Administrative Procedure

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Subject: Handling Allegations of Research Misconduct

1.0. PURPOSE:

California State University, Los Angeles (CSULA), is committed to excellence in teaching, research and public service, as well as to the conduct of these activities with the highest possible ethical standards. This document establishes policies and procedures for handling allegations of research misconduct. The document is also available online at http://www.calstatela.edu/academic/aa/orad/.

2.0. ORGANIZATIONS AFFECTED:

All organizational units of the University, including Auxiliary organizations.

3.0. REFERENCES:

3.1. CSU Executive Order 890, Administration of Grants and Contracts in Support of Sponsored Programs.

3.2. 42 Code of Federal Regulations (CFR) Part 93 Public Health Service Policies on Research Misconduct.

3.3. U.S. Department of Health and Human Services Office of Research Integrity Sample Policy and Procedures for Responding to Allegations of Research Misconduct.

3.4. CSULA Administrative Procedure 395, Complaint Procedure for Discrimination, Harassment and Retaliation Complaints.

4.0. POLICY:

4.1. CSULA is guided by ethical principles when members of its academic community engage in research, scholarship and creative activities, and complies with pertinent federal and state regulations. Individuals who wish to report instances of research misconduct should promptly do so by notifying the Research Integrity Officer (RIO).

4.2. CSULA will respond to all reports of research misconduct in a timely and appropriate manner. If the complaint has merit, CSULA will promptly take actions to prevent recurrence and remedy the effects of research misconduct, to the extent possible. Persons who are found to have engaged in research misconduct may be subject

Approved: _____ **Date:** _____

to subsequent reprimand and/or disciplinary action, following procedures specified in Collective Bargaining Agreements between the California State University (CSU) Board of Trustees and the employee's relevant bargaining unit, University policies and procedures applicable to non-represented staff, policies and procedures of University Auxiliary Services, Inc., or the CSU Student Conduct Procedures, as applicable. In determining whether an action violates this policy, the totality of the circumstances shall be considered.

4.3. CSULA will not retaliate nor tolerate retaliation against parties reporting alleged research misconduct. This policy prohibits retaliation against complainants and requires the University to address and counter any retaliatory acts. Reports of retaliation will be handled in accordance with the relevant Collective Bargaining Agreement and/or campus Administrative Procedure 395.

4.4. While portions of this policy specifically address requirements of the U.S. Department of Health and Human Services' (HHS) Office of Research Integrity (ORI), which has oversight of research sponsored by the Public Health Service (PHS), the general procedures contained herein apply to all research activity conducted by CSULA staff, faculty, and students, regardless of the source or amount of funding for that activity.

4.5. The timelines in this policy may be extended by the RIO if the person requesting additional time can present documentation of extenuating circumstances in support of an extension and provides compelling reasons that warrant such an extension. Any extension granted must be communicated in writing to all parties, as well as to the Provost and Vice President for Academic Affairs. If an inquiry or investigation takes longer than the allotted time to complete, the relevant inquiry record or investigation report must include documentation of the reasons for exceeding the prescribed time period. For investigations which involve PHS funding, the University must complete the investigation in one hundred twenty (120) days or obtain written approval from the ORI for an extension.

5.0. DEFINITIONS:

5.1. Allegation - A disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication.

5.2. A preponderance of the evidence - Proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

5.3. Complainant - A person who in good faith makes an allegation of research misconduct.

5.4. Day - The term "day" as used in this procedure refers to a calendar day. The time in which an act is to be done is computed by excluding the first day and including the last, unless the last day is a holiday or other day on which the University is not regularly open for business, and then it is also excluded.

5.5. Deciding Official (DO) - The person who shall make the final determination as to whether research misconduct has taken place, and shall initiate appropriate administrative action against those found to have committed research misconduct in accordance with the relevant Collective Bargaining Agreement(s).

5.6. Fabrication - Making up data, or results and recording or reporting them.

5.7. 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.

5.8. Inquiry - Preliminary information-gathering and preliminary fact-finding of an allegation of research misconduct.

5.9. Inquiry Committee - Committee appointed by the RIO, in consultation with the Chair of the Academic Senate and other institutional officials, as appropriate, for the purpose of conducting an initial review of the available evidence to determine whether to conduct an investigation.

5.10. Investigation - The formal development of a factual record and the examination of that record leading to a finding as to whether research misconduct did or did not occur.

