

Policy and Procedures for Responding to Allegations of Research Misconduct

Table of Contents

Introduction.....	3
Scope.....	3
Definitions.....	4
Rights and Responsibilities.....	5
Research Integrity Officer.....	5
Complainant.....	5
Respondent.....	6
Deciding Official	6
General Policies and Principles	6
Responsibility to Report Misconduct.....	6
Protecting the Complainant.....	6
Protecting the Respondent	7
Confidentiality	7
Cooperation with Inquiries and Investigations	7
Preliminary Assessment of Allegations	7
Conducting the Inquiry	8
Initiation and Purpose of the Inquiry	8
Sequestration of the Research Records.....	8
Appointment of the Inquiry Committee.....	8
Charge to the Committee and the First Meeting.....	8
Inquiry Process.....	9
The Inquiry Report.....	9
Elements of the Inquiry Report.....	9
Comments on the Draft Report by the Respondent and the Complainant.....	9
Inquiry Decision and Notification	9
Time Limit for Completing the Inquiry	10
Conducting the Investigation	10
Purpose of the Investigation.....	10
Additional Sequestration of Research Records.....	10
Appointment of the Investigation Committee.....	10
Charge to the Committee and the First Meeting.....	11
Investigation Process	11
Evidentiary Standards	12
The Investigation Report.....	12
Elements of the Investigation Report.....	12
Comments on the Draft Report	12
Transmittal of the Final Investigation Report to Deciding Official.....	13
Institutional Review and Decision	13
Transmittal of the Final Investigation Report to a Federal Agency.....	13
Time Limit for Completing the Investigation.....	13
Additional Requirements for Reporting.....	14
Institutional Administrative Actions.....	14

Other Considerations	15
Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation.....	15
Restoration of the Respondent's Reputation	15
Protection of the Complainant and Others.....	15
Allegations Not Made in Good Faith.....	15
Interim Administrative Actions	16
Records Retention.....	16
Appendix A: Federal Policy on Research Misconduct.....	17

South Dakota State University
Office of Research
Policies and Procedures Manual

Subject: Policy and Procedures for Responding to Allegations of Research Misconduct

Policy number: VPR-08-001-RM

Applicable Federal regulations: Office of Science and Technology Policy, Executive Office of the President; Federal Policy on Research Misconduct, Notice of Final Policy. Federal Register: December 6, 2000 (Volume 65, Number 235), United States Public Health Service regulation at 42 CFR Part 93, and other Federal agency regulations pertaining to research misconduct.

Introduction

South Dakota State University (SDSU) is committed to the highest level of scientific and academic integrity in research conducted under its auspices. This SDSU policy on research integrity has been designed to meet the requirements of the U.S. Public Health Service (PHS) and other Federal agency regulations.

According to Federal policy, research misconduct, also referred to as scientific misconduct is defined as “fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.” (Federal Register: December 6, 2000 (Volume 65, Number 235) p. 76262) It does not include honest error or honest differences in interpretations or judgments of data. A complete definition and standards of determination are provided in Appendix A.

Scope:

This policy and the associated procedures apply to all individuals at SDSU engaged in research. This includes any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at SDSU. The policy is specifically designed to meet the Federal Policy on Research Misconduct and the requirements for research activities supported by, or for which support is requested from the United States Public Health Service (PHS) a unit within the U.S. Department of Health and Human Services (HHS), and to meet other Federal agency research misconduct policies. SDSU extends its policy and procedures to all research, unfunded or funded, regardless of funding source.

The policy and associated procedures will be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of SDSU, PHS or other Federal agencies. Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation, and will be approved in advance by the Research Integrity Officer and the Deciding Official.

Definitions

Many of the definitions herein are taken from or based on the PHS regulation, 42 CFR 93, Subpart B.

Allegation means a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or other (Federal) official.

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

Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

Deciding Official means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. The Deciding Official is the President of SDSU.

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. An allegation or cooperation with a research misconduct proceeding is not in good faith if made with knowing or reckless disregard for information that would negate the allegation or testimony. Good faith as applied to a committee member means cooperating with the research misconduct proceeding by carrying out the duties assigned impartially for the purpose of helping an institution meet its responsibilities under this part.

