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

Research: A systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) relating broadly to a particular discipline or subject by establishing, discovering, developing, elucidating or confirming information about the discipline or subject of the research.

Research Integrity Officer (RIO): The RIO is responsible for: (1) assessing Allegations of Research Misconduct to determine if they fall within the definition of Research Misconduct, are covered by federal regulations, 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; (2) overseeing Inquiries and Investigations and (3) the other responsibilities described in this policy. The RIO is the Associate Vice President for Research and Sponsored Programs or his/her designee.

Research Misconduct: Fabrication, falsification, plagiarism or other practices in the conduct of research, scholarly, or creative activity that seriously deviate from those that are commonly accepted within the academic community for proposing, performing, or reviewing research, or in reporting research results. Misconduct in research does not include honest error or differences of opinion.

Research record: 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 a federal agency or University official by a Respondent(s) in the course of the Research Misconduct proceeding.

Respondent(s): The person against whom an Allegation of Research Misconduct is directed or who is the subject of a Research Misconduct proceeding. There can be more than one Respondent in any Inquiry or Investigation.

Retaliation: An adverse action taken against a Complainant or witness in response to (1) a good faith Allegation of Research Misconduct; or (2) good faith cooperation with a Research Misconduct proceeding.

4.0 RIGHTS AND RESPONSIBILITIES

4.1 Research Integrity Officer (RIO)

The Associate Vice President for Research and Sponsored Programs shall serve as the RIO and have primary responsibility for implementation of this policy. The RIO may appoint the Director of Research Integrity and Compliance as the designee for all RIO responsibilities. The RIO's responsibilities include the following duties related to Research Misconduct proceedings:

4.1.1 Consult confidentially with persons uncertain about whether to submit an Allegation of Research Misconduct;

4.1.2 Receive Allegations of Research Misconduct either in writing or orally;

4.1.3 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;

4.1.4 As necessary, take interim action and notify ORI of special circumstances, in accordance with this policy;

4.1.5 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 laws and regulations;

4.1.6 Provide confidentiality to those involved in the Research Misconduct proceeding as required by 42 CFR 93.108, other applicable law, and institutional policy;

4.1.7 Notify the Respondent(s) and provide opportunities for him/her to review/ comment/respond to Allegations, evidence, and committee reports in accordance with this policy;

4.1.8 Inform Respondent(s), Complainants, and witnesses of the procedural steps in the Research Misconduct proceeding;

4.1.9 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;

4.1.10 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;

4.1.11 Keep the DO and others who need to know apprised of the progress of the review of the Allegation of Research Misconduct;

4.1.12 Notify and make reports to ORI as required by 42 CFR Part 93 or any other relevant federal regulations and/or notify and make reports to the appropriate regulatory agency or sponsors as required by regulations and this policy;

4.1.13 Ensure that administrative actions taken by the University 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

4.1.14 Maintain records of the Research Misconduct proceeding and make them available to ORI in accordance with this policy.

4.2 Complainant

The Complainant is responsible for making Allegations in good faith 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 typed notes, or recording of the interview for correction. The Complainant must be interviewed during an Investigation, and be given the typed notes or recordings of the interview for correction.

4.3 Respondent(s)

The Respondent(s) is responsible for cooperating with the conduct of an Inquiry and Investigation. The Respondent(s) should be given the opportunity to admit that Research Misconduct occurred and that he/she committed the Research Misconduct. Upon receipt of an admission, the RIO may notify the DO and/or other appropriate institutional officials. The DO may terminate the institution's review of an Allegation that has been admitted if the University's acceptance of the admission and any proposed settlement is approved by ORI.

The Respondent(s) is entitled to:

4.3.1 A good faith effort from the RIO to notify the Respondent(s) in writing at the time of or before beginning an Inquiry;

4.3.2 Be notified of the outcome of the Inquiry, and receive a copy of the Inquiry report that includes a copy of, or refers to 42 CFR Part 93 and the institution's policies and procedures on Research Misconduct; an opportunity to comment on the Inquiry report and have his/her comments attached to the report;

4.3.3 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 University 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;

4.3.4 Be interviewed during the Investigation, have the opportunity to correct the typed notes or recordings, and have the corrections included in the record of the investigation;

4.3.5 Submit to the committee a list of persons who may have relevant information and request that they be interviewed during the Investigation; have the typed notes or recording provided to the witness for correction, and have the corrections included in the record of Investigation; and

4.3.6 Receive a copy of the preliminary 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 University and addressed in the final report.

