Pittsburg State University

Policy for Responding to Allegations of Research Misconduct

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I. Introduction

I. A. General Policy

Pittsburg State University is a comprehensive university supporting the academic functions of instruction, research and service. The PSU scholarly community is committed to advancing and preserving their academic reputation by assuring to their sponsors and to the public that their faculty and students observe the highest standards of ethical conduct in professional and personal activities. The PSU Policy on Responding to Allegations of Research Misconduct is a formal statement to guide the academic community in its internal policing of scholarly activities. **Research misconduct** is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results as well as misconduct that violates the ethical standards of any discipline within the University. It does not include honest error or honest differences in interpretations or judgments of data. The term "employee" includes any person paid by, under the control of, or affiliated with the institution, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

In an effort to consolidate the federal policy for all federal agencies regarding research misconduct (previously defined as "research misconduct" or "misconduct in science"), the Office of Science and Technology (OSTP), Executive Office of the President, published notification of final policy on December 6, 2000. This policy applies to all federally-funded research and proposals submitted to Federal agencies for research funding. The policy also establishes the scope of the Federal government's interest in the accuracy and reliability of the research record and the processes involved in its development. It consists of a definition of research misconduct and basic guidelines for the response to allegations of research misconduct. Federal agencies were given one year to implement this new policy. Previous revisions of PSU's policy adhered strictly to the U.S. Public Health Service (PHS) regulation 42 C.F.R. Part 50, Subpart A (see appendix A) and applied to any research, research-training or research-related grant or cooperative agreement with PHS. This policy has been revised to apply to PHS requirements as well as the Office of Science and Technology Policy as set forth in the Federal Register, December 6, 2000 (Volume 65, Number 235), pages 76260-76264

The scholarly community at PSU is vitally interested in preserving the best research environment for intellectual inquiry. A favorable climate can best be maintained by PSU scholars assuming that faculty and students are expected to always act in a professional manner by recognizing that among reasonable people actions are subject to many interpretations and that the institution should have a mechanism for hearing differing interpretations within the community. Scholars assume professional responsibility, which is a two-sided coin. One side assures that the scientist assumes responsibility for the total conduct of their work with no supervision for their independent research expertise and professional integrity is sufficient to guide their work. The other side of professionalism requires all

members of the academy to be self-policing. Self-policing is a difficult but necessary obligation to one's discipline that requires every professional to report perceived violations of professional ethics. This reporting of a perceived violation of professional ethics is commonly called “whistleblowing.” Once an alleged violation is reported it is the duty of the University to assure that a fair inquiry into the controversial matter is held.

The PSU Policy for Responding to Allegations of Research Misconduct provides the institutional framework for assuring that allegations of misconduct are investigated in a timely fashion and that whistleblower (complainant)s are protected in performing their duty to report possible instances of research misconduct and that respondents accused of misconduct are given an open and fair hearing.

B. The Presumption of Innocence

As in many legal matters, once a person is accused of some misconduct or crime the accused has a right (1) to know the accusation, (2) to have access to the formal charges (3) to the discovery of evidence, (4) to be afforded (the respondent and whistleblower (complainant)) confidential treatment to the maximum extent possible, and (5) to be presumed innocent of the charges until the recommendations of the Investigating Committee determine otherwise.

C. Scope

This policy and the associated procedures apply to all individuals at Pittsburg State Unverisity engaged in research that is supported by or for which support is requested from any federal, state or private sponsor. In the case the research is supported by the U.S. Public Health Service (PHS), the PHS regulation 42 C.F.R. Part 50, Subpart A (see appendix A) applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to 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 Pittsburg State University.

The policy and associated procedures will normally be followed when an institutional official receives an allegation of possible misconduct in science. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of Pittsburg State Unverisity and the supporting Federal agency. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Research Integrity Officer of Pittsburg State University.

II. Definitions

A. *Allegation* means any written or oral statement or other indication of possible research misconduct made to an institutional official.

B. *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.

C. *Deciding Official* means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. At Pittsburg State Unverisity the deciding official will be the Vice President for Academic Affairs.

D. *Employee* means, for the purpose of these instructions only, any person paid by, under the control of, or affiliated with the institution, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

E. *Fabrication* is making up data or results and recording or reporting them as well as 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.

F. *Good faith allegation* means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is knowingly false or made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

G. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

H. *Institutional counsel* means legal counsel who represents the institution during the research misconduct inquiry and investigation and who is responsible for advising the Research Integrity Officer, the inquiry and investigation committees, and the Deciding Official on relevant legal issues. The institutional counsel does not represent the respondent, the whistleblower (complainant), or any other person participating during the inquiry, investigation, or any follow-up action, except the institutional officials responsible for managing or conducting the institutional research misconduct process as part of their official duties.

I. *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

J. *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 research misconduct and research integrity activities of the U.S. Public Health Service.

K. *PHS* means the U.S. Public Health Service, an operating component of the DHHS.

L. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

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

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

O. *Research* 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.

P. *Research misconduct* means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

Q. *Research Integrity Officer* means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. At Pittsburg State Unverisity the Research Integrity Officer will be the Assistant to the President and Legislative Liaison.