Inquiry means preliminary information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has or has not occurred and, if so, to determine the responsible person, the seriousness of the misconduct and to recommend any appropriate actions.

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

PHS regulation means the Public Health Service regulation set forth at 42 C.F.R. Part 93, entitled, "Public Health Service Policies on Research Misconduct."

PHS support means PHS grants, contracts, cooperative agreements or applications therefor.

Research Integrity Officer means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.

Research record means the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding.

Respondent means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

Retaliation means an adverse action taken against a complainant, witness, or committee member by an institution or one of its members because the individual has in good faith, made an allegation of scientific misconduct or has cooperated in good faith with an investigation of such allegation.

Rights and Responsibilities

Research Integrity Officer:

The President will appoint the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with the SDSU policies and procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer will report to Federal agencies as required by regulation and keep them apprised of any developments during the course of the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation or that they need to know to ensure appropriate use of Federal funds and otherwise protect the public interest. (Federal Register: December 6, 2000 (Volume 65, Number 235) p. 76263)

Complainant:

The complainant will have an opportunity to testify before the inquiry and investigation committees, may review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, will be informed of the results of the inquiry and investigation, and will

be protected from retaliation. The complainant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

Respondent:

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

Deciding Official:

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, make the final decision as to whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

General Policies and Principles

Responsibility to Report Misconduct:

All employees or individuals associated with SDSU should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may contact the Research Integrity Officer at (605) 688-6975 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

Protecting the Complainant:

Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations (Federal Register: December 6, 2000 (Volume 65, Number 235) p. 76263). The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also the institution will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity may no longer be guaranteed.

Protecting the Respondent:

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

Confidentiality:

Disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding, and as allowed by law. Provided, however, that the institution must disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings under Sec. 93.403 and to other Federal agencies as required by their regulations.

Except as may otherwise be prescribed by applicable law, confidentiality must be maintained 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. (Source: PHS regulation 42 CFR 93.108)

Cooperation with Inquiries and Investigations:

Institutional employees will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS or other Federal support or PHS/Federal applications for funding are involved, and whether the allegation falls under the Federal definition of scientific misconduct.

Conducting the Inquiry

Initiation and Purpose of the Inquiry:

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up and falls under the Federal definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is **not** to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

The respondent will be informed of the allegations before an inquiry is opened.

Sequestration of the Research Records:

After determining that an allegation falls within the definition of misconduct in science, the Research Integrity Officer will take all reasonable and practical steps to ensure that all original research records and materials relevant to the allegation are immediately secured. Sequestration will take place either before, or upon notification to the respondent of the allegation.

Appointment of the Inquiry Committee:

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution. The Research Integrity Officer will notify the respondent of the proposed committee membership in 5 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

Charge to the Committee and the First Meeting:

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS or other Federal regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

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

Inquiry Process:

The inquiry committee will normally interview the complainant, the respondent and key witnesses as well as examining relevant research records and materials. Then the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

The Inquiry Report

Elements of the Inquiry Report:

A written inquiry report will be prepared in accordance with 42 CFR 93.309 and will include the name and title of the committee members and experts, if any; the allegations; PHS support, if applicable; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether and investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

Comments on the Draft Report by the Respondent and the Complainant:

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and if appropriate, will provide the complainant with portions of the draft inquiry report (or a summary of the inquiry findings) that address the complainant's role and opinions in the investigation.

The Research Integrity Officer will establish reasonable conditions for review to protect the confidentiality of the draft report.

Within 10 working days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

Inquiry Decision and Notification:

The Research Integrity Officer will transmit the final report and any comments or recommendations to the Deciding Official, who will make the final determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation.

