

Maryland Department of Health and Mental Hygiene

Policy and Procedures

for Responding to

Allegations of Scientific Misconduct

I. Policy

This policy and the associated procedures apply to all Department of Health and Mental Hygiene's (DHMH) employees and affiliated personnel engaged in research that is supported by or for which support is requested from the Public Health Service (PHS). The PHS regulation at 42 CFR Part 50, Subpart 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 DHMH, including employees, trainees, students, fellows, guest researchers, or collaborators of DHMH.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by a DHMH official. Particular circumstances in an individual case may dictate variation from the normal procedure when deemed in the best interests of DHMH and PHS. 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 Secretary of the Department of Health and Mental Hygiene.

II. Definitions:

1. The following terms, as defined, are used within this policy:
 - a. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person or with the DHMH's interest, where potential bias may occur due to prior or existing personal or professional relationships.
 - b. *Deciding Official* refers to the Secretary of the Department of Health and Mental Hygiene or designee who shall make final determinations on allegations of scientific misconduct and any responsive DHMH actions.
 - c. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.
 - d. *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.

- e. *Office of Research Integrity (ORI)* means the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the Public Health Service.
- f. *The Research Integrity Officer* means the person responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations.
- g. *Scientific misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include good faith error or good faith differences in interpretations or judgments of data.
- h. *Whistleblower* means a person who makes an allegation of scientific misconduct.

III. STANDARDS:

1. All employees or individuals associated with DHMH shall report observed, suspected, or apparent misconduct in science to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she shall call the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer shall refer the individual or allegation to other offices or officials with responsibility for resolving the problem.
2. The Research Integrity Officer shall monitor the treatment of individuals who bring allegations of misconduct or of inadequate DHMH response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer shall ensure that these persons are not retaliated against in the terms and conditions of their employment or other status within DHMH and shall review instances of alleged retaliation for appropriate action.
3. Inquiries and investigations shall be conducted in a manner that ensures fair treatment and confidentiality to the respondent(s) and whistleblower(s) in the course of the inquiry or investigation. However, this protection shall not compromise public health and safety or preclude a thorough inquiry or investigation.
4. DHMH employees shall cooperate with DHMH's inquiries and investigations conducted under this policy.

5. Upon receiving an allegation of scientific misconduct, the Research Integrity Officer shall immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.
6. The Research Integrity Officer, following the preliminary assessment, shall determine if the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, shall immediately initiate the inquiry process. The Research Integrity Officer shall clearly identify the original allegation and any related issues that shall be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation.
7. The Research Integrity Officer, after determining that an allegation falls within the definition of misconduct in science, shall ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer shall consult with ORI for advice and assistance in this regard.
8. The Research Integrity Officer, in consultation with other DHMH officials, as appropriate, shall appoint an Inquiry Committee and Committee Chairman within 10 days of the initiation of the inquiry.
 - a. The Inquiry Committee shall 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; and
 - b. The Inquiry Committee members shall be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside DHMH.
9. The Research Integrity Officer shall prepare a charge for the Inquiry Committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation as required by the PHS regulation. At the committee's first meeting, the Research Integrity Officer shall review the charge

with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer and DHMH Counsel shall be present or available throughout the inquiry to advise the committee as needed.

10. The Inquiry Committee shall interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. Then the inquiry committee shall evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and DHMH Counsel, the Inquiry Committee shall decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation.
11. The Inquiry Committee shall prepare an Inquiry Report which shall contain the following elements:
 - a. name and title of the committee members and experts, if any;
 - b. the allegations;
 - c. a summary of the inquiry process;
 - d. a list of the research records reviewed;
 - e. summaries of any interviews;
 - f. a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and
 - g. the Inquiry Committee's determination on whether an investigation is recommended and whether any other actions shall be taken if an investigation is not recommended.
 - h. DHMH Counsel shall review the report for legal sufficiency.
12. The Research Integrity Officer shall provide the respondent with a summary of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if identifiable, with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation.
 - a. The whistleblower and respondent, within 14 calendar days of their receipt of the draft report, shall provide their comments, if any, to the inquiry committee.