4.4 Deciding Official (DO)

The Provost and Senior Vice President of Academic Affairs at California State University, Long Beach or designee serve as the DO. The DO will receive the Inquiry report 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) where applicable]. Any finding that an Investigation is warranted must be made in writing by the DO and must be provided to ORI where applicable or the appropriate regulatory agency, together with a copy of the Inquiry report meeting the requirements of 42 CFR 93.309 where applicable, within 30 days of the receipt of the report by

the DO. 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 or the appropriate regulatory agency 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 where applicable or the appropriate regulatory agency.

5.0 GENERAL POLICIES AND PROCEDURES

5.1 Responsibility to Report Misconduct

All University members shall 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/she may meet with or contact the RIO 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 may refer the individual or Allegation to other appropriate offices.

5.2 Cooperation with Research Misconduct Proceedings

University employees shall cooperate with the RIO and other University officials in the review of Allegations and the conduct of Inquiries and Investigations. University employees have an obligation to provide evidence relevant to Research Misconduct Allegations to the RIO or other University officials.

5.3 Confidentiality

The RIO shall (1) limit disclosure of the identity of the Respondent(s), Complainants and witnesses to those who need to know in order to carry out a thorough, competent, objective and fair Research Misconduct Investigation consistent with applicable laws and regulations; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a Research Misconduct Investigation.

5.4 Protecting Complainants, Witnesses, and Committee Members

University employees may not retaliate in any way against Complainants, witnesses, or committee members. University employees should immediately report any allegations of retaliation against Complainants, witnesses or committee members to the RIO, who shall review the matter and take appropriate corrective action.
http://www.calstate.edu/eo/EO-929.html
http://daf.csulb.edu/offices/univ_svcs/internalauditing/whistleblower.html
http://www.foundation.csulb.edu/policies/index.htm

5.5 Protecting the Respondent(s)

As requested and as appropriate, the RIO shall make 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 Respondent(s) receive all the notices and opportunities provided for in federal regulations or the policies and procedures of the University.

5.6 Interim Administrative Actions and Notifying ORI 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 or other sponsor funds and equipment, or the integrity of the PHS or other sponsor supported research process. In the event of such a threat, the RIO will, in consultation with the Provost and ORI or other appropriate regulatory agencies and/or sponsor, 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/sponsor funds and equipment, reassignment of personnel or of the responsibility for the handling of federal/sponsor funds and equipment, additional review of research data and results or delaying of publication. The RIO shall, at any time during a Research Misconduct proceeding, notify ORI or any other appropriate regulatory agency and/or other sponsor immediately if he/she has reason to believe that any of the following conditions exist:

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

5.6.2 HHS or other sponsor resources or interests are threatened;

5.6.3 Research activities should be suspended;

5.6.4 There is a reasonable indication of possible violations of applicable law or regulations;

5.6.5 Federal action is required to protect the interests of those involved in the Research Misconduct Investigation;

5.6.6 The Research Misconduct Investigation findings may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or

5.6.7 The research community or public should be informed.

5.7 Appeals

Respondent(s) have a right to appeal the decision. The appeal shall be in writing and should include a detailed statement of any disputed facts and any new defenses to the Allegations. Any additional relevant information may also be included in the appeal.

6.0 CONDUCTING THE ASSESSMENT AND INQUIRY

6.1 Assessment of Allegations

Upon receiving an Allegation of Research Misconduct, the RIO shall assess the Allegation to determine: whether it is sufficiently credible and sufficiently specific, so that potential evidence of Research Misconduct may be identified; whether it is within the jurisdictional criteria of federal agencies; and whether the Allegation if proven would constitute Research Misconduct as defined in this policy and any applicable federal regulations. An Inquiry must be conducted if these criteria are met.

The assessment period should be brief. In conducting the assessment, the RIO need not interview the Complainant, Respondent(s), or other witnesses, or gather data beyond that 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 that the Respondent(s) 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 the Notice to Respondent(s); Sequestration of Research Records section below.

6.2 Initiation of Purpose of Inquiry

If the RIO determines that the criteria for an Inquiry are met, the RIO shall initiate the Inquiry. 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.