5.11. Investigation Committee - Committee appointed by the RIO, in consultation with the Chair of the Academic Senate and other institutional officials, as appropriate, for the purpose of conducting an investigation to develop a factual record leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent.

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

5.13. Research Misconduct - Fabrication, falsification, or plagiarism in proposing, performing, reporting or reviewing research, scholarly and creative activities. Research misconduct does not include honest error or differences of opinion (See sections 5.6., 5.7. and 5.12. for specific definitions of fabrication, falsification, and plagiarism). In a finding of research misconduct, (a) there must be a **significant departure** from accepted practices of the relevant research community; (b) the misconduct must be **committed intentionally, knowingly, or recklessly**; and (c) the allegation is **proven by a preponderance of the evidence**.

5.14. Research Integrity Officer (RIO) - The person who has primary responsibility for implementation of the institution's policies and procedures on research misconduct.

5.15. Respondent - The person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.

6.0. RESPONSIBILITIES:

6.1. The President, or designee, shall serve as the DO, who shall make the final determination as to whether research misconduct has taken place, and who shall initiate appropriate administrative action against those found to have committed research misconduct in accordance with the relevant Collective Bargaining Agreement(s).

6.2. The Provost and Vice President for Academic Affairs shall appoint the RIO who shall have primary responsibility for implementation of the institution's policies and procedures on research misconduct.

6.3. The Research Integrity Officer (RIO):

6.3.1. Informs institutional members about university policies and procedures for allegations of research misconduct, and the institution's commitment to compliance with the policies and procedures; to promote research integrity such as, (1) by routinely disseminating the policy to each faculty member, (2) education of research misconduct policy at faculty meetings, (3) having faculty members acknowledge that they have read the policy by signing a form, (4) involvement of faculty in development of responsible conduct of research (RCR) courses, (5) training for senior administrators on the RIO's role, (6) training for Institutional Review Board (IRB) staff, and (7) training for RCR staff.

6.3.2. Shall obtain and maintain an active Assurance Procedure with ORI. An Assurance will be filed annually.

6.3.3. Shall keep accurate records and provide the ORI with accurate data each year on allegations, investigations and any other material the ORI requests. The RIO shall file an annual report with the ORI which contains information specified by the ORI on the institution's compliance such as the number of allegations of misconduct, inquires, and research misconduct.

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

6.3.5. Shall initiate the inquiry process immediately, if it is determined that the criteria for an inquiry are met.

6.3.6. 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.

6.3.7. Will appoint an Inquiry Committee and Committee Chair, in consultation with the Chair of the Academic Senate and other institutional officials, as appropriate, as soon after the initiation of the inquiry as is practical, but within fourteen (14) days of the determination that an inquiry is warranted.

6.3.8. Will serve as Executive Secretary of the Inquiry Committee.

6.3.9. Shall review the situation, throughout the research misconduct proceeding, 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 shall, in consultation with other institutional officials and the ORI, if applicable, take appropriate interim action to protect against any such threat.

6.3.10. Shall, at any time during a research misconduct proceeding in which the ORI has oversight, notify the ORI immediately if he/she has reason to believe that any of the following conditions exist:

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

6.3.11. Shall 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.

6.3.12. Shall notify the respondent and complainant whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment, and include a copy of or refer to this policy, the University policy on Protection Against Misconduct in Research, and 42 CFR Part 93, if appropriate.

6.3.13. Shall secure and maintain for seven (7) years after the termination of the inquiry sufficiently detailed documentation of the inquiry, if the DO decides that an investigation is not warranted.

6.3.14. Will provide the ORI with the DO's written decision and a copy of the inquiry report within thirty (30) calendar days of the DO's decision that an investigation is warranted.

6.3.15. Will also notify those institutional officials who need to know of the DO's decision.

6.3.16. Shall appoint an Investigation Committee and the Committee Chair, in consultation with the Academic Senate Chair and other institutional officials, as appropriate, as soon after the beginning of the investigation as is practical, but within fourteen (14) days of the determination that an investigation is warranted.

6.3.17. 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 specified by this policy.

6.3.18. Will provide the Investigation Committee with a copy of the statement of policy and procedures and 42 CFR Part 93, if the latter is applicable.

6.3.19. Will be present or available throughout the investigation to advise the Committee as needed.

6.3.20. Shall assist the Investigation Committee in finalizing the draft investigation report.

6.3.21. Must give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based.

6.3.22. Shall notify both the respondent and the complainant in writing when a final decision on the case has been reached.

