SOUTHERN ILLINOIS UNIVERSITY SCHOOL OF MEDICINE

MISCONDUCT IN SCIENCE: POLICY AND PROCEDURES

INTRODUCTION

The principles embodied in this policy apply equally to all scholarly endeavors at Southern Illinois University School of Medicine. This policy document defines misconduct in science and describes the procedures for reviewing, investigating, and reporting allegations of misconduct in science at Southern Illinois University School of Medicine. The policy applies to all biomedical and behavioral research conducted at Southern Illinois University School of Medicine.

In order to address all allegations of misconduct in science expeditiously, the Southern Illinois University School of Medicine has designated senior official(s) to whom allegations should be reported. This senior official(s) will pursue all allegations to resolution. The official(s) will counsel confidentially any individual who comes forward with an allegation of misconduct. If the concern brought to the official's attention does not fall within the scope of the policies to address misconduct, the official(s) will seek to assist in the resolution of the concern through Southern Illinois University School of Medicine processes appropriate to the particular case such as referral to the department chair, the personnel office, or the faculty grievance procedure.

This policy defines misconduct in science as "fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data." All individuals affiliated with Southern Illinois University School of Medicine have the responsibility both to report apparent occurrences of misconduct and to take action to correct the scientific record when they discover error. In many cases, however, a person may not be able to determine whether the problem he or she perceives with a research project constitutes misconduct or error. The senior official(s) listed in this document to whom formal allegations should be brought can provide guidance in ambiguous situations.

The responsibility to pursue an allegation of misconduct in science belongs to the Southern Illinois University School of Medicine and must be carried out fully to resolve questions regarding the integrity of the research. Even in the absence of a specific complaint, the Southern Illinois University School of Medicine should be alert to questionable academic conduct that might raise legitimate suspicion of misconduct in science.

In the event of a case of alleged misconduct, all persons involved in the proceedings are expected to cooperate fully and to conduct themselves in an ethical manner. They have an obligation to strive for fairness and objectivity, with ample respect for the care needed in reviewing allegations of misconduct and the harm that can result from

unfounded allegations. They should focus on the substance of the issues and not allow personal conflicts between colleagues to obscure the facts.

DEFINITION OF MISCONDUCT IN SCIENCE

The key to defining misconduct in science is intent. Misconduct in science does not include honest error or honest differences in interpretation or judgments of data. The term "misconduct in science" includes the following:

- Fabrication of data.
- Falsification of data.
- 3. Plagiarism.
- Any other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research.

PROCESS FOR HANDLING ALLEGATIONS OF MISCONDUCT IN SCIENCE

The review process for cases of alleged misconduct in science consists of an inquiry and, if it is determined from the inquiry that it is warranted, an investigation. Procedures for both of these steps of the review process are described below. Also described are procedures for reporting to the funding agency (where applicable) and taking interim administrative action when serious circumstances call for immediate precautions. There are also provisions for appealing a determination of misconduct in science.

In order to address all allegations of misconduct in science expeditiously, the Southern Illinois University School of Medicine has formed a standing committee, the Misconduct in Science Committee. The committee will consist of five tenured faculty members appointed by the Dean and Provost. Committee representation should reflect the broad range of academic disciplines at the Southern Illinois University School of Medicine. Committee members will serve for three years; terms will be staggered to further allow for continuity. The committee will interpret the Southern Illinois University School of Medicine policy on misconduct in science and will initiate and carry out inquiries and investigations. In situations where allegations of misconduct in science involve a School of Medicine employee(s) on the Carbondale campus, the Dean and Provost shall request that the Vice-President for Academic Affairs and Research appoint a tenured faculty member, who shall serve as an ex officio, non-voting member of the Misconduct in Science Committee for purposes of participating in any inquiry or investigation that may occur.

Allegations may be reported to the chair of the committee, Dean and Provost, or Associate Dean for Research for discussion and possible referral to the committee. Any of these persons may counsel confidentially any individual who comes forward with an

allegation of misconduct. Some concerns brought to their attention may not fall within the scope of the policies and procedures developed to address misconduct, and in such cases they will refer the matter to whatever institutional processes may be appropriate to the particular case. If they determine that the concern does fall under the jurisdiction of the Misconduct in Science Committee, they will discuss the inquiry and investigation procedures with the individual who has questions about the integrity of a research project or other misconduct in science (the complainant). If the individual chooses to make a formal allegation, the matter will be brought before the committee as soon as possible but not less than 10 calendar days from the date the formal allegation is received by the chair of the committee, Dean and Provost, or Associate Dean for Research. If the individual chooses not to make a formal allegation but the Dean and Provost or Associate Dean for Research or committee chair believes there is sufficient basis for conducting an inquiry, the matter will be referred to the committee for appropriate action.