6.3 Notice to Respondent(s); Sequestration of Research Records

Upon or before commencement of an Inquiry, the RIO must notify the Respondent by means of a written charge letter (45 CFR 93.202) that will contain, but is not limited to, a written copy or summary of the allegation, and shall make available a copy of this policy. 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 shall take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the Research Misconduct Inquiry, inventory the records and evidence and sequester them in a secure manner, except 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 the appropriate regulatory agency for advice and assistance in this regard.

6.4 Appointment of Inquiry Committee

The RIO, 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 appropriate scientific expertise to evaluate the evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Inquiry.

6.5 Charge to the Committee and First Meeting

6.5.1 The RIO will prepare a charge for the Inquiry committee that:

6.5.1.1 Sets forth the time for completion of the Inquiry;

6.5.1.2 Describes the Allegations and any related issues identified during the Allegation assessment;

6.5.1.3 States that the purpose of the Inquiry is to conduct an initial review of the evidence, including the testimony of the Respondent(s), Complainant and key witnesses, to provide information to the RIO who will communicate to the DO whether an Investigation is warranted, not to determine whether Research Misconduct definitely occurred or who was responsible;

6.5.1.4 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 the appropriate federal code where applicable; and, (2) the Allegation may have substance, based on the committee's review during the Inquiry.

6.5.1.5 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.

6.5.2 At the committee's first meeting, the RIO 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 RIO shall be present or available throughout the Inquiry to advise the committee as needed.

6.6 Inquiry Process

The Inquiry committee shall normally interview the Complainant, the Respondent(s) and key witnesses as well as examine relevant research records and materials. The Inquiry committee shall evaluate the evidence, including the testimony obtained during the Inquiry. After consultation with the RIO, the committee will decide whether an Investigation is warranted based on the criteria in this policy and in any applicable federal or other applicable regulations (42 CFR 93.307(d)). The scope of the Inquiry is not required to and does not normally 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(s), misconduct may be

determined at the Inquiry stage if all relevant issues are resolved. In that case, the University shall promptly consult with the ORI or appropriate federal regulatory agency to determine the next steps that should be taken. If a non-federal sponsor is involved without federal funds, the RIO will consult with appropriate University officials to determine the next steps.

6.7 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(s) and all witnesses shall cooperate by timely response to request for documents and/or information from the Inquiry committee.

7.0 INQUIRY REPORT

7.1 Elements of the Inquiry Report

A written Inquiry report shall be prepared that includes the following information: (1) the name and position of the Respondent(s); (2) a description of the Allegations of Research Misconduct; (3) the funding support, if any (incl. grant numbers, grant applications, contracts and publications listing specific financial support); (4) the names and titles of the committee members who conducted the Inquiry; (5) a summary of the Inquiry process used; (6) a list of research records reviewed; (7) summaries of any interviews; (8) the basis for recommending or not recommending that the Allegations warrant an Investigation; (9) any comments on the draft report by the Respondent(s) or Complainant and (10) whether any actions should be taken if an Investigation is not recommended. University counsel should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the Inquiry committee.

7.2 Notification to the Respondent(s) and Opportunity to Comment

The RIO shall notify the Respondent(s) whether the Inquiry found an Investigation to be warranted, include a copy of the draft Inquiry report for comment within 10 working days, and include a copy of or refer to the applicable federal or other appropriate regulations and this policy.

Any comments that are submitted will be attached to the final Inquiry report. Based on the comments, the Inquiry committee may revise the draft report as appropriate and prepare it in final form. The committee will deliver the final report to the RIO.

7.3 Decision by Deciding Official

The RIO will transmit the final Inquiry report and any comments to the DO, who will determine in writing whether an Investigation is warranted. The Inquiry is completed when the DO makes this determination.

7.4 Notification to ORI

If it is decided by the DO that an Investigation is warranted, the RIO will provide ORI (or other appropriate regulatory agency and/or sponsor, if any) with the DO's written decision and a copy of the Inquiry report within 30 calendar days of the decision. The RIO will also notify those University officials who need to know of the DO's decision. The RIO must provide the following information to ORI upon request: (1) the institutional policies and procedures under which the Inquiry was conducted; (2) the research records and evidence reviewed, typed notes, or recordings of any interviews, and copies of all relevant documents; and (3) the Allegations to be considered in the Investigation.