6.3.23. Is responsible for ensuring compliance with all notification requirements of the ORI and of relevant funding or sponsoring agencies.

6.4. The Inquiry Committee:

6.4.1. Will normally interview the complainant, the respondent and key witnesses, as well as examine relevant research records and materials.

6.4.2. Shall evaluate the evidence, including the testimony obtained during the inquiry.

6.4.3. Shall recommend to the DO, after consultation with the RIO, whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d), if the latter is relevant.

6.5. The Investigation Committee and the RIO are responsible for preparing a written draft report of the investigation.

6.6. University Counsel should review the draft report for legal sufficiency prior to distribution to the respondent and complainant. Modifications should be made, as appropriate, in consultation with the RIO and the Inquiry Committee.

6.7. The Complainant is responsible for making allegations in good faith, maintaining confidentiality to the extent possible under the law, and cooperating with the inquiry and investigation.

6.8. The Respondent is responsible for maintaining confidentiality to the extent possible under the law and cooperating with the conduct of an inquiry and investigation.

6.9. All institutional members shall report observed, suspected, or apparent research misconduct to the RIO.

7.0. PROCEDURES:

7.1. General Policies and Principles

7.1.1. The RIO shall have primary responsibility for implementation of the institution's policies and procedures on research misconduct.

7.1.2. Responsibility to Report Misconduct

7.1.2.1. All institutional members shall report through a written or oral statement or other communication, observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO 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 but warrant further inquiry, the RIO shall refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

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

7.1.3. Cooperation with Research Misconduct Proceedings

7.1.3.1. Institutional members shall cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations.

7.1.3.2. Institutional members, including respondents, have an obligation to make a good faith effort to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

7.1.3.3. Individuals involved in research misconduct proceedings shall be protected from retaliation to the extent provided by this policy, and shall continue to enjoy those rights and protections provided to them by the respective Collective Bargaining Agreement, University policy, and state and federal laws.

7.1.4. Confidentiality

7.1.4.1. The RIO shall:

7.1.4.1.1. To the extent possible under the law, 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; provided, however, that, (1) the institution must disclose the identity of respondents and complainants to the ORI pursuant to an ORI review of research misconduct proceedings under ’93.403, and (2) under ’93.517(g), HHS administrative hearings must be open to the public.

7.1.4.1.2. Maintain confidentiality, except as may otherwise be prescribed by law, for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

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

7.1.5. Protecting Complainants, Witnesses, and Committee Members

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

7.1.5.2. 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.

7.1.5.3. Reports of retaliation will be handled in accordance with the relevant Collective Bargaining Agreement and/or campus Administrative Procedure 395.

7.1.6. Protecting the Respondent

7.1.6.1. The Respondent is entitled to:

7.1.6.1.1. A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry.

7.1.6.1.2. Seek representation, including legal representation, and to have a representative or legal counsel present during any interviews or meetings.

7.1.6.1.3. An opportunity to comment on the inquiry report and have his/her comments attached to the report.

7.1.6.1.4. 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, if applicable, and the institution's policies and procedures on research misconduct.

7.1.6.1.5. 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 thirty (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 allegation.

7.1.6.1.6. Be interviewed during the investigation, have the opportunity to correct the recording or transcript, and have the proposed corrections to the recording or transcript included in the record of the investigation.

7.1.6.1.7. 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 investigation.

7.1.6.1.8. 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 thirty (30) days of the date on which the copy was received and that the comments shall be considered by the institution and addressed in the final report.

7.1.6.2. The respondent shall be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct.

7.1.6.3. As requested or 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.

7.1.7. Interim Administrative Actions and Notifying the ORI of Special Circumstances

7.1.7.1. Throughout the research misconduct proceeding, the RIO shall 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 shall, in consultation with other institutional officials and the ORI, if applicable, take appropriate interim action to protect against any such threat.

7.1.7.2. 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.

7.1.7.3. The RIO shall, at any time during a research misconduct proceeding in which the ORI has oversight, notify the ORI immediately if he/she has reason to believe that any of the following conditions exist:

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

7.2. Conducting the Assessment and Inquiry

7.2.1. Assessment of Allegations

7.2.1.1. Upon receiving an allegation of research misconduct, the RIO shall 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), the ORI, and whether the allegation falls within the definition of research misconduct in 42 CFR § 93.103. An inquiry must be conducted if any of these criteria are met.