R. *Research record* means any data or results that embody the facts resulting from scientific inquiry, and includes, but is not limited to documents, computer files, computer diskettes, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

S. *Respondent* means the person against whom an allegation of research 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.

T. *Retaliation* means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation

U. *Research misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the relevant research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

V. *Whistleblower (Complainant)* means a person who makes an allegation of research misconduct.

III. Rights and Responsibilities

A. Research Integrity Officer

The Assistant to the President and Legislative Liaison will serve as the Research Integrity Officer (RIO). The RIO will have primary responsibility for implementation of the procedures set forth in this document. The RIO is well qualified by her/his Pittsburg State University oversight responsibilities 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 these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files for all procedural documents and evidence and for assuring the confidentiality and the security of the files.

The Research Integrity Officer will report to ORI as required by regulation and keep sponsors apprised of any developments during the course of the inquiry or investigation that may affect current or potential sponsor funding for the individual(s) under investigation or that the sponsor needs to know to ensure appropriate use of Federal or private funds and otherwise protect the public and sponsor interest.

B. Whistleblower (Complainant)

The whistleblower (complainant) will have an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. Also, if the Research Integrity Officer has determined that the whistleblower

(complainant) may be able to provide pertinent information on any portions of the draft report, these portions will be given to the whistleblower (complainant) for comment.

The whistleblower (complainant) is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation committee.

C. Respondent

The respondent will be informed in writing within 3 days of an official filing 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 and presence of counsel at all meetings.

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

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the whistleblower (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, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

E. Inquiry Hearing Committee

The Inquiry Hearing Committee will be composed of five full-time, tenured faculty who will elect their own chairperson. The chairperson will be responsible for scheduling the inquiry, contacting all parties involved, chairing the Inquiry and the deliberations and writing the findings of the committee. Each committee member will have one vote. The Research Integrity Officer will serve as an ex officio member and the Office of Continuing and Graduate Studies will provide any assistance needed by the Inquiry Committee.

1. For each specific Inquiry Hearing Committee, the five faculty members will be selected as follows:

    a. Using random selection procedures, thirteen names will be selected from the potential pool of those that are tenured, full-time faculty eligible for this inquiry procedure.

b. A representative of the respondent and a representative selected by the whistleblower (complainant) will establish necessary ground rules in accordance with the intent of this policy, select the names for the committee (using the procedure described in III.E.1.a), orient committee members as appropriate and make determinations on any challenges for cause of committee members.

c. The respondent and the whistleblower (complainant) will each have the prerogative of striking four names from among the names generated in the procedure described in III.E.1.a. The respondent will strike the first name. If more than one individual is charged with misconduct, the individuals involved will act as one in striking the names.

d. In the event a committee member is eliminated through a challenge for cause or is disqualified for any reason, three more names will be chosen by random number selection procedure from the potential pool of those eligible. The respondent and the whistleblower(s) (complainant) will each strike one name from the list.

e. A faculty member will not be selected for two Inquiry Hearing Committees that will be operating during the same period of time.

f. In the event the Inquiry Hearing Committee is unable to reach a decision, the Committee will be dissolved and the process described in III.E.1.a will be reinitiated. No member from the first Inquiry Hearing Committee will be eligible to serve on the Investigation Committee.

g. No restraining, coercive, discriminatory, or retaliatory action of any type will be taken against an employee by any supervisor because of the employee's desire to initiate or participate in an inquiry.

h. All parties shall recognize a mutual professional obligation to keep discussions confidential during the procedural stages of a grievance. Records of the inquiry procedures will be kept separate from the personnel files, but all the documents must be readily available to proper authority and the parties.

F. Investigation Committee

The Investigation Hearing Committee will be composed of five individuals who may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. The Investigation Hearing Committee will elect its own chairperson. Individuals appointed to the previous Inquiry Committee may not serve on the Investigation Committee. The Investigation 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

allegations, interview the principals and key witnesses, and conduct the investigation. The chairperson will be responsible for scheduling the inquiry, contacting all parties involved, chairing the Investigation and the deliberations and writing the findings of the committee. Each committee member will have one vote. The Research Integrity Officer will serve as an ex officio member and the Office of Continuing and Graduate Studies will provide any assistance needed by the Investigation Committee.