- b. The whistleblower and respondent's comments shall become part of the final inquiry report and record.
 - c. The inquiry committee shall revise the report as appropriate, based on the comments received from the whistleblower and respondents.
13. The Research Integrity Officer shall transmit the final report and any comments to the Deciding Official, who shall make a determination within 60 days of the first meeting of the Inquiry Committee of whether findings from the inquiry provides sufficient evidence of possible scientific misconduct to justify conducting an investigation. Any extension of this period will be based on good cause and recorded in the inquiry file.
 14. The Research Integrity Officer shall notify both the respondent and the whistleblower 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 shall also notify all appropriate DHMH officials of the Deciding Official's decision.
 15. The purpose of the investigation shall be 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 shall 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 shall be set forth in an investigation report.
 16. The Research Integrity Officer shall immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration shall occur before or at the time the respondent is notified that an investigation has begun.
 17. The Research Integrity Officer, in consultation with other DHMH officials as appropriate, shall appoint an Investigation Committee and the Committee Chairman within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The Investigation Committee shall consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principal and key witnesses, and conduct the investigation. These individuals shall be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they

may be from inside or outside DHMH. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee.

18. The Research Integrity Officer shall notify the respondent of the proposed committee membership within 5 days. The respondent shall submit a written objection to any appointed member of the Investigation Committee or expert, the Research Integrity Officer shall determine whether to replace the challenged member or expert with a qualified substitute.
19. The Research Integrity Officer shall define the subject matter of the investigation in a written charge to the Committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge shall state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. If additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the Committee shall notify the Research Integrity Officer, who shall determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents. The Research Integrity Officer shall attend the first meeting of the Investigation Committee to review the charge to the Committee, the need for confidentiality, and the procedures the Committee shall follow. In the event that PHS funding is involved, a copy of the PHS regulations will also be provided.
20. The Investigation Committee shall 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.
21. The final report submitted to ORI must include:
 - a. a description of the policies and procedures under which the investigation was conducted;
 - b. a description of how and from whom information relevant to the investigation was obtained;
 - c. the findings with relevant explanations;
 - d. the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct; and

- e. a description of any sanctions imposed and administrative actions taken by DHMH.
22. The draft report of the Investigation Committee will be made available to the respondent, complainant, and DHMH Counsel on a confidential basis as follows:
- a. The respondent shall be allowed 7 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 shall take into account the respondent's comments in addition to all the other evidence.
 - b. The Research Integrity Officer shall provide the whistleblower, if identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report shall be modified, as appropriate, based on the whistleblower's comments.
 - c. The draft investigation report shall be transmitted to the DHMH Counsel for a review of its legal sufficiency. Comments shall be incorporated into the report as appropriate.
 - d. The Research Integrity Officer shall require recipients of the draft report to sign a nondisclosure agreement.
23. Based on a preponderance of the evidence, the Deciding Official shall make the final determination whether to accept the investigation report including the findings and the recommended actions. If the Deciding Official's determination varies from that of the Investigation Committee, the Deciding Official shall explain in detail the basis for rendering a decision different from the recommendations of the Investigation Committee in the DHMH letter transmitting the report to ORI. The Deciding Official's explanation shall be consistent with the PHS definition of scientific misconduct, DHMH policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee. The Deciding Official shall 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, shall constitute the final investigation report for purposes of ORI review.
24. The Research Integrity Officer shall notify both the respondent and the complainant in writing when a final decision on the case has been reached. In addition, the Deciding Official shall determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the

work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer shall be responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies,

25. An investigation shall 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 report to the ORI.
26. The general requirements for reporting to ORI on the status of the process are:
 - a. The decision to initiate an investigation shall be reported in writing to the director, ORI, on or before the date the investigation begins. The notification shall 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 PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI 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 DHMH policies and procedures shall be explained in any reports submitted to ORI.
 - b. If DHMH plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer shall submit a report of the planned termination to ORI, including a description of the reasons for the termination.
 - c. If DHMH determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer shall submit to ORI 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 shall file periodic progress reports as requested by the ORI.
 - d. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer shall contact ORI for consultation and advice. The individual making the admission shall be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the DHMH cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

27. The Research Integrity Officer shall notify ORI at any stage of the inquiry or investigation if:
 - a. there is an immediate danger to the health of individuals or the public;
 - b. there is an immediate need to protect Federal funds or equipment;
 - c. 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;
 - d. it is probable that the alleged incident is going to be reported publicly; or
 - e. the allegation involves a public health sensitive issue, e.g. a clinical trial; or
 - f. there is a reasonable indication of possible criminal violation. In this instance, the DHMH shall inform ORI within 24 hours of obtaining that information.