7.2.1.2. The assessment period should be brief, and concluded within seven (7) days.

7.2.1.3. 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.

7.2.2. Initiation and Purpose of the Inquiry

7.2.2.1. If the RIO determines that the criteria for an inquiry are met, he or she shall immediately initiate the inquiry process.

7.2.2.2. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation.

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

7.2.3. Notice to Respondent and Sequestration of Research Records

7.2.3.1. 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.

7.2.3.2. 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 when 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 respondent will be allowed copies of, or reasonable supervised access to, the research records.

7.2.4. Appointment of the Inquiry Committee

7.2.4.1. The RIO, in consultation with the Chair of the Academic Senate and other institutional officials, as appropriate, will

appoint an Inquiry Committee and Committee Chair as soon after the initiation of the inquiry as is practical, but within fourteen (14) days of the determination that an inquiry is warranted.

7.2.4.2. The RIO will serve as Executive Secretary of this committee.

7.2.4.3. The Inquiry Committee must consist of five (5) individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and shall 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. To meet this requirement, the committee may include members from outside the University.

7.2.5. The Inquiry Process

7.2.5.1. The Inquiry Committee will normally interview the complainant, the respondent and key witnesses as well as examine relevant research records and materials. Tape recording and transcription of all interviews and investigations are required. All parties have the right to have a representative or legal counsel present during any interview or meeting.

7.2.5.2. The Inquiry Committee shall evaluate the evidence, including the testimony obtained during the inquiry.

7.2.5.3. After consultation with the RIO, the committee members shall recommend to the DO whether an investigation is warranted based on the criteria in this policy and 42 CFR § 93.307(d), if the latter is relevant.

7.2.5.4. 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, misconduct may be determined at the inquiry stage if all relevant issues are resolved.

7.2.6. Time for Completion

7.2.6.1. 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 sixty (60) calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period.

7.2.6.2. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the sixty (60) day period.

7.3. The Inquiry Report

7.3.1. Elements of the Inquiry Report

7.3.1.1. A written inquiry report must be prepared that includes the following information:

- The name and position of the respondent;
- A description of the allegations of research misconduct;
- Any federal grant support, including, for example, grant numbers, grant applications, contracts and publications listing PHS as the source of support;
- The basis for recommending or not recommending that the allegations warrant an investigation; and,
- Any comments on the draft report by the respondent or complainant.

7.3.1.2. University Counsel shall review the draft report for legal sufficiency prior to distribution to the respondent and complainant. Modifications should be made as appropriate in consultation with the RIO and the Inquiry Committee.

7.3.2. Notification to the Respondent and Complainant and Opportunity to Comment

7.3.2.1. Within seven (7) days after the draft inquiry report is completed, the RIO shall make a good faith effort to notify the respondent and complainant whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment, and include a copy of or refer to this policy, the University policy on Protection Against Misconduct in Research, and 42 CFR Part 93, if appropriate.

7.3.2.2. In distributing the draft report, or portions thereof, to the respondent and complainant, the RIO shall inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions, such as signing of a confidentiality agreement, to ensure such confidentiality to the extent possible under the law.

7.3.2.3. Any comments that are submitted by the respondent or complainant shall be received within ten (10) days of receipt by those individuals, and shall 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.

7.3.2.4. The Committee shall make every effort to deliver the final report to the RIO immediately upon its completion.

7.4. Institutional Decision and Notification of Investigation

7.4.1. Decision by Deciding Official

7.4.1.1. Within seven (7) days of receipt, the RIO shall transmit the final inquiry report and any comments to the DO.

7.4.1.2. Within seven (7) days of receipt, the DO will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

7.4.2. Notification to the U.S. Department of Health and Human Services (HHS) Office of Research Integrity (ORI)

7.4.2.1. Within thirty (30) calendar days of the DO's decision that an investigation is warranted, the RIO will provide the ORI with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision.

7.4.2.2. The RIO must provide the following information to the ORI upon request:

- The institutional policies and procedures under which the inquiry was conducted;
- The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and,
- The charges to be considered in the investigation.

7.4.3. Documentation of Decision Not to Investigate

7.4.3.1. 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.