The Research Integrity Officer will notify the respondent in writing of the Deciding Official's decision of whether to proceed to an investigation along with a copy of the inquiry report and will remind him or her of the obligation to cooperate in the event an investigation is opened. The Research Integrity Officer also will notify others, including ORI or other Federal agencies, as appropriate, of the Deciding Official's decision. If an investigation is found to be warranted, the documents to be provided to ORI and other Federal agencies will include a copy of the inquiry report and the findings and determination made by the deciding official. Upon request, all other relevant documents will be made available. An institution's decision to initiate an investigation must be reported in writing to the Federal Agency official 30 days after finding an investigation is warranted and on or before the date the investigation begins. Documentation of a decision not to investigate shall be provided to Federal officials, upon request.

Time Limit for Completing the Inquiry:

The institution will normally complete the inquiry process in 60 calendar days, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

Conducting the Investigation

Purpose of the Investigation:

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important when the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

Additional Sequestration of Research Records:

The Research Integrity Officer will sequester any additional pertinent research records that were not previously sequestered during the inquiry. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations revealed 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 prior to the inquiry.

Appointment of the Investigation Committee:

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key

witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

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

Charge to the Committee and the First Meeting:

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, and witnesses, including the complainant to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

Investigation Process:

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provided a sufficient basis for conducting an investigation.

The investigation will involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. All interviews will be transcribed or recorded. Transcripts or recordings of the interviews will be provided to the interviewed party for comment or revision, and included as part of the investigatory file.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

Evidentiary Standards:

An institutional finding of research misconduct must be proved by a preponderance of the evidence. The institution or Federal agency has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or Federal agency establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.

The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether the institution has carried the burden of proof imposed by this part, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

The Investigation Report

Elements of the Investigation Report:

The report will be prepared in accordance with 42 CFR 93.313 and will describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution (adjudication).

Comments on the Draft Report:

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. Supervised access to the evidence upon which the report is based will be provided, upon request. The respondent will be allowed 10 working days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

When appropriate, the Research Integrity Officer will provide the complainant and the witnesses with those portions of the draft investigation report (or a summary of the inquiry findings) that address the complainant's and witnesses' role and opinions in the investigation. The report may be modified, as appropriate, based on the complainant's or witnesses' comments.

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

In distributing the draft report to the respondent the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer

may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

Transmittal of the Final Investigation Report to Deciding Official:

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's comments, to the Deciding Official, through the Research Integrity Officer.

Institutional Review and Decision:

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and, if research misconduct is found, decide what, if any, institutional administrative actions are appropriate. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to Federal officials. The Deciding Official's explanation should be consistent with the Federal definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official also may return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of Federal agency review.

When a final decision on the case has been reached, the Research Integrity Officer will notify the respondent. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose administrative actions following a research misconduct proceeding. (Source PHS regulation 42 CFR 93.106)

In addition, the Deciding Official, with the help of the Research Integrity Officer and university counsel as appropriate, will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

Transmittal of the Final Investigation Report to a Federal agency:

The final report with attachments will be transmitted to the Federal agency, as appropriate, from the Deciding Official, through the Research Integrity Officer.

Time Limit for Completing the Investigation:

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the final report to any Federal official.

If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI or other Federal agency, if appropriate a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the Federal official.

Additional Requirements for Reporting

When the case involves PHS funds, the Research Integrity Officer may contact ORI for consultation and advice. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI. When scientific misconduct has been determined to have occurred, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct.

If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination. The institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

In accordance with 42 CFR 93.318, the Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

- there is an immediate health hazard involved;
- there is an immediate need to protect Federal funds or equipment;
- there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
- it is probable that the alleged incident is going to be reported publicly;
- the allegation involves a public health sensitive issue, *e.g.*, a clinical trial; or
- there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

Institutional Administrative Actions

SDSU will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken. The actions may include any or all of the following:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found

- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment
- restitution of funds as appropriate

Other Considerations

Termination of Employment or Resignation Prior to Completing Inquiry or Investigation:

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

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

Restoration of the Respondent's Reputation:

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

Protection of the Complainant and Others:

Regardless of whether the institution or Federal agency determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect complainants who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

Allegations Not Made in Good Faith:

If relevant, the Deciding Official will determine whether the complainant's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the complainant.

Interim Administrative Actions:

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

Records Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven years after completion of the case to permit later assessment of the case. ORI or other authorized Federal agency personnel will be given access to the records upon request. If a Federal agency requests records, the seven year retention window will not begin until their process is complete.

