

**SAN JOSÉ STATE UNIVERSITY
ONE WASHINGTON SQUARE
SAN JOSÉ, CA 95192**

**F12-5, Policy Recommendation, Responding to Allegations of
Research Misconduct**

Legislative History: Replaces S99-10

At its meeting of November 19, 2012, the Academic Senate approved the following policy recommendation brought to the Senate by Senator Peter for the Professional Standards Committee.

**Action by University President: Approved by President
Mohammad Qayoumi on
November 26, 2012**

**Policy Recommendation
Responding to Allegations of Research Misconduct
Replaces S99-10**

Resolved: That the attached document be accepted as University Policy.

Rationale: The University has been notified that its current policy (S99-10) on scientific misconduct in funded research is insufficient to meet federal requirements. For SJSU to continue to receive federal research funds it must bring its policies into compliance with new federal regulations. The attached proposal was drafted by Pam Stacks, AVP for Graduate Studies and Research, in conjunction with Jerri Carmo, Director of Sponsored Programs for the University Foundation. They worked from a template provided by the federal government and also from modifications to that template already approved at CSU Chico. The draft was reviewed by Dr. Sandra Titus, Compliance Reviewer for ORI (Office of Research Integrity.) This policy complies with federal requirements as specified in the Code of Federal Regulations (42CFR93).

The Professional Standards Committee discussed the draft with AVP Stacks at some length. There are limits to our ability to modify the policy without creating issues with federal compliance, and so Professional Standards made minimal changes—chiefly to be more specific about the composition of the relevant committees created by this policy. We did feel it was useful to issue this as a University Policy rather than a Presidential Directive since we

believe that the enforcement of ethical standards ought to be supported by the faculty's elective body and not be imposed from above. Furthermore, passage by the Senate will help to increase awareness of the policy and its standards.

The new federal regulations require that a university receiving federal funds have in place a rigorous system for investigating and responding to allegations of research misconduct. This differs from prior policy in that the system must be available for all forms of research and not strictly "scientific" research, and it must also apply to all research and not just government funded research. Research can include faculty, staff, and students—all of whom could be subjected to the provisions of this policy. These changes dramatically expand the scope of the SJSU policy.

The federal template is highly legalistic and controls, step by step, the procedures to be used from the first allegation of misconduct, through a preliminary assessment, to a formal inquiry, to a formal investigation, to a final decision. Key figures in the process are the Responsibility Integrity Officer who will be our AVP for Graduate Studies and Research, the Deciding Officer who will be the President, and three member committees of experts who assist in the investigation. The policy assures confidentiality, lack of retaliation, due process for both the complainant and the respondent (accused), and compliance with ORI regulations.

*Approved: (October 1, 2012)
Vote: (10-0-0)
Present: (Green, Semerjian, Reade, Maldonado-Colon, Gleixner, Winnard, Brown, Hsu, Peter, Condon)*

*Amended: October 29, 2012
Vote: (10-0-0)
Present: (Green, Semerjian, Reade, Maldonado-Colon, Gleixner, Winnard, Brown, Hsu, Peter, Condon)*

Financial Impact: Adoption will probably have no net impact since cases of misconduct must be dealt with in one way or another. Failure to adopt this measure though, would put us out of compliance with Federal Regulations and endanger all federal funding to SJSU.

Workload Impact: Serious cases of misconduct arise rarely, perhaps only once every few years. There probably would be no net impact on workload, although this policy will shift workload from the existing system to a new model.

Responding to Allegations of Research Misconduct

I. Introduction

A. General Policy

All members (faculty, staff, and students) of the San José State University (SJSU, University) community are expected to perform their scholarly and scientific activities with the highest ethical standards, honesty, and integrity. Instances of misconduct in research threaten the academic commitment to truth. San José State University will not tolerate misconduct in any aspect of research or scholarly endeavor and will vigorously investigate allegations of misconduct, taking all reasonable steps to protect the rights and interests of individuals whose work or performance is questioned.

B. Scope and Application

This policy applies to research conducted under an externally funded sponsored project that is awarded to the University or one of its auxiliary organizations, internally funded research and unfunded research conducted by faculty, staff, or students. Any individual who may work on or contribute to such a project, whether for monetary compensation or not, is covered by this policy.