7.5. Conducting the Investigation

7.5.1. Initiation and Purpose

7.5.1.1. The investigation must begin within thirty (30) calendar days after the determination by the DO that an investigation is warranted.

7.5.1.2. 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.

7.5.1.3. The investigation also will determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

7.5.1.4. The findings of the investigation must be set forth in an investigation report.

7.5.2. Notifications and Sequestration of Research Records

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

7.5.2.1.1. Notify the respondent in writing of the allegations to be investigated; and,

7.5.2.1.2. If applicable, notify the ORI Director of the decision to begin the investigation and provide ORI a copy of the inquiry report.

7.5.2.2. The RIO also must give the respondent written notice of any new allegations of research misconduct within seven (7) days of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

7.5.2.3. The RIO shall, prior to notifying the 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 investigation that were not previously sequestered during the inquiry.

7.5.2.4. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution’s decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured.

7.5.3. Appointment of the Investigation Committee

7.5.3.1. The RIO, in consultation with the Academic Senate Chair and other institutional officials, as appropriate, shall appoint an Investigation Committee and the Committee Chair as soon as

is practical after the beginning of the investigation but within fourteen (14) days of the determination that an investigation is warranted.

7.5.3.2. The Investigation Committee must consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation and shall include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant and conduct the investigation.

7.5.3.3. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee, when no other qualified individuals are available to serve.

7.5.3.4. Within fourteen (14) days of the committee's formation, the RIO will convene the first meeting of the Investigation Committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation specified by this policy, including the necessity for confidentiality and for developing a specific investigation plan.

7.5.3.5. The Investigation Committee will be provided with a copy of this statement of policy and procedures and 42 CFR Part 93, if the latter is applicable.

7.5.3.6. The RIO will be present or available throughout the investigation to advise the committee as needed.

7.5.4. Investigation Process

7.5.4.1. The Investigation Committee and the RIO must:

7.5.4.1.1. 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. Tape recording and transcription of meetings and interviews are required.

7.5.4.1.2. Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical.

7.5.4.1.3. 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.

7.5.4.1.4. 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.

7.5.5. Time for Completion

7.5.5.1. The investigation is to be completed within one hundred twenty (120) days of its initiation, including conducting the investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to the ORI, when applicable.

7.5.5.2. For research funded by the PHS, if the RIO determines that the investigation will not be completed within this 120-day period, he/she shall submit to the ORI a written request for an extension, setting forth the reasons for the delay.

7.5.5.3. The RIO shall ensure that periodic progress reports are filed with the ORI, if the ORI grants the request for an extension and directs the filing of such reports.

7.6. The Investigation Report

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

7.6.1.1. Describes the nature of the allegation of research misconduct, including identification of the respondent.

7.6.1.2. Describes and documents the types of research support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing federal and nonfederal support.

7.6.1.3. Describes the specific allegations of research misconduct considered in the investigation.

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

7.6.1.5. Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody, but not reviewed.

7.6.1.6. Includes a statement of findings for each allegation of research misconduct identified during the investigation.

7.6.2. Each statement of findings must:

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

7.6.2.2. 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 the 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.

7.6.2.3. Identify the source(s) of federal and nonfederal research support, if any.

7.6.2.4. Identify whether any publications need correction or retraction.

7.6.2.5. Identify the person(s) responsible for the misconduct.

7.6.2.6. List any known applications or proposals for support that the respondent has pending with federal and nonfederal agencies.

7.7. Comments on the Draft Report and Access to Evidence

7.7.1. Respondent

7.7.1.1. Within seven (7) days of the completion of the draft investigation report, the RIO shall provide the respondent a copy of the report for comment and, concurrently, provide a copy of, or supervised access to the evidence on which the report is based.

7.7.1.2. The respondent will be allowed thirty (30) days from the date he/she received the draft report to submit comments to the RIO.

7.7.1.3. The respondent's comments must be included and considered in the final report.

7.7.2. Complainant

7.7.2.1. Within seven (7) days of the completion of the draft investigation report, the RIO shall provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment.

7.7.2.2. The complainant's comments must be submitted to the RIO within thirty (30) days of the date on which he/she received the draft report and the comments must be included and considered in the final report.

7.8. Confidentiality

7.8.1. In distributing the draft report, or portions thereof, to the respondent and complainant, 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. For example, the RIO may require that the recipient sign a confidentiality agreement, requiring confidentiality to the extent possible under the law.