Even if the subject of the allegations (the respondent) leaves the Southern Illinois University School of Medicine before the case is resolved, the Southern Illinois University School of Medicine will continue the examination of the allegations in accordance with this policy. If there is a finding of misconduct in science, the Southern Illinois University School of Medicine may notify the institution with which the subject of the investigation is currently affiliated. Furthermore, the Southern Illinois University School of Medicine will cooperate with other institutions' processes to resolve such questions.

Inquiry - Step I

A. Purpose

The first step of the review process, an inquiry, is triggered by an allegation of misconduct or by information obtained from other sources, such as review of reports. Whenever an allegation involving the possibility of misconduct is brought before it, the Misconduct in Science Committee will initiate an inquiry. In the inquiry, factual information is gathered and expeditiously reviewed to determine if the allegation or apparent instance of misconduct warrants an investigation. An inquiry is not a formal hearing; it is designed to separate allegations deserving of further investigation from frivolous, unjustified, or clearly mistaken allegations.

B. Structure

The Misconduct in Science Committee must ensure that it has the academic and scientific expertise necessary to judge the allegations being made. Therefore, it may call in on- or off-campus consultants as necessary and appropriate to assist in reviewing a case. If a member of the committee has a real or apparent conflict of interest with a given case, that member will not participate in the review process for the case. If the committee deems necessary, it will recommend to the

Dean and Provost an ad hoc member be substituted for the nonparticipating member.

C. Process

To initiate an inquiry, the committee convenes and notifies the respondent within a reasonable time but not later than 10 calendar days after the committee convenes, of the basis of the inquiry and the process that will follow. Notification will be made in writing and copies will be securely maintained and held confidential in the Office of the Associate Dean for Research,

The date the committee convenes to consider an allegation of misconduct marks the initiation of an inquiry. The inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If an agency funding the research in question requires that inquiries be completed in a shorter amount of time, the committee will comply with this requirement.

To the greatest extent possible, the inquiry proceedings will be kept confidential in order to protect the rights and privacy of all parties involved.

Whether a case can be reviewed effectively without the involvement of the complainant in the committee proceedings depends upon the nature of the allegation and the evidence available. Cases that depend specifically upon the observations or statements of the complainant cannot proceed without the involvement of that individual in the committee proceedings; other cases that can rely on documentary evidence may permit the complainant to remain anonymous to the committee.

The respondent is obligated to cooperate in providing the material necessary to conduct the inquiry and will be so informed by the committee when the inquiry is initiated. Uncooperative behavior may result in immediate implementation of a formal investigation and appropriate institutional sanctions. The respondent will be given an opportunity to comment on the allegations during the inquiry and to respond to a draft copy of the inquiry findings. If he or she comments on that report, the comments will be made part of the final inquiry record.

Inquiries should be resolved expeditiously. The inquiry phase must be completed and the final written report of the findings submitted to the Dean and Provost within 60 calendar days of initiation of the inquiry, unless circumstances clearly warrant a longer period, or within a shorter time period if required by a funding agency. If the committee anticipates that the established deadline cannot be met, it should submit to the Dean and Provost a report citing the reasons for the delay and describing progress to date; it should also inform the respondent and other involved individuals. Further, the record of inquiry must include documentation of the reason for exceeding the 60-day period.

D. Findings of the Inquiry

The completion of an inquiry is marked by a determination of whether an investigation is warranted, and by submission of the written report of the inquiry findings to the Dean and Provost. The report should state what evidence was reviewed, summarize relevant interviews, and describe the process and conclusions of the inquiry. It should be sufficiently detailed to permit a later assessment of the reasons supporting the inquiry finding. The report and all other inquiry records will be retained in the confidential and secure file in the Office of Associate Dean for Research for at least three years after the completion of the inquiry. The complainant will be informed by the committee whether or not the allegations will be subject to an investigation. The respondent will be given a copy of the final report of inquiry.