When an allegation is made and an inquiry (preliminary assessment) is warranted, the Associate Vice-President for Graduate Studies and Research (AVP GS&R) will act as the Research Integrity Officer (RIO) and recommend to the Deciding Officer (DO, the campus President) who will determine if the inquiry will be investigated (formal development of a factual record to determine whether research misconduct has been committed, by whom, and to what extent).

Allegations of misconduct directed at faculty research involving sponsored projects will be adjudicated through the policy and procedures established by this policy. Allegations of misconduct directed at faculty research, whether funded by a source other than sponsored projects or unfunded but falling within the scope of the individual's employment for SJSU will be adjudicated through these procedures in consultation with the Division of Academic Affairs.

Allegations of misconduct directed at student research involving sponsored projects will be adjudicated through the policy and procedures established by this policy. Allegations of misconduct directed at student research, funded by a source other than sponsored projects or unfunded, will be adjudicated through these procedures in consultation with the Division of Student Affairs.

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 funds resulted in an award. The scope of this policy does not apply to authorship or collaboration disputes. It applies only to allegations of

research misconduct that occurred within six years of the date the institution or the sponsor received the allegation, subject to the subsequent use, health and safety of the public, and grandfather exceptions in 42CFR93.105(b).

II. Definitions

- **Allegation** means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement. Anonymous allegations will not be accepted.
- **Complainant** means a person who in good faith makes an allegation of research misconduct.
- **Deciding Official (DO)** is the person responsible for making the final decision on misconduct findings, administrative actions, and other items as listed in this policy and procedures. The Deciding Official will be the campus President since the CSU Chancellor's Office Executive Order 890 names the campus president as ultimately responsible for the implementation of this policy.
- **Evidence** means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.
- **Fabrication** means making up data or results and recording or reporting them.
- **Falsification** means 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, means 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. A report is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the charges. 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** means preliminary information-gathering and preliminary fact-finding that meets the criteria and follows the procedures set forth in federal regulations, currently 42CFR93.307-93.309.
- **Investigation** means the formal development of a factual record and the examination of that record leading to a decision not to make a 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)** means the office to which the Health and Human Services Secretary has delegated responsibility for addressing research integrity and misconduct issues related to Public Health Service supported activities.
- **Plagiarism** means the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- **Preponderance of Evidence** means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
- **Research** means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research) 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)** means the institutional official responsible for: (1) assessing allegations of research misconduct to determine if they fall within the definition of research misconduct, are covered by 42 CFR Part 93, and warrant an inquiry on the basis that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified; (2) overseeing inquiries and investigations; and (3) the other responsibilities described in this policy. For this policy, the RIO is the Associate Vice-President for Graduate Studies and Research unless otherwise designated by the President.
- **Research Misconduct** is fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the academic community for proposing, conducting, or reporting research. Misconduct does not

include honest error or honest differences in interpretations or judgments of data. This definition will be used to define research misconduct where “research” means all basic, applied, and demonstration research in all fields of inquiry.

- **Research Record** means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to a university official by a respondent in the course of the research misconduct proceeding.
- **Respondent** means the person against whom an allegation of research misconduct is directed or who is the subject of a research misconduct proceeding.
- **Retaliation** means an adverse action taken against a complainant, witness, or committee member by the University or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

III. Rights and Responsibilities

A. Research Integrity Officer (RIO)

The Associate Vice-President for Graduate Studies and Research (AVP GS&R) will serve as the RIO. The RIO will have primary responsibility for implementation of the University’s policies and procedures on research misconduct. These responsibilities include the following duties related to research misconduct proceedings:

- Consult confidentially with persons uncertain about whether to submit an allegation of research misconduct;
- Receive allegations of research misconduct;
- Assess each allegation of research misconduct in accordance with this policy to determine whether it falls within the definition of research misconduct and warrants an inquiry;