7.9. Decision by Deciding Official (DO)

7.9.1. The RIO shall assist the Investigation Committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, within fourteen (14) days after comments by the respondent and complainant are received.

7.9.2. Within seven (7) days of completion of the final investigation report, the RIO will transmit the final investigation report to the DO.

7.9.3. Within fourteen (14) days of receipt of the final investigation report, the DO will determine in writing:

7.9.3.1. Whether the institution accepts the investigation report, its findings, and the recommended institutional actions.

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

7.9.4. 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.

7.9.5. Alternatively, the DO may return the report to the Investigation Committee with a request for further fact-finding or analysis.

7.9.6. When a final decision on the case has been reached, the RIO shall notify both the respondent and the complainant in writing within seven (7) days.

7.9.7. The DO shall 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.

7.9.8. The RIO is responsible for ensuring compliance with all notification requirements of the ORI and of relevant funding or sponsoring agencies. In cases that involve private philanthropic organizations, such notification shall be coordinated with the Division of University Advancement.

7.10. Notice to the ORI of Institutional Findings and Actions

7.10.1. The outcome of investigations involving the PHS-funded research must be reported to the ORI.

7.10.2. Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation, submit the following to the ORI:

7.10.2.1. A copy of the final investigation report with all attachments.

7.10.2.2. A statement of whether the institution accepts the findings of the investigation report.

7.10.2.3. A statement of whether the institution found misconduct and, if so, who committed the misconduct.

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

7.11. Requirements for Cases under Jurisdiction of the ORI

7.11.1. Maintaining Records for Review by the ORI

7.11.1.1. The RIO must maintain and provide to the ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317.

7.11.1.2. Unless custody has been transferred to the HHS or the 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.

7.11.1.3. The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by the ORI to carry out its review of an allegation of research misconduct or of the institution’s handling of such an allegation.

7.11.2. Completion of Cases; Reporting Premature Closures to the ORI

7.11.2.1. Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently.

7.11.2.2. The RIO must notify the ORI in advance if there are plans to close a case at the inquiry or investigation stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except:

- Closing of a case at the inquiry stage on the basis that an investigation is not warranted; or,
- A finding of no misconduct at the investigation stage, which must be reported to the ORI, as prescribed in this policy and 42 CFR § 93.315.

7.12. Institutional Administrative Actions

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

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

7.12.1.2. Removal of the responsible person from the particular project and/or special monitoring of future work.

7.12.1.3. Initiation of disciplinary action proceedings, subject to procedures specified in Collective Bargaining Agreements between the CSU Board of Trustees and the employee's relevant bargaining unit, University policies and procedures applicable to non-represented staff, policies and procedures of University Auxiliary Services, Inc., or the CSU Student Conduct Procedures, as applicable.

7.12.1.4. Restitution of funds to the grantor agency, as appropriate.

7.12.1.5. Other action appropriate to the research misconduct.

7.12.2. Given the opportunity of the respondent to reply to the inquiry report and investigation report, and consistent with 42 CFR Part 93, the decisions of the DO regarding the finding of misconduct and institutional actions to be taken are final.

7.13. Other Considerations

7.13.1. Termination or Resignation Prior to Completing Inquiry or Investigation

7.13.1.1. 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 research misconduct proceeding

or otherwise limit any of the institution’s responsibilities under 42 CFR Part 93.

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

7.13.1.3. If the respondent refuses to participate in the process after resignation, 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 failure to cooperate and its effect on the evidence.

7.13.2. Restoration of the Respondent's Reputation

7.13.2.1. Following a final finding of no research misconduct, including the ORI concurrence where required by 42 CFR Part 93, the University must undertake reasonable and practical efforts, if requested or as appropriate, 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.

7.13.2.2. Depending on the particular circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file.

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

7.13.3. Protection of the Complainant, Witnesses and Committee Members

7.13.3.1. During the research misconduct proceeding and upon its completion, regardless of whether the institution or the 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 misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

7.13.3.2. The DO shall 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.

7.13.3.3. The RIO is responsible for implementing any steps the DO approves.

7.13.4. Allegations Not Made in Good Faith

7.13.4.1. If relevant, the DO shall 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.

7.13.4.2. If the DO determines that there was an absence of good faith he/she shall determine whether any administrative action should be taken against the person who failed to act in good faith.

8.0. APPENDICES:

N/A