1. For each specific Investigation Hearing Committee, the five faculty members will be selected as follows:

    a. Using random selection procedures, thirteen names will be selected from the potential pool of those that are eligible for this inquiry procedure.

    b. A representative of the respondent and a representative selected by the whistleblower (complainant) will establish necessary ground rules in accordance with the intent of this policy, select the names for the committee (using the procedure described in IV.F.1.a), orient committee members as appropriate and make determinations on any challenges for cause of committee members.

    c. The respondent and the whistleblower (complainant) will each have the prerogative of striking four names from among the names generated in the procedure described in IV.F.1.a. The respondent will strike the first name. If more than one individual is charged with misconduct, the individuals involved will act as one in striking the names.

    d. In the event a committee member is eliminated through a challenge for cause or is disqualified for any reason, three more names will be chosen by random number selection procedure from the potential pool of those eligible. The respondent and the whistleblower(s) (complainant) will each strike one name from the list.

    e. A faculty member will not be selected for two Hearing and Investigation Committees that will be operating during the same period of time.

    f. In the event the Investigation Hearing Committee is unable to reach a decision, the Committee will be dissolved and the process described in IV.F.1.a will be reinitiated. No member from the Inquiry Hearing Committee will be eligible to serve on the Investigation Committee.

    g. No restraining, coercive, discriminatory, or retaliatory action of any type will be taken against an employee by any supervisor because of the employee's desire to initiate or participate in an inquiry.

h. All parties shall recognize a mutual professional obligation to keep discussions confidential during the procedural stages of a grievance. Records of the inquiry procedures will be kept separate from the personnel files, but all the documents must be readily available to proper authority and the parties.

IV. General Policies and Principles

A response to an allegation of research misconduct consists of several phases. The first phase is the inquiry, the assessment of whether the allegation has substance and if an investigation is warranted. The second phase is the 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. The final phase is adjudication, during which recommendations are reviewed and appropriate corrective actions are determined.

A. Responsibility to Report Misconduct

All employees or individuals associated with Pittsburg State Unverisity 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 research misconduct, he or she may call the Research Integrity Officer at (620) 235-4102 to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research 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.

B. Protecting the Whistleblower (Complainant)

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 whistleblower (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 whistleblower (complainant) will be advised that if the matter is referred to an investigation committee and the whistleblower's (complainant) testimony

is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

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

The Research Integrity Officer will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Confidentiality

Institutional employees who make, receive, or learn of an allegation of research misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the whistleblower (complainant), the respondent, and other affected individuals. The Research Integrity Officer may establish reasonable conditions to ensure the confidentiality of such information.

E. 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.

F. Preliminary Assessment of Allegations

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

V. Conducting the Inquiry

A. 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, involve sponsor support, and falls under the Federal, state or private definitions of research 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, whistleblower (complainant), and key witnesses to determine whether there is sufficient evidence of possible research 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**.

B. Sequestration of the Research Records

After determining from the Inquiry that an allegation falls within the definition of misconduct in science and involves outside funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with the sponsor for advice and assistance in this regard.

C. 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 will be five full-time, tenured faculty who will elect their own chairperson. The Research Integrity Officer will notify the respondent of the proposed committee membership at least 10 days before the hearings beginning date. 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 from the pool of faculty.

D. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge paper for the Inquiry Committee that describes the allegations and any related issues identified during the allegation assessment. It will state that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower (complainant), and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation as required by this policy. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

At the Inquiry 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 and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The Inquiry Committee will normally interview the whistleblower (complainant), the respondent and key witnesses as well as examine 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 and institutional counsel, the committee members will decide whether there is **sufficient evidence of possible research misconduct to recommend further investigation**. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that includes the name and title of the committee members and experts (if any), the allegations, the sponsor support, 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 an 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.

B. Comments on the Draft Report by the Respondent and the Whistleblower (Complainant)

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower (complainant), if he or she is identifiable, with portions of the draft inquiry report that address the whistleblower’s (complainant) role and opinions in the investigation

1. Confidentiality

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

2. Receipt of Comments

Within 14 calendar days of their receipt of the draft report, the whistleblower (complainant) and respondent will provide their comments, if any, to the Inquiry Committee. Any comments that the whistleblower (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.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the whistleblower (complainant) in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report

The Inquiry Committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, 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.

VII. Conducting the Investigation to Determine Research misconduct

A. 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

where 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.

B. Sequestration of the Research Records or other Evidence

The Research Integrity Officer will immediately sequester any additional pertinent research records or other evidence that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records 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 Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an Investigation Committee of five members and the Committee Chair within 10 class days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable or extendable on agreement by both parties. The Investigation 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 allegations, interview the principals and key witnesses, and conduct the investigation. These five 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 inquiry committee may not serve on the investigation committee.

The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will replace the challenged member or expert with a qualified substitute from the pool of qualified faculty that is acceptable to the respondent.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and the related issue identified during the inquiry, defines research 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, whistleblower (complainant), and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

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.

2. The First Meeting

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 sponsor funding is involved, the sponsor regulations.

E. 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 provide a sufficient basis for conducting an investigation.

The investigation will normally 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 and other evidence. Whenever possible, the committee should interview the whistleblower(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded or transcribed. All other interviews should be transcribed, tape recorded, or summarized. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

Three elements must be met to establish a finding of research misconduct. One of these elements is a showing that the respondent had the requisite level of intent to commit the misconduct. The intent element is satisfied by showing that the misconduct was committed intentionally, or knowingly, or recklessly. Only one of these needs to be demonstrated to satisfy this element of a research misconduct finding.

F. Inventory of the Records

A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

G. Security and Chain of Custody

The Research Integrity Officer will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the institutional counsel.

VIII. The Investigation Report

A. Elements of the Investigation Report

The final report submitted to Pittsburg State University must 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 and recommendations of the Investigation Committee. 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.

B. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 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.

2. Whistleblower (complainant)

The Research Integrity Officer will provide the whistleblower (complainant), if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower’s (complainant) role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower’s (complainant) comments.

3. Institutional Counsel

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.

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and whistleblower (complainant), 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.

C. Rendering a Recommendation

The Investigation Committee will make a report of the investigation and render a recommendation on the findings – yes or no to the charge.

D. 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 the recommended institutional actions. 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 and will discuss the significant departures of the Deciding Officer with the investigating committee and explain those significant departures in the institution's letter of transmittal covering the report to any sponsor or state agency. The Deciding Official's explanation should be consistent with the sponsor's definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also 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 the institutional review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the whistleblower (complainant) in writing. In addition, the Deciding Official 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.

E. Transmittal of the Final Investigation Report to Sponsors and State Agencies

After the Deciding Officer's 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 and whistleblower (complainant)'s comments, to the Deciding Official, through the Research Integrity Officer for transmittal to state and federal sponsors.

F. Time Limit for Completing the Investigation Report

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 Investigation Report to the sponsor and state agencies by the RIO.

IX. Requirements for Reporting to ORI

A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the sponsor's (Federal) definition of research misconduct, and the sponsor (Federal) applications or grant number(s) involved. The Pittsburg State University Research Integrity Officer must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to the sponsor.

B. If the institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the sponsor's regulation, the Research Integrity Officer will submit a report of the planned termination to the sponsor, including a description of the reasons for the proposed termination.

C. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to the sponsor 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 ORI.

D. When Federal funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct.

When the case involves external funds, the institution cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

1. There is an immediate health 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(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;

4. It is probable that the alleged incident is going to be reported publicly; or

5. The allegation involves a public health sensitive issue, *e.g.* a clinical trial; or

6. There is a reasonable indication of possible criminal violation. In this instance, the institution must inform the sponsor within 24-hours of obtaining that information.

X. Institutional Administrative Actions

Pittsburg State University 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, after consultation with the Research Integrity Officer. The actions may include

A. Appropriate steps to correct the research record.

B. Letter(s) of reprimand.

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

D. Removal of the responsible person from the particular project, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment.

E. Restitution of funds as appropriate.

F. Referral of Non-Research Misconduct Issues

When the institution's review of the allegation identifies non-research misconduct issues, the Research Integrity Officer should refer these matters to the proper institutional or Federal office for action. Issues requiring referral are described below.

1. HHS Criminal Violations[1]

   Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General, HHS-OIG Hot line, P.O. Box 17303, Baltimore, MD 21203-7303, telephone (800) 368-5779. If the possible criminal violation is identical to the alleged research misconduct (*e.g.*, alleged false statements in a FEDERAL grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.

2. Violation of Human and Animal Subject Regulations

   Potential violations of human subject regulations should be referred to the Office of Human Research Protections, Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, Rockville, MD 20892-7507. Phone: 301-496-7005. Email: ohrp@osophs.dhhs.gov.

   Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare, National Institutes of Health, 6705 Rockledge Drive, RKL1, Suite 1050, MSC 7982, Bethesda, MD 20892-7982, Phone: 301-402-5913.

3. Violation of FDA Regulations

   Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, HFC-230 TWBK 715, Rockville, MD 20857, telephone (301) 827-0420.

4. Fiscal Irregularities

   Potential violations of cost principles or other fiscal irregularities should be referred as follows:

   i. For all NIH Agencies--Office of Management Assessment, NIH, Building 31, Room 1B05, Bethesda, MD 2089 telephone (301) 496-1361.

   ii. For all other PHS Agencies--PHS Office of Grants and Contracts,5600 Fishers Lane, Room 17A39, Rockville, MD 20857, telephone (301) 443-6630.

If there are any questions regarding the proper referral of non-research misconduct issues, the Research Integrity Officer may call the ORI Division of Research Investigations at (301) 443-5330 to obtain advice.

XI. Other Considerations

A. Termination of Institutional 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 research 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 prior to the initiation of an inquiry, but 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 allegation, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and the sponsor concurs, 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 research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Whistleblower (complainant) and Others

Regardless of whether the institution or the sponsor determines that research misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblower (complainant)s who made allegation of research 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 whistleblower (complainant), what steps, if any, are needed to restore the position or reputation of the whistleblower (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 whistleblower (complainant).

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the whistleblower (complainant)'s allegations of research 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 whistleblower (complainant).

E. Interim Administrative Actions

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

XII. Record 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 three years after completion of the case to permit later assessment of the case. The sponsor will be given access to the records upon request.

XIII. Appendix A

TITLE 42--PUBLIC HEALTH

CHAPTER 1 - PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Code of Federal Regulations
Title 42, Volume 1
Revised as of October 1, 2003

42 C.F.R. Part 50--Policies of General Applicability
Subpart A--Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Sections:

Subpart A--Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science

Authority: Sec. 493, Public Health Service Act, as amended, 99 Stat. 874-875 (42 U.S.C. 289b); Sec. 501(f), Public Health Service Act, as amended, 102 Stat. 4213 (42 U.S.C. 290aa(f)).