- When an inquiry is warranted, determine if the inquiry will be investigated by the RIO, by Faculty Affairs, or by Student Affairs and refer the investigation to the appropriate university officer;
- As necessary, take interim action and, when required, notify the Federal Office of Research Integrity (ORI) of special circumstances, in accordance with this policy and current federal regulation;
- Sequester research data and evidence pertinent to the allegation of research misconduct in accordance with this policy and maintain it securely in accordance with this policy and applicable law and regulation;
- Provide confidentiality to those involved in the research misconduct proceeding as required by 42CFR93.108, other applicable law, and University policy;
- Notify the respondent and provide opportunities for him/her to review/comment/respond to allegations, evidence, and committee reports in accordance with this policy;
- Inform respondents, complainants, and witnesses of the procedural steps in the research misconduct proceeding;
- Appoint the chair and members of the inquiry and investigation committees, when the need arises, ensure that those committees are properly staffed and that there is expertise appropriate to carry out a thorough and authoritative evaluation of the evidence;
- Determine whether each person involved in handling an allegation of research misconduct has an unresolved personal, professional, or financial conflict of interest and take appropriate action, including recusal, to ensure that no person with such conflict is involved in the research misconduct proceeding;
- In cooperation with other University officials, take all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and counter potential or actual retaliation against them by respondents or other institutional members;

- Keep the Deciding Official and others who need to know apprised of the progress of the review of the allegation of research misconduct;
- Notify and make reports to ORI as required by 42CFR93 or any other relevant federal regulations and/or notify and make reports to the appropriate regulatory agency or sponsor as required by regulations and this policy;
- Ensure that administrative actions taken by the University and/or ORI, when appropriate, are enforced and take appropriate action to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards of those actions; and
- Maintain records of the research misconduct proceeding and make them available to ORI or other regulatory agency, as required by law or regulation, in accordance with this policy and any relevant regulations.

B. Complainant

The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with the inquiry and investigation. As a matter of good practice, the complainant will be interviewed at the inquiry stage and given the transcript or recording of the interview for correction. The complainant must be interviewed during an investigation, and be given the transcript or recording of the interview for correction. On a case-by-case basis, the University may provide to the complainant for comment: (1) relevant portions of the inquiry report (within a timeframe that permits the inquiry to be completed within 60 days of its initiation); and (2) the draft investigation report or relevant portions of it. Comments on the draft investigation report shall be submitted within 30 days of the date on which the complainant received the draft report. The University will take into consideration any comments made by the complainant on the draft investigation report and include those comments in the final investigation report.

C. Respondent

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

- A good faith effort from the RIO to notify the respondent in writing at the time of or before beginning an inquiry;
- An opportunity to comment on the inquiry report and have his/her comments attached to the report;

- Be notified of the outcome of the inquiry, and receive a copy of the inquiry report that includes a copy of, or refers to 42CFR93 (where appropriate and any subsequent or other relevant regulatory requirements) and the University's policies and procedures on research misconduct;
- Be notified in writing of the allegations to be investigated within a reasonable time

after the determination that an investigation is warranted, but before the investigation begins (within 30 days after the 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;

- Be interviewed during the investigation, have the right to be accompanied by a representative of his/her choosing during the interview, have the opportunity to correct the recording or transcript, and have the corrected recording or transcript included in the record of the investigation;
- Have interviewed during the investigation any witness who has been reasonably identified by the respondent as having information on relevant aspects of the investigation, have the recording or transcript provided to the witness for correction, and have the corrected recording or transcript included in the record of investigation; and
- Receive a copy of the draft investigation report and, concurrently, a copy of, or supervised access to the evidence on which the report is based, and be notified that any comments must be submitted within 30 days of the date on which the copy was received and that the comments will be considered by the University and addressed in the final report.

The respondent will be given the opportunity to admit that research misconduct occurred and that he/she committed the research misconduct. With the advice of the RIO (when appropriate) and/or other University officials, the Deciding Official may terminate the University's review of an allegation that has been admitted, if the University's acceptance of the admission and any proposed settlement is approved by the Office of Research Integrity (when appropriate) or other involved regulatory agency or sponsor.

D. Deciding Official (DO)

The campus president, as the Deciding Official, shall receive the inquiry report and after consulting with the RIO or other involved regulatory agency or sponsor, decide whether any investigation is warranted under the criteria in any applicable regulations, including federal regulations such as 42CFR93.307(d). Any finding that an investigation is warranted shall be made in writing by the Deciding Official and shall be provided to ORI (when appropriate) or other involved regulatory agency or sponsor, together with a copy of the inquiry report meeting the requirements of the appropriate federal or other regulations, within 30 days of the finding. If it is found that an investigation is not warranted, the Deciding Official and RIO or other involved regulatory agency or sponsor shall ensure that detailed documentation of the inquiry is retained for at least 7 years after termination of the inquiry, so that ORI or other appropriate parties may assess the reasons why the University decided not to conduct an investigation.