7.5 Documentation of Decision Not to Investigate

If the DO decides that an Investigation is not warranted, the RIO shall secure and maintain for seven (7) years after the termination of the Inquiry sufficiently detailed documentation of the Inquiry to permit a later assessment by ORI (or other appropriate regulatory agency and/or sponsor) of the reasons why an Investigation was not conducted. These documents must be provided to ORI or other authorized HHS personnel upon request.

8.0 CONDUCTING THE INVESTIGATION

8.1 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. In conducting the Investigation, the RIO will pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any

evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion. If in the course of the Investigation, the RIO determines there are additional Allegations of Research Misconduct, the RIO will notify the Respondent(s).

8.2 Notifying ORI and Respondent(s); Sequestration of Research Records

On or before the date on which the Investigation begins, the RIO will: (1) notify ORI (or any appropriate regulatory agency or sponsor official where applicable) of the decision to begin the Investigation and provide a copy of the Inquiry report as requested; and (2) notify the Respondent(s) in writing of the Allegations to be investigated. The RIO will also provide the Respondent(s) written notice of any new Allegations of Research Misconduct within a reasonable amount of time of the decision to pursue Allegations not addressed during the Inquiry or in the initial notice of the Investigation.

The RIO will, prior to notifying Respondent(s) 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 proceedings that were not previously sequestered during the Inquiry. The need for additional sequestration of records for the Investigation may occur for any number of reasons, including the University's decision to investigate additional Allegations not considered during the Inquiry stage or the identification of records during the Inquiry 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.

8.3 Appointment of the Investigation Committee

The RIO, in consultation with other University officials as appropriate, will appoint an Investigation Committee and the committee chair within 10 days of the beginning of the Investigation or as soon thereafter as practical. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved in the Investigation, are not a Complainant and, where practical, should include individuals with appropriate scientific or professional expertise to evaluate the evidence and issues related to the Allegation. Individuals appointed to the Investigation Committee may also have served on the Inquiry committee.

8.4 Charge to the Committee and First Meeting

8.4.1 The RIO will define the subject matter of the Investigation in a written charge to the committee that:

8.4.1.1 Describes the Allegations and related issues identified during the Inquiry;

8.4.1.2 Identifies the Respondent(s);

8.4.1.3 Informs the committee that it must conduct the Investigation as prescribed below in the Investigation Process section;

8.4.1.4 Defines Research Misconduct;

8.4.1.5 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;

8.4.1.6 Informs the committee that in order to determine that the Respondent(s) committed Research Misconduct it must find that a preponderance of the evidence establishes that: (1) Research Misconduct, as defined in this policy, occurred (Respondent(s) has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including 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(s) committed the Research Misconduct intentionally, knowingly, or recklessly; and

8.4.1.7 Informs the committee that it must prepare or direct the preparation of a written Investigation Report that meets the requirements of this policy and any applicable federal regulations (42 CFR 93.313).

8.4.2 The RIO shall 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 shall be provided with a copy of this policy and any applicable federal regulations. The RIO shall be present or available throughout the Investigation to advise the committee as needed.

8.5 Investigation Process

The Investigation Committee and the RIO will:

8.5.1 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;

8.5.2 Take reasonable steps to ensure an impartial and unbiased Investigation;

8.5.3 Interview each Respondent(s), Complainant, and any other available person who has been identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent(s), and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the typed notes or recordings in the record of the Investigation; and

8.5.4 Pursue diligently all relevant information including evidence of any possible Research Misconduct, and continue the Investigation to completion.

8.6 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 or other appropriate regulatory agency or sponsor, where applicable. However, if the RIO determines that the Investigation will not be completed within this120-day period, when appropriate, 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.

9.0 THE INVESTIGATION REPORT

9.1 Elements of the Investigation Report

The Investigation Committee and the RIO are responsible for preparing a written draft report of the Investigation that:

9.1.1 Describes the nature of the Allegation of Research Misconduct, including identification of the Respondent(s);

9.1.2 Describes and documents the applicable PHS and/or other support, if any (incl. grant numbers, grant applications, contracts, publications listing sponsor support, and any other documentation found);

9.1.3 Describes the specific Allegations of Research Misconduct considered in the Investigation;

9.1.4 Includes the University policies and procedures under which the Investigation was conducted, unless those policies and procedures were provided to ORI previously;

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

9.1.6 Includes a statement of findings for each Allegation of Research Misconduct identified during the Investigation. Each statement of findings shall: (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 analyses that support the conclusion and consider the merits of any reasonable explanation by the Respondent(s), including any effort by the Respondent(s) 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 financial support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the Research Misconduct; and (6) list any current support or known applications or proposals for support that the Respondent(s) has pending with any federal agencies or other sponsors.