Source: 54 FR 32449, Aug. 8, 1989, unless otherwise noted.

§ 50.101 Applicability.
This subpart applies to each entity which applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act. It requires each such entity to establish uniform policies and procedures for investigating and reporting instances of alleged or apparent misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the PHS Act. This subpart does not supersede and is not intended to set up an alternative to established procedures for resolving fiscal improprieties, issues concerning the ethical treatment of human or animal subjects, or criminal matters.

§ 50.102 Definitions.
As used in this subpart:

Act means the Public Health Service Act, as amended, (42 U.S.C. 201, *et seq.*).

Inquiry means information gathering and initial factfinding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

Institution means the public or private entity or organization (including federal, state, and other agencies) that is applying for financial assistance from the PHS, e.g., grant or cooperative agreements, including continuation awards, whether competing or noncompeting. The organization assumes legal and financial accountability for the awarded funds and for the performance of the supported activities.

Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

Misconduct or *Misconduct in Science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the relevant

research community for proposing, conducting, or reporting research. It does not include honest error or differences in interpretations or judgments of data.

OSI means the Office of Scientific Integrity, a component of the Office of the Director of the National Institutes for Health (NIH), which oversees the implementation of all PHS policies and procedures related to research misconduct; monitors the individual investigations into alleged or suspected research misconduct conducted by institutions that receive PHS funds for biomedical or behavioral research projects or programs; and conducts investigations as necessary.

OSIR means the Office of Scientific Integrity Review, a component of the Office of the Assistant Secretary for Health, which is responsible for establishing overall PHS policies and procedures for dealing with misconduct in science, overseeing the activities of PHS research agencies to ensure that these policies and procedures are implemented, and reviewing all final reports of investigations to assure that any findings and recommendations are sufficiently documented. The OSIR also makes final recommendations to the Assistant Secretary for Health on whether any sanctions should be imposed and, if so, what they should be in any case where research misconduct has been established.

PHS means the Public Health Service, an operating division of the Department of Health and Human Services (HHS). References to PHS include organizational units within the PHS that have delegated authority to award financial assistance to support scientific activities, e.g., Bureaus, Institutes, Divisions, Centers or Offices.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved may be delegated.

§ 50.103 Assurance - Responsibilities of PHS awardee and applicant institutions.

(a) *Assurances*. Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant:

(1) Has established an administrative process, that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and

(2) Will comply with its own administrative process and the requirements of this Subpart.

(b) *Annual Submission*. An applicant or recipient institution shall make an annual submission to the OSI as follows:

(1) The institution's assurance shall be submitted to the OSI, on a form prescribed by the Secretary, as soon as possible after November 8, 1989, but no later than January 1, 1990, and updated annually thereafter on a date specified by OSI. Copies of the form may be requested through the Director, OSI.

(2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.

(c) *General Criteria*. In general, an applicant institution will be considered to be in compliance with its assurance if it:

(1) Establishes, keeps current, and upon request provides the OSIR, the OSI, and other authorized Departmental officials the policies and procedures required by this subpart.

(2) Informs its scientific and administrative staff of the policies and procedures and the importance of compliance with those policies and procedures.

(3) Takes immediate and appropriate action as soon as misconduct on the part of employees or persons within the organization's control is suspected or alleged.

(4) Informs, in accordance with this subpart, and cooperates with the OSI with regard to each investigation of possible misconduct.

(d) *Inquiries, Investigations, and Reporting--Specific Requirements*. Each applicant's policies and procedures must provide for:

(1) Inquiring immediately into an allegation or other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

(2) Protecting, to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

(3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

(4) Notifying the Director, OSI, in accordance with § 50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in § 50.104(b) exist.

(5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department's Office of Inspector General.

(6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorize HHS personnel.

(7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to

relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

(8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

(9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

(10) Preparing and maintaining the documentation to substantiate the investigation's findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution's findings.

(11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purpose of the Federal financial assistance are carried out.

(12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

(13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

(14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

(15) Notifying the OSI of the final outcome of the investigation.

§ 50.104 Reporting to the OSI.

(1) An institution's decision to initiate an investigation must be reported in writing to the Director, OSI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved. Information provided through the notification will be held in confidence to the extent permitted by law, will not be disclosed as part of the peer review and Advisory Committee review processes, but may be used by the Secretary in making decisions about the award or continuation of funding.

(2) An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report

available for comment by the subjects of the investigation, and submitting the report to the OSI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation.

(3) Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements under 50.103(d), a report of such planned termination, including a description of the reasons for such termination, shall be made to OSI, which will then decide whether further investigation should be undertaken.

(4) The final report submitted to the OSI must describe the policies and procedures under which the investigation was conducted, how and from whom information was obtained relevant to the investigation, the findings, and the basis for the findings, and 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 taken by the institution.

(5) If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the OSI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the OSI. If satisfactory progress is not made in the institution's investigation, the OSI may undertake an investigation of its own.