The Deciding Official shall receive the investigation report and, after consulting with the RIO, or other involved regulatory agencies or sponsor, and other appropriate officials, decide the extent to which the University accepts the findings of the investigation and, if research misconduct is found, decide what, if any, University administrative actions are appropriate. The Deciding Official shall ensure that the final investigation report, the findings of the Deciding Official and a description of the any pending or completed administrative action are provided to ORI or the appropriate regulatory agency or sponsor, as required by federal or other regulations and this policy.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All University members will report observed, suspected, or apparent research misconduct to the Research Integrity Officer (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, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

B. Cooperation with Research Misconduct Proceedings

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

C. Confidentiality

The RIO shall (1) limit disclosure of the identity of respondents, complainants and witnesses to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding 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 proceeding. The RIO should use appropriate mechanisms to ensure that there is no disclosure of identifying information.

D. Protecting Complainants, Witnesses, and Committee Members

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

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made. During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive all the notices and opportunities provided for in federal regulations and the policies and procedures of the University.

F. 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 other University officials 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 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:

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

- U.S. Dept. of HHS or other sponsor resources or interests are threatened;
- Research activities should be suspended;
- There is a reasonable indication of possible violations of civil or criminal law;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving an allegation of research misconduct, the RIO shall immediately 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 falls within the definition of research misconduct in this policy and any applicable federal regulations. An inquiry shall 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, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified. The RIO shall, on or before the date which the respondent is notified of the allegation, obtain custody of, inventory, and sequester all research records and evidence needed to conduct the research misconduct proceeding, as provided in the Notice to Respondent; Sequestration of Research Records section below.

B. Initiation and Purpose of Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process after consultation with the DO. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must notify the respondent in writing. 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 proceeding, inventory the records and evidence and sequester them in a secure manner, except that where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The RIO may consult with the appropriate regulatory agency for advice and assistance in this regard.

D. Appointment of Inquiry Committee

The RIO, in consultation with other institutional officials as appropriate, will appoint an inquiry committee of at least three members including a committee chair as soon after the initiation of the inquiry as is practical. The inquiry committee shall 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.

The Inquiry Committee will be Chaired by a tenured full Professor of San José State University who will be selected for professional objectivity regarding both the complainant and respondent to the case. It is desirable but not mandatory that the Chair have the appropriate scientific or professional expertise necessary to evaluate the evidence and issues related to the inquiry. The committee shall have two additional members who must have the appropriate scientific or professional expertise necessary to evaluate the evidence and issues related to the inquiry. One or both of these members may be drawn from other universities and each shall be a tenured full Professor.

The respondent shall be notified of the proposed committee membership and shall have 10 calendar days to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Deciding Official (the President of San José State University or his/her designee) shall make the final determination of whether a conflict exists. If a conflict is found then a new committee member shall be appointed and a new period for objection shall be granted.

E. Charge to the Committee and First Meeting

The RIO shall prepare a charge for the inquiry committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment;
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to 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;
- 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; and, (2) the allegation may have substance, based on the committee's review during the inquiry.
- Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy.

At the committee's first meeting, the RIO shall 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.

F. Inquiry Process

The inquiry committee shall normally interview the complainant, the respondent and key witnesses as well as examining 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 members will decide whether an investigation is warranted based on the criteria in this policy and in any applicable federal or other appropriate regulations. 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. In that case, the University shall promptly consult with the 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.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the Deciding Official on whether an investigation is warranted, shall 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.

VI. The Inquiry Report

A. 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; (2) a description of the allegations of research misconduct; (3) the funding support, if any, for example, grant numbers, grant applications, contracts and publications listing specific financial support; (4) the names and titles of the committee members and experts 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 or complainant and (10) whether any actions should be taken if an investigation is not recommended. University counsel and/or other official with compliance background should review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent whether the inquiry found an investigation to be warranted, include a copy of the draft inquiry report for comment within 10 working days, and include a copy of or refer to the applicable federal or other appropriate regulations and the University policy on research misconduct.

Any comments that are submitted 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. The committee will deliver the final report to the RIO.