This policy was made effective on February 15, 2000 by Peggy Gordon Elliott (Miller) President, South Dakota State University, and revised in 2007.

Approved:

David L. Chicoine
President, South Dakota State University

(date)

Appendix A

Federal Policy on Research Misconduct¹

I. Research² Misconduct Defined

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

¹No rights, privileges, benefits or obligations are created or abridged by issuance of this policy alone. The creation or abridgment of rights, privileges, benefits or obligations, if any, shall occur only upon implementation of this policy by the Federal agencies.

²Research, as used herein, includes all basic, applied, and demonstration research in all fields of science, engineering, and mathematics. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.³

³The research record is the record of data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, and journal articles.

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

Research misconduct does not include honest error or differences of opinion.

II. Findings of Research Misconduct

A finding of research misconduct requires that:

There be a significant departure from accepted practices of the relevant research community; and

The misconduct be committed intentionally, or knowingly, or recklessly; and

The allegation be proven by a preponderance of evidence.

III. Responsibilities of Federal Agencies and Research Institutions⁴

Agencies and research institutions are partners who share responsibility for the research process. Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and

for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.

⁴The term "research institutions" is defined to include all organizations using Federal funds for research, including, for example, colleges and universities, intramural Federal research laboratories, Federally funded research and development centers, national user facilities, industrial laboratories, or other research institutes. Independent researchers and small research institutions are covered by this policy.

Agency Policies and Procedures. Agency policies and procedures with regard to intramural as well as extramural programs must conform to the policy described in this document. **Agency Referral to Research Institution.** In most cases, agencies will rely on the researcher's home institution to make the initial response to allegations of research misconduct. Agencies will usually refer allegations of research misconduct made directly to them to the appropriate research institution. However, at any time, the Federal agency may proceed with its own inquiry or investigation. Circumstances in which agencies may elect not to defer to the research institution include, but are not limited to, the following: the agency determines the institution is not prepared to handle the allegation in a manner consistent with this policy; agency involvement is needed to protect the public interest, including public health and safety; the allegation involves an entity of sufficiently small size (or an individual) that it cannot reasonably conduct the investigation itself. **Multiple Phases of the Response to an Allegation of Research Misconduct.** A response to an allegation of research misconduct will usually consist of several phases, including: (1) an inquiry--the assessment of whether the allegation has substance and if an investigation is warranted; (2) an investigation--the formal development of a factual record, and the examination of that record leading to dismissal of the case or to a recommendation for a finding of research misconduct or other appropriate remedies; (3) adjudication--during which recommendations are reviewed and appropriate corrective actions determined.

Agency Follow-up to Institutional Action. After reviewing the record of the investigation, the institution's recommendations to the institution's adjudicating official, and any corrective actions taken by the research institution, the agency will take additional oversight or investigative steps if necessary. Upon completion of its review, the agency will take appropriate administrative action in accordance with applicable laws, regulations, or policies. When the agency has made a final determination, it will notify the subject of the allegation of the outcome and inform the institution regarding its disposition of the case. The agency finding of research misconduct and agency administrative actions can be appealed pursuant to the agency's applicable procedures.

Separation of Phases. Adjudication is separated organizationally from inquiry and investigation. Likewise, appeals are separated organizationally from inquiry and investigation.

Institutional Notification of the Agency. Research institutions will notify the funding agency (or agencies in some cases) of an allegation of research misconduct if (1) the allegation involves Federally funded research (or an application for Federal funding) and meets the Federal definition of research misconduct given above, and (2) if the institution's inquiry into the allegation determines there is sufficient evidence to proceed to an investigation. When an investigation is complete, the research institution will forward to the agency a copy of the

evidentiary record, the investigative report, recommendations made to the institution's adjudicating official, and the subject's written response to the recommendations (if any). When a research institution completes the adjudication phase, it will forward the adjudicating official's decision and notify the agency of any corrective actions taken or planned.