(6) Upon receipt of the final report of investigation and supporting materials, the OSI will review the information in order to determine whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness and competence. The OSI may then request clarification or additional information and, if necessary, perform its own investigation. While primary responsibility for the conduct of investigations and inquiries lies with the institution, the Department reserves the right to perform its own investigation at any time prior to, during, or following an institution's investigation.

(7) In addition to sanctions that the institution may decide to impose, the Department also may impose sanctions of its own upon investigators or institutions based upon authorities it possesses or may possess, if such action seems appropriate.

(b) The institution is responsible for notifying the OSI if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exist:

(1) There is an immediate health 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(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;

(4) It is probable that the alleged incident is going to be reported publicly.

(5) There is a reasonable indication of possible criminal violation. In that instance, the institution must inform OSI within 24 hours of obtaining that information. OSI will immediately notify the Office of the Inspector General.

§50.105 Institutional compliance.

Institutions shall foster a research environment that discourages misconduct in all research and that deals forthrightly with possible misconduct associated with research for which PHS funds have been provided or requested. An institution's failure to comply with its assurance and the requirements of this subpart may result in enforcement action against the institution, including loss of funding, and may lead to the OSI's conducting its own investigation.

XIV. Appendix B

FEDERAL REGISTER

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Research Misconduct Policy
65 CFR 76260
December 6, 2000
Pages 76260-76264

[Federal Register: December 6, 2000 (Volume 65, Number 235)]
[Notices]
[Page 76260-76264]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr06de00-72]

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Executive Office of the President; Federal Policy on Research Misconduct; Preamble for Research Misconduct Policy
AGENCY: Office of Science and Technology Policy.
ACTION: Notification of Final Policy.

SUMMARY: The Office of Science and Technology Policy (OSTP) published a request for public comment on a proposed Federal research misconduct policy in the October 14, 1999 Federal Register (pp. 55722-55725). OSTP received 237 sets of comments before the public comment period closed on December 13, 1999. After consideration of the public comments, the policy was revised and has now been finalized. This notice provides background information about the development of the policy, explains how the policy has been modified, and discusses plans for its implementation.

EFFECTIVE DATE: December 6, 2000.

FOR FURTHER INFORMATION CONTACT: Holly Gwin, Office of Science and Technology Policy, Executive Office of the President, Washington, DC 20502. Tel: 202-456-6140; Fax: 202-456-6021; e-mail: hgwin@ostp.eop.gov.

SUPPLEMENTARY INFORMATION: Advances in science, engineering, and all fields of research depend on the reliability of the research record, as do the benefits associated with them in areas such as health and national security. Sustained public trust in the research enterprise also requires confidence in the research record and in the processes involved in its ongoing development. For these reasons, and in the interest of achieving greater uniformity in Federal policies in this area, the National Science and Technology Council (NSTC) initiated discussions in April 1996 on the development of a research misconduct policy. The Office of Science and Technology Policy (OSTP) provided leadership and coordination. The NSTC approved the proposed draft policy in May 1999, clearing the way for the October 14, 1999 Federal Register notice. Public comments in response to that notice have been reviewed. The purpose of this notice is to provide information about the policy as it has now been finalized.

This policy applies to federally-funded research and proposals submitted to Federal agencies for research funding. It thus applies to research conducted by the Federal agencies, conducted or managed for the Federal government by contractors, or supported by the Federal government and performed at research institutions, including universities and industry.

The policy establishes the scope of the Federal government's interest in the accuracy and

reliability of the research record and the processes involved in its development. It consists of a definition of research misconduct and basic guidelines for the response of Federal agencies and research institutions to allegations of research misconduct.

The Federal agencies that conduct or support research will implement this policy within one year of the date of publication of this notice. An NSTC interagency research misconduct policy implementation group has been established to help achieve uniformity across the Federal agencies in implementation of the research misconduct policy. In some cases, this may require agencies to amend or replace extant regulations addressing research misconduct. In other cases, agencies may need to put new regulations in place or implement the policy through administrative mechanisms.

The policy addresses research misconduct. It does not supersede government or institutional policies or procedures for addressing other forms of misconduct, such as the unethical treatment of human research subjects or mistreatment of laboratory animals used in research, nor does it supersede criminal or other civil law. Agencies and institutions may address these other issues as authorized by law and as appropriate to their missions and objectives.

Summary of Comments

The Office of Science and Technology Policy received 237 comments on the proposed Federal Research Misconduct Policy. Letters were signed by individuals, and by representatives of universities, university associations, Federal agencies, and private entities. Comments are available for review. Comments that resulted in a modification of the policy are summarized below. A section that addresses other questions raised by the comments follows the summary of modifications.

Uniform Federal Policy

Issue: Many comments recommended various mechanisms to ensure uniform implementation of this policy.
Response: An NSTC research misconduct policy implementation group has been formed to foster uniformity among the agencies in their implementation of the policy.

Section I: Research Misconduct Defined

Issue: A number of comments suggested that the definition of fabrication be modified to read as follows: ``Fabrication is making up data or results and recording or reporting them." (Italicized words are suggested addition.) This change is to clarify that the raw data collected or generated in the research process can be fabricated just as can the results of the research.