9.2 Comments on the Draft Report and Access to Evidence

9.2.1 The RIO shall give the Respondent(s) 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(s) shall be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The Respondent(s)'s comments shall be attached and considered in the final report.

9.2.2 In distributing the draft report, or portions thereof, to the Respondent(s), the RIO shall inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. The RIO may require that the recipient sign a confidentiality agreement.

9.3 Decision by the Deciding Official

The RIO shall assist the Investigation Committee in finalizing the Investigation Report, and transmit the final Investigation Report to the DO, who shall determine in writing: (1) whether the University accepts the Investigation Report, its findings, and the recommended institutional actions; and (2) the appropriate University actions in response to the accepted findings of Research Misconduct. If this determination varies from the findings of the Investigation Committee, the DO shall, 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 further fact-finding or analysis.

When a final decision on the case has been reached, the RIO shall notify both the Respondent(s) and the Complainant in writing. After informing the appropriate federal regulatory agency and/or other sponsors, the DO shall determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified information may have been published, collaborators of the Respondent(s) in the work, or other persons with legitimate reason to know should be notified of the outcome of the DO's decision.

9.4 Notice to the Appropriate Federal Agency and/or Other Sponsor

The RIO shall be responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. Unless an extension has been granted, the RIO must within the 120-day period for completing the Investigation prepare the following: (1) a copy of the final Investigation Report with all attachments and any appeal; (2) a statement of whether the University accepts the findings of the Investigation Report or the outcome of the appeal; (3) a statement of whether the University found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the Respondent(s).

9.5 Maintaining Records for Review by ORI

The RIO must maintain and provide to ORI (or other appropriate regulatory agencies or sponsors) upon request "records of Research Misconduct proceedings" as that term is defined by 42 CFR 93.317 or any subsequent regulations. 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 seven (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 of the University's handling of the Allegation.

10.0 COMPLETION OF CASES; REPORTING OF CASE CLOSURES

Inquiries and Investigations shall be completed. The RIO must notify the appropriate regulatory agency, including ORI when required, in advance if there are plans to close a case at the Inquiry, Investigation, or appeal stage on the basis that the Respondent(s) has admitted guilt, a settlement with the Respondent(s) 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.

11.0 INSTITUTIONAL ADMINISTRATIVE ACTIONS

When the DO decision concludes that an employee of the University or of the University Research Foundation engaged in Research Misconduct, the DO or other appropriate administrator, after consultation with the RIO, shall take appropriate corrective action.

12.0 OTHER CONSIDERATIONS

12.1 Termination or resignation Prior to Completing Inquiry or Investigation

The termination of the Respondent's University or University Research Foundation employment, by resignation 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 University or University Research Foundation

responsibilities under applicable law (42 CFR 93). If the Respondent(s), without admitting to the misconduct, elects to resign his or her position after the University receives an Allegation of Research Misconduct, the Inquiry and Investigation of the Allegation shall proceed. If the Respondent(s) refuses to participate in the process after separation from employment, the RIO and any Inquiry or Investigation Committee shall use their best efforts to reach a conclusion concerning the Allegations, noting in the report the Respondent(s)'s failure to cooperate and its effect on the evidence.

12.2 Restoration of the Respondent(s)'s Reputation

Following a final finding of no Research Misconduct and upon the request of the Respondent(s), the RIO shall undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances and the views of the Respondent(s), the RIO shall publicize the final outcome in any forum in which the Allegation of Research Misconduct was previously publicized. Any institutional actions to restore the Respondent(s)'s reputation should first be approved by the DO.

12.3 Protection of Complainant, Witnesses and Committee Members

During the Research Misconduct proceeding and upon its completion, regardless of whether it was determined that Research Misconduct occurred, the RIO shall take steps to counter potential or actual retaliation against any Complainant who made Allegations of Research Misconduct in good faith and any witnesses and committee members who cooperate in good faith with the Research Misconduct proceeding.

12.4 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 corrective action should be taken against the person who failed to act in good faith.