Other Reasons to Notify the Agency. At any time during an inquiry or investigation, the institution will immediately notify the Federal agency if public health or safety is at risk; if agency resources or interests are threatened; if research activities should be suspended; if there is reasonable indication of possible violations of civil or criminal law; if Federal action is required to protect the interests of those involved in the investigation; if the research institution believes the inquiry or investigation may be made public prematurely so that appropriate steps can be taken to safeguard evidence and protect the rights of those involved; or if the research community or public should be informed.

When More Than One Agency is Involved. A lead agency should be designated to coordinate responses to allegations of research misconduct when more than one agency is involved in funding activities relevant to the allegation. Each agency may implement administrative actions in accordance with applicable laws, regulations, policies, or contractual procedures.

IV. Guidelines for Fair and Timely Procedures

The following guidelines are provided to assist agencies and research institutions in developing fair and timely procedures for responding to allegations of research misconduct. They are designed to provide safeguards for subjects of allegations as well as for informants. Fair and timely procedures include the following: **Safeguards for Informants.** Safeguards for informants give individuals the confidence that they can bring allegations of research misconduct made in good faith to the attention of appropriate authorities or serve as informants to an inquiry or an investigation without suffering retribution. Safeguards include protection against retaliation for informants who make good faith allegations, fair and objective procedures for the examination and resolution of allegations of research misconduct, and diligence in protecting the positions and reputations of those persons who make allegations of research misconduct in good faith.

Safeguards for Subjects of Allegations. Safeguards for subjects give individuals the confidence that their rights are protected and that the mere filing of an allegation of research misconduct against them will not bring their research to a halt or be the basis for other disciplinary or adverse action absent other compelling reasons. Other safeguards include timely written notification of subjects regarding substantive allegations made against them; a description of all such allegations; reasonable access to the data and other evidence supporting the allegations; and the opportunity to respond to allegations, the supporting evidence and the proposed findings of research misconduct (if any).

Objectivity and Expertise. The selection of individuals to review allegations and conduct investigations who have appropriate expertise and have no unresolved conflicts of interests help to ensure fairness throughout all phases of the process. **Timeliness.** Reasonable time limits for the conduct of the inquiry, investigation, adjudication, and appeal [[Page 76264]] phases (if any), with allowances for extensions where appropriate, provide confidence that the process will be

well managed. Confidentiality During the Inquiry, Investigation, and Decision-Making Processes. To the extent possible consistent with a fair and thorough investigation and as allowed by law, knowledge about the identity of subjects and informants is limited to those who need to know. Records maintained by the agency during the course of responding to an allegation of research misconduct are exempt from disclosure under the Freedom of Information Act to the extent permitted by law and regulation.

V. Agency Administrative Actions

Seriousness of the Misconduct. In deciding what administrative actions are appropriate, the agency should consider the seriousness of the misconduct, including, but not limited to, the degree to which the misconduct was knowing, intentional, or reckless; was an isolated event or part of a pattern; or had significant impact on the research record, research subjects, other researchers, institutions, or the public welfare.

Possible Administrative Actions. Administrative actions available include, but are not limited to, appropriate steps to correct the research record; letters of reprimand; the imposition of special certification or assurance requirements to ensure compliance with applicable regulations or terms of an award; suspension or termination of an active award; or suspension and debarment in accordance with applicable government-wide rules on suspension and debarment. In the event of suspension or debarment, the information is made publicly available through the List of Parties Excluded from Federal Procurement and Nonprocurement Programs maintained by the U.S. General Services Administration. With respect to administrative actions imposed upon government employees, the agencies must comply with all relevant federal personnel policies and laws.

In Case of Criminal or Civil Fraud Violations. If the funding agency believes that criminal or civil fraud violations may have occurred, the agency shall promptly refer the matter to the Department of Justice, the Inspector General for the agency, or other appropriate investigative body.

VI. Roles of Other Organizations

This Federal policy does not limit the authority of research institutions, or other entities, to promulgate additional research misconduct policies or guidelines or more specific ethical guidance.

Source: Office of Science and Technology Policy, Executive Office of the President; Federal Policy on Research Misconduct, Notice of Final Policy. Federal Register: December 6, 2000 (Volume 65, Number 235) Pages 76262-76264.