Response: This change was accepted.
Issue: A number of commenters interpreted the definition of plagiarism to imply that using material gathered during the peer review process was acceptable as long as it is cited.

Response: The policy is intended to address the problem of reviewers who take material from the peer review process and use it without attribution. This constitutes plagiarism. We have deleted the phrase ``including those obtained through confidential review of others' research proposals and manuscripts'' to avoid any appearance of condoning a breach of confidentiality in the peer review process.

Issue: Despite general support for the rationale for the phrase ``does not include honest error or honest differences of opinion,'' several comments requested various clarifications.

Response: This phrase is intended to clarify that simple errors or mere differences of judgment or opinion do not constitute research misconduct. The phrase does not create a separate element of proof. Institutions and agencies are not required to disprove possible ``honest error or differences of opinion.'' The phrase has been retained, with the deletion of the second ``honest'' of the phrase as redundant.

Issue: A number of comments raised questions about what fields of research are included in the definition of research. For example, some readers were unsure about the applicability of [[Page 76261]] the policy as written to medicine or the social sciences.

Response: The policy applies to research funded by the Federal agencies. In order to be responsive to specific inquiries about what fields of research are covered by the policy, an illustrative, non-exclusive list of selected fields of research is now included in the policy itself.

Section II: Findings of Research Misconduct

Issue: Several comments stressed the need for greater precision in the phrase ``significant departure from accepted practices of the scientific community.''

Response: This phrase is intended to make it clear that behavior alleged to involve research misconduct should be assessed in the context of community practices, meaning practices that are generally understood by the community but that may not be in a written form. For clarification purposes and in order to be more comprehensive, the term ``scientific community'' has been modified to read ``relevant research community.'' The policy is not intended to ratify those ``accepted practices'' but rather to indicate that these may vary among different communities.

Issue: Several comments requested clarification regarding the level of intent that is required to be shown in order to reach a finding of research misconduct.

Response: Under the policy, three elements must be met in order to establish a finding of research misconduct. One of these elements is a
showing that the subject had the requisite level of intent to commit the misconduct. The intent

element is satisfied by showing that the misconduct was committed ``intentionally, or knowingly, or recklessly.'' Only one of these needs to be demonstrated in order to satisfy this element of a research misconduct finding.

Section III: Responsibilities of Federal Agencies and Research Institutions

Issue: Some comments indicated that this section could be incorrectly construed to require appeal of the agency misconduct finding back to the institution.

Response: The policy has been clarified to affirm that each agency should establish an appeals process for persons found by the agency to have engaged in research misconduct. The subject of the agency finding cannot appeal the agency decision back to the institution, although some institutions do offer an appeal of the institutional finding at the institutional level.

Section IV: Guidelines for Fair and Timely Procedures

Issue: The comments indicated some uncertainty about to whom the actions section applied.

Response: The actions delineated are those that may be taken by the Federal agencies if research misconduct has been shown to have occurred. The section has thus been renamed ``Agency Administrative Actions.''

Issue: The suggestion was made that publications based on false or fabricated data, or including such data, should be required to be officially withdrawn.

Response: Correction of the research record has been added to the list of possible actions to be taken if a researcher is found to have engaged in research misconduct.

Issue: The suggestion was made that safeguards for informants and subjects of allegations be made more explicit.

Response: More explicit safeguards have been added to the policy for both informants and subjects.

Other Comments

Several comments and clarifications are addressed in the following question and answer format rather than through modification of the policy.

Will agencies be required to announce the details of their implementation plans? Yes. Agencies will announce the details of their implementation plans, including those plans that do not require formal rulemaking.

What types of misconduct are covered by this policy? This policy is limited to addressing misconduct related to the conduct and reporting of research, as distinct from misconduct that occurs in the research setting but that does not affect the integrity of the research record, such as misallocation of funds, sexual harassment, and discrimination. This policy does not limit agencies or research institutions from addressing these other issues under appropriate policies, rules, regulations, or laws. In addition, should the behavior associated with research misconduct also trigger the applicability of other laws (including criminal law) this policy is not intended to limit agencies
or research institutions from pursuing these matters under separate
authorities.

Does this policy address misrepresentation of a researcher's credentials or publications? Yes, misrepresentation of a researcher's qualifications or ability to perform the research in grant applications or similar submissions may constitute falsification or fabrication in proposing research.

Are authorship disputes covered by this policy? Authorship disputes are not covered by this policy unless they involve plagiarism. Does research misconduct include the mistreatment of human subjects or animals in research? This policy addresses activity that occurs in the course of human subjects or animal research that involves research misconduct as defined by the policy. Thus, falsification, fabrication, or plagiarism that occurs during the course of human or animal research is addressed by this policy. However, other issues concerning the ethical treatment of human or animal subjects are covered under separate procedures and are not affected by this policy.

Why doesn't the policy provide immunity for research misconduct investigative committees? Providing immunity to research misconduct investigative committees and other participants in institutional and agency research misconduct proceedings would require significant statutory or regulatory initiatives which will be explored separately from this policy.