In the case of allegations found to warrant an investigation, the Dean and Provost will notify the director(s) of any funding agencies sponsoring the research in question that an investigation will be conducted (see next section). In addition, the committee will notify the respondent's department chair of the impending investigation, if the chair had not previously been contacted in the context of the inquiry.

If an allegation is found to be unsupported but has been submitted in good faith, no further formal action, other than informing all parties involved in the inquiry, should be taken. The records and findings of the inquiry, including the identity of the respondent, will be held confidential to the greatest extent possible to protect the parties involved. In such cases the Southern Illinois University School of Medicine will undertake diligent efforts to protect the complainant against retaliation. Individuals engaging in acts of retaliation will be subject to disciplinary action and/or grievance proceedings.

Unsupported allegations <u>not</u> brought in good faith may lead to disciplinary action against the complainant.

Procedures for Reporting to the Funding Component

The agency sponsoring a research project in which misconduct is suspected must be notified by the Dean and Provost in writing on or before the date the investigation begins. Agency guidelines for such situations should be followed. In the case of Public Health Service grants, notification is made to the Director of the Office of Scientific Integrity (OSI), National Institutes of Health. Notification to OSI should include, at a minimum, the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the Public Health Service application or grant number(s) involved.

The Southern Illinois University School of Medicine also will notify the funding agency at any stage of the inquiry or investigation if it is ascertained that any of the following conditions exist:

- 1. There is an immediate health and/or environmental hazard involved.
- 2. There is an immediate need to protect Federal funds or equipment.
- 3. There is an immediate need to protect the interests of the person 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.
- 4. It is probable that the alleged incident is going to be reported publicly.

In the case of Public Health Service grants, if the inquiry indicates possible criminal violation, the Office of Scientific Integrity must be notified within 24 hours of obtaining the information.

Interim Administrative Action

After the Southern Illinois University School of Medicine has notified the funding agency that an investigation is warranted, or that any of the conditions listed in the preceding section exist, the agency may take interim action to protect the rights of involved parties, to protect the welfare of human or animal subjects of research, to protect Federal funds, to ensure that the purposes of Federal financial assistance are carried out, etc. Such action can range from minor restrictions, requests for assurances, or deferral of a continuation grant application all the way to suspension of the grant.

Interim administrative action also may be taken by the Southern Illinois University School of Medicine in the event that any of the conditions listed in the preceding section exist. Interim action does not constitute a finding, but is a precautionary measure necessitated by serious circumstances. The Dean and Provost may take such action when justified by the need to protect Federal funds, the health and safety of research subjects and patients, research data, records, materials or other information that may be the subject of an inquiry or investigation, or the interests of students, colleagues, or the general public. Such action can range from minor restrictions to suspension of the activities of the respondent. Interim administrative action should be taken in full awareness of how it might affect the individuals and the ongoing research within the Southern Illinois University School of Medicine.

Investigation - Step II

A. Purpose

The Misconduct in Science Committee will initiate an investigation only after it has made an inquiry finding that an investigation is warranted. An investigation is the formal examination and evaluation of all pertinent facts to determine if misconduct in science has occurred. Among other things, the investigation should look carefully at the substance of the inquiry findings and examine all relevant evidence. The investigation findings and recommendations are advisory. They will be submitted to and reviewed by the Dean and Provost, who will make the final determination on the case.

To the greatest extent possible, the investigation proceedings will be kept confidential. However, it should be noted that complete confidentiality cannot be assured during an investigation, which is a much more formal, wide-ranging proceeding than an inquiry.

B. Structure

Any committee member who has a close professional or personal affiliation with the complainant or the respondent in a given case should not participate in the investigation of that case. The committee shall request that the Dean and Provost appoint an ad hoc member to substitute for the nonparticipating member. Committee members should be unbiased, have appropriate scientific expertise for judging the issues being raised, and have no real or apparent conflicts of interest with the case being investigated, The composition of the committee may be challenged for cause by the respondent or by the complainant (if any); the chair of the committee will decide the validity of a challenge for cause. In the event the chair is challenged for cause, the Dean and Provost will decide the validity of the challenge. As in an inquiry, the committee may call in on- or off-campus consultants as necessary and appropriate to assist it in the investigation.

C. Process

Upon completing an inquiry and finding that an investigation is warranted, the Misconduct in Science Committee will submit its report to the Dean and Provost, make the campus notifications stipulated under "Inquiry," part D (respondent, complainant, department chair), and initiate the investigation within 30 calendar days of the date on which its report was submitted to the Dean and Provost.