C. University Decision and Notification

1. Decision by Deciding Official

The RIO will transmit the final inquiry report and any comments to Deciding Official (DO), who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to ORI

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide ORI or other appropriate regulatory agency and/or sponsor 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. 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, transcripts or recordings of any interviews, and copies of all relevant documents; and (3) the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

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

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation shall begin within 30 calendar days after the determination by the Deciding Official 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 instances of research misconduct, he or she will notify the Respondent.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO shall: (1) notify the ORI Director of the decision to begin the investigation and provide any appropriate regulatory agency or sponsor a copy of the inquiry report; and (2) notify the respondent in writing of the allegations to be investigated. The RIO shall also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceedings that were not previously sequestered during the inquiry. 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 need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The RIO, in consultation with other University officials as appropriate, shall 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 shall consist of at least three individuals who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the investigation nor is a complainant.

The Investigation Committee will be Chaired by a tenured full Professor of San José State University faculty member who will be selected for professional objectivity regarding both the complainant and respondent to the case. It is desirable but not mandatory that the Chair have the appropriate scientific or professional expertise necessary to evaluate the evidence and issues related to the allegation. The committee shall have two additional members who must have the appropriate scientific or professional expertise necessary to evaluate the evidence and issues related to the allegation. One or both of these members may be drawn from other universities and each shall be a tenured full Professor. The committee should interview the respondent and complainant and conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The respondent shall be notified of the proposed committee membership and shall have 10 calendar days to object to a proposed member based upon a personal, professional, or financial conflict of interest. The Deciding Official (the President of San José State University or his/her designee) shall make the final determination of whether a conflict exists. If a conflict is found then a new committee member shall be appointed and a new period for objection shall be granted.

D. Charge to the Committee and First Meeting

1. Charge to the Committee

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

- Describes the allegations and related issues identified during the inquiry;

- Identifies the respondent;
- Informs the committee that it must conduct the investigation as prescribed below in the Investigation Process section;
- Defines research misconduct;
- Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
- Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defenses raised, including honest error or a difference of opinion); (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and
- Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy and any applicable federal regulations.

2. First Meeting

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.

E. Investigation Process

The investigation committee and the RIO shall:

- Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
- Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
- Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of the investigation; and
- Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to ORI or other appropriate regulatory agency or sponsor. However, if the RIO determines that the investigation will not be completed within this 120-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.

VIII. The Investigation Report

A. Elements of the Investigation Report

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

- Describes the nature of the allegation of research misconduct, including identification of the respondent;
- The respondent's c.v. or resume;

- Describes and documents the PHS and/or other support, including, for example, the numbers of any grants that are involved, grant applications, contracts, publications listing sponsor support, and any other documentation found;
- Describes the specific allegations of research misconduct considered in the investigation;
- Includes the University policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously;
- Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
- Includes a statement of findings for each allegation of research misconduct identified during the investigation. Each statement of findings 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 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; (3) identify the specific financial support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with any federal agencies or other sponsors.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

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

2. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, 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.

C. Decision by the Deciding Official

The RIO shall assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's comments are included and considered, 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 normally notify both the respondent 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 reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO shall be responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Notice to the Appropriate Federal Agency and/or Other Sponsor

Unless an extension has been granted, the RIO shall 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 institution accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the institution found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

E. 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 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 institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to Appropriate Regulatory Agency

Generally, all inquiries and investigations shall be carried through to completion and all significant issues will be pursued diligently. The RIO shall notify the appropriate regulatory agency, specifically 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 respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage.

X. Institutional Administrative Actions

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

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment as guided by appropriate university officials and Collective Bargaining Agreements;
- Restitution of funds to the grantor agency as appropriate; and
- Other action appropriate to the misconduct.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities under federal law. 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 shall proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any 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.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct and upon the request of the respondent, 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, 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 reputation should first be approved by the Deciding Official

C. 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 undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding. The DO 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. The RIO shall be responsible for implementing any steps the Deciding Official approves.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official 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. If the Deciding Official determines that there was an absence of good faith he/she will determine whether any administrative action should be taken against the person who failed to act in good faith.

XII. References

1. *Title 42 Code of Federal Regulations, Part 93, Subparts A,B,C,D,E* – Public Health Service Policies on Research Misconduct.
2. PHS Sample Policy and Procedures for Responding to Allegations of Research Misconduct. <http://ori.hhs.gov/ori-policies>