Aren't there circumstances when omission of data or results is appropriate? A number of commenters suggested that there are circumstances when it may be appropriate to omit data in reporting research results. It is not the intent of this policy to call accepted practices into question. However, the omission of data is considered falsification when it misleads the reader about the results of the research.

Does this policy supersede institutional policies regarding research misconduct? Non-federal research institutions have authority to establish policies for research and employee misconduct that serve their own institutional purposes. However, the Federal research misconduct policy (as implemented by the agencies) provides the relevant guidance to institutions for purposes of Federal action. Does this policy supersede other agency policies, procedures, rules, and regulations? Agencies must comply with all relevant Federal personnel policies and laws in responding to allegations of research misconduct. However, personnel actions may not

adequately protect the public from the consequences of falsified, fabricated or plagiarized research. For example, Federal personnel policies may permit termination of an employee who commits research misconduct, but may not address the problem of research misconduct or seek to prevent it from recurring. The administrative actions available under the Federal research misconduct policy, such as debarment from federal funding, supervision and certification of research, and correction [[Page 76262]] of the literature, are designed to specifically address the problems raised by research misconduct.
Must all three elements in the Finding of Research Misconduct section be present for there to be a finding of research misconduct? Yes.

Who makes the final determination about whether or not there is a finding of research misconduct? The Federal agency will make the final decision about whether to make an agency finding of research misconduct. However, within its own internal jurisdiction, a non-Federal research institution may establish policies and take actions as appropriate to its needs and as consistent with other relevant laws. Shouldn't the burden of proof be more stringent, e.g., require ``clear and convincing evidence'' to support a finding of research misconduct? While much is at stake for a researcher accused of research misconduct, even more is at stake for the public when a researcher commits research misconduct. Since ``preponderance of the evidence'' is the uniform standard of proof for establishing culpability in most civil fraud cases and many federal administrative proceedings, including debarment, there is no basis for raising the bar for proof in misconduct cases which have such a potentially broad public impact. It is recognized that non-Federal research institutions have the discretion to apply a higher standard of proof in their internal misconduct proceedings. However, when their standard differs from that of the Federal government, research institutions must report their findings to the appropriate Federal agency under the applicable Federal
government standard, i.e., preponderance.

Why don't the Federal agencies conduct all inquiries and investigations? Research institutions are much closer to what is going on in their own institutions and are in a better position to conduct inquiries and investigations than are the Federal agencies. While the Federal agencies could have taken on the task of investigating all allegations of research misconduct, or established a separate agency for this purpose, this would have involved a substantial new Federal bureaucracy, which is not thought desirable. An agency may take steps, as appropriate, should a research institution demonstrate a lack of commitment to the policy's guidelines.

How will a lead agency be identified? If more than one Federal agency has jurisdiction over allegations of research misconduct, those agencies should work together to designate a lead agency. What criteria will be used for selecting the research institution that will handle the response to the allegation of research misconduct? In most cases, agencies will rely on the researcher's home institution to respond to allegations of research misconduct. However, in cases where the subject has switched institutions, it may be more appropriate for the institution where the alleged research misconduct occurred to respond to the allegation. The institution where the questioned research was conducted may have better access to the evidence

and witnesses and therefore will have the capability to undertake a more efficient and thorough response.

Shouldn't the policy be more explicit about time lines for a response to allegations of misconduct? In establishing reasonable time lines the Federal agencies must balance the interests of concluding the process expeditiously while ensuring it has been conducted fairly and thoroughly. This will allow flexibility for the research institutions while at the same time ensuring that the process does not extend for an unreasonably long period. Research institutions should have the option to request reasonable extensions of agency timelines in individual cases.
What can informants or subjects of allegations expect with regard to confidentiality? The policy strives for confidentiality for all involved to the extent consistent with a fair and thorough process and as allowed by law, including applicable Federal and state freedom of information and privacy laws.

Should the policy punish informants who act in bad faith or individuals who harass informants? The principal aim of this policy is to communicate to the research community those behaviors that constitute research misconduct and to take actions where research misconduct is found to have occurred. As employers and managers of the research, non-Federal research institutions may adopt policies to address the consequences of false, malicious, or capricious allegations and to respond to retaliation against informants. Agencies may also address this issue in their implementation of this policy.
How should the ``seriousness'' of the research misconduct be evaluated and how will this relate to any actions taken? In determining what action to take, agencies should fully consider the level of intent of the misconduct, the consequences of the behavior, and other aggravating and mitigating factors.

Next Steps

The Federal agencies have up to one year from the date of publication of this notice to implement the policy. An interagency implementation group has been established under the auspices of the National Science and Technology Council to assist agencies in their implementation process and to strive for the highest level of uniformity possible and as appropriate in their implementation plans.

Federal Policy on Research Misconduct \1\

I. Research \2\ Misconduct Defined

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

\1\ No 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.

\2\ Research, 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\

\3\ The 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.

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III. Responsibilities of Federal Agencies and Research Institutions
\4\

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.

\4\ The 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.

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