To the extent feasible, the committee's procedures in conducting the investigation should be in compliance with any agency guidelines that must be followed if the research is supported by external funding. The investigation may consist of a combination of activities including, but not limited to:

1. Review and copying of relevant research data, proposals correspondence, memoranda of telephone calls, or memoranda to file, and other pertinent documents at the Southern Illinois University School

- 2. Review of published materials and manuscripts submitted or in preparation.
- 3. Inspection of laboratory or clinical facilities and/or materials.
- 4. Interviewing of parties with an involvement in or knowledge about the case, including both the complainant and the respondent. Complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the documentary record of the investigation.

In the course of an investigation, additional information may emerge that justifies broadening the scope of the investigation beyond the initial allegations. The respondent should be informed when significant new directions of investigation are undertaken.

The committee should notify the Dean and Provost of any major developments that could warrant interim action or that must be reported to the funding agency. In the latter case, such developments include disclosure of facts that may affect current or potential funding for the individual(s) under investigation, that may affect the health and safety of research subjects and patients or the interests of students or colleagues, or that the funding agency needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest. Significant developments during the investigation will be reported in writing by the Dean and Provost to the funding agency as necessary, in accordance with agency guidelines.

After conducting the investigation in accordance with the process outlined above, the committee will develop a preliminary report relative to whether its investigative findings indicate possible misconduct in science on the part of the respondent, and, if so, possible sanctions that are in keeping with the gravity of any misconduct. The preliminary report should include at least the following: a description of the policies and procedures under which the investigation was conducted; a description of how and from whom or where information relevant to the investigation was obtained; a specific statement of the committee's preliminary investigative findings relative to possible misconduct in science, or the lack thereof, and the basis of those findings; and a statement of the committee's recommendations for resolution of the matter, including recommended sanctions, if any, and the rationale in support thereof. All written materials and other documents forming part of the record, including interview summaries, shall be attached to the preliminary report. Tangible scientific property, e.g., slides, specimens, etc., shall be incorporated into the

report by reference and retained in the custody or control of the committee chairperson.

After the preliminary report of the investigation has been reduced to writing, a copy of the report, including all attachments, shall be provided to the respondent for the purpose of affording him or her the opportunity to respond. The respondent will be given at least ten (10) calendar days to respond to the preliminary report. The respondent will be informed that he or she has the right to respond in writing and to request the opportunity to appear before the committee with an adviser of choice to respond in person. Should the respondent elect to meet with the committee, he or she will be permitted to make an oral presentation to the committee and to present documentary, testimonial, and rebuttal evidence. This meeting will be recorded at the University's expense and a transcript of the meeting will be made available to the respondent at no cost.

Following the conclusion of any such meeting held with the respondent and after receipt of the respondent's written response to the preliminary report, the committee will have the responsibility to carefully review and consider the entire record in the matter, including the respondent's response (and related information and evidence), to conduct further investigation if necessary, and to generate a final investigative report setting forth the detailed findings of the committee (See Section II.D. below) and any recommended sanctions. The final report shall parallel the preliminary report in format, and shall include the same categories of information. It shall also include the actual text or an accurate summary of the response of the respondent.

The committee then will submit the final investigative report to the Dean and Provost. The respondent also will receive the final report of the investigation. (When there is more than one respondent, each will receive all those parts of the report that are pertinent to his or her role.) If the identity of the complainant is known to the committee, he or she should be provided with those portions of the final report that address his or her role and opinions in the investigation.

The investigation is complete when the Dean and Provost has reviewed the report, made a determination on the case, and submitted to the funding agency the final report along with a description of any sanctions to be taken by the Southern Illinois University School of Medicine. Investigations should be conducted as expeditiously as possible. An investigation ordinarily should be completed within 120 calendar days of its initiation (including submission of the final report to the funding agency). However, the nature of some cases may render the deadline difficult to meet. If the committee determines that the full process cannot be completed in 120 calendar days, it must notify the Dean and Provost of

In the case of Public Health Service grants, the following procedure will then apply: the Dean and Provost will submit to the Office of Scientific Integrity (OSI) a written request for an extension including an explanation for the delay, an interim report from the committee on its progress to date, and an estimate for the date of completion of the report and other necessary steps. Any request for extension must balance the need for a thorough and rigorous examination of the facts and the interests of the respondent and the funding agency in a timely resolution of the matter. If the request is granted, the Southern Illinois University School of Medicine will file periodic progress reports as requested by OSI. Non-Public Health Service funding agencies may have other guidelines or regulations to be followed.

If the deadline cannot be met in an investigation of research that involves no external funding, the committee should submit an interim report to the Dean and Provost.

D. Findings of the Investigation

Findings of an investigation may include the following:

- 1. A finding of misconduct in science.
- 2. A finding that no misconduct in science was committed, but serious scientific errors were discovered in the course of the investigation.
- 3. A finding that no misconduct in science or serious scientific error was committed.

The Dean and Provost will review the committee report and make a determination on the case. The section below titled "Resolution" details the follow-up action that must be taken after the determination is made.

The findings and other records of the investigation will be securely and confidentially maintained, in accordance with pertinent federal and state laws, in a file in the Office of the Associate Dean for Research.

Southern Illinois University School of Medicine will carry its investigation through to completion and will pursue diligently all significant issues. If Southern Illinois University School of Medicine anticipates terminating an inquiry or investigation for any reason without completing all requirements outlined above, a report of such planned termination, including a description of the reasons for such termination, will be sent to the funding agency.

Appeal/Final Review

The respondent may file a written appeal of the determination of the Dean and Provost with the President of Southern Illinois University in accordance with University Grievance Procedures. The appeal should be filed within 30 calendar days after the date of the Dean and Provost's notification of his determination in this matter. (A time extension, where there is appropriate justification, may be requested of the President.) The appeal should be restricted to the body of evidence already presented, and the grounds for appeal should be limited to failure to follow appropriate procedures in the investigation or arbitrary and capricious decision-making. New evidence may warrant a new investigation, in which case the President may reconvene the Committee or take other appropriate action.

If the decision of the President affirms the determination of the Dean and Provost, the respondent may submit an application for appeal to the Board of Trustees, in accordance with the requirements of the Board's Bylaws. The decision of the Board review is final.

Resolution

A. Finding of No Misconduct in Science.

All persons and agencies/organizations informed of the investigation must be notified promptly of a finding of no misconduct in science. Notification will be made by the Dean and Provost. The Dean and Provost will undertake diligent efforts, as appropriate, to restore the reputation of the respondent when there is a finding of no misconduct in science.

If the unsubstantiated allegations of misconduct in science are found to have been maliciously motivated, appropriate disciplinary action may be taken. If the allegations, however incorrect, are found to have been made in good faith, no disciplinary measures will be taken and efforts will be made to prevent retaliatory actions and to restore the reputation of the person so accused.

B. Finding of No Misconduct in Science, But Finding of Serious Scientific Error.

All persons and agencies/organizations informed of the investigation must be notified promptly of the finding of no misconduct in science. Notification will be made by the Dean and Provost.

The Southern Illinois University School of Medicine, however, will need to consider means to correct the scientific record. In the event that the committee discovers serious scientific errors, it will include in its final report specific recommendations for action, such as notifying editors of journals in which the respondent's research was published, other institutions with which the respondent

licensing boards (if applicable), etc. The Dean and Provost will refer these recommendations to the appropriate administrative official (department chair or higher administrator) for follow-up action.

C. Finding of Misconduct in Science.

All persons and agencies/organizations informed of the investigation must be notified promptly of the finding of misconduct in science. Notification will be made by the Dean and Provost.

In its final report, the committee should recommend specific sanctions to be imposed on the respondent(s), including the reasons therefor. Sanctions can range from a reprimand or removal from the research project to termination of employment. The Dean and Provost will then be responsible for disposition of the matter. Sanctions or other actions also may be taken by the funding agency.

The committee should also recommend necessary actions to correct the scientific record as specified in B. above.

PERIODIC REVIEW OF THIS POLICY

This policy will be reviewed annually by the Misconduct in Science Committee with a view to revising procedures based on accumulated experience.

NOTE: This document owes a substantial debt to the <u>Framework for Institutional Policies and Procedures to Deal with Fraud in Research</u>, developed by representatives of ten organizations, including the Association of American Medical Colleges, the Council on Graduate Schools, the Association of American Universities, and the National Association of State Universities and Land-Grant Colleges. The policy complies with U.S. Public Health Service requirements for grantee institutions for handling cases of alleged misconduct.

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