28. The Deciding Official shall take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated as governed by DHMH policies and by the Personnel Rules of the State of Maryland. These actions shall include:
 - a. withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found;
 - b. disciplinary action; and
 - c. restitution of funds as appropriate.

29. Termination of the respondent's employment, either by resignation or otherwise and either before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures. In the event the respondent refuses to participate in the process after resignation, the Investigation Committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the Investigation Committee's review of all the evidence.

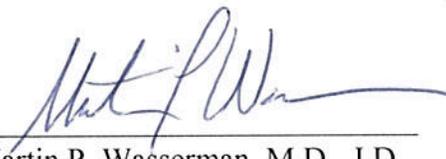
30. If DHMH finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer shall undertake reasonable efforts to restore the respondent's reputation.

31. Regardless of whether DHMH or ORI determines that scientific misconduct occurred, the Research Integrity Officer shall undertake reasonable efforts to protect the whistleblower who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an inquiry or an investigation, the Deciding Official shall determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower and the appropriate means of implementing those actions. The Research Integrity Officer shall monitor this process and report to the Deciding Official on the status of it.
32. If it is determined that an allegation was not made in good faith, the Deciding Official shall determine whether any administrative action shall be taken against the whistleblower.
33. The Deciding Official shall take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.
34. After completion of a case and all ensuing related actions, the Research Integrity Officer shall 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 shall keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized U.S. Dept of Human and Health Services personnel shall be given access to the records upon request.

Effective Date

Sept 30, 97

Approved



Martin P. Wasserman, M.D., J.D.
Secretary

Department of Health and Mental Hygiene

APPENDIX A
REGULATORY REQUIREMENTS FOR SCIENTIFIC MISCONDUCT POLICIES

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

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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 scientific community for proposing, conducting, or reporting research. It does not include honest error or honest 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 scientific misconduct; monitors the individual investigations into alleged or suspected scientific 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 scientific 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 authorized 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.

(a)(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 seem 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.

**ANNUAL REPORT ON
POSSIBLE RESEARCH MISCONDUCT**

Period Covered by this Report

January 1, 2003 to December 31, 2003

Please make any mailing changes in the space to the right: 

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INSTITUTIONAL OFFICIAL'S NAME

INSTITUTIONAL OFFICIAL'S TITLE

NAME OF INSTITUTION

MAILING ADDRESS OF INSTITUTIONAL OFFICIAL

Section I. Administrative Policy

Each institution which receives or applies for a PHS research, research-training or research-related grant or cooperative agreement must have established an administrative policy for responding to allegations of research misconduct that complies with the PHS regulation (42 CFR Part 50, Subpart A) and certify that it will comply with that policy. This regulation does not cover regulated research under the jurisdiction of the Food and Drug Administration (FDA).

- Has your institution established the administrative policy for responding to allegations of research misconduct required by the PHS regulation?
 Yes No

Section II. Types of Misconduct Activity Related to PHS Applications and Awards

- A. **PLEASE CHECK THE BOX** (to the left) if your institution has **NOT** received any allegations or conducted any inquiries or investigations of allegations during the reporting period that (1) fall under the PHS definition of research misconduct and (2) involve receipt of or requests for PHS funding, then complete Section III. Otherwise, please complete Section II.
- B. Please provide the requested information for each incident of alleged misconduct that involved a request for or receipt of PHS funds that fell within the PHS definition of research misconduct. Please note that, in accordance with section 50.103(d)(4), all investigations are to be reported to the Office of Research Integrity (ORI) before or immediately upon commencement of the investigation.

PLEASE NOTE: For each incident of alleged research misconduct resulting in an allegation, inquiry, and/or investigation at your institution: (1) provide the ORI case number, if assigned; (2) check the type of activity (allegation, inquiry, and/or investigation – may include more than one activity type for each reported incident); and (3) check the type of misconduct involved with each activity (may include more than one type of misconduct). Attach a separate sheet if additional space or clarification is required.

Do **NOT** include any alleged fiscal misconduct, human or animal subject abuses, conflicts of interest, or violations of FDA regulated research.

1. **Activity continued into 2003:**

Incident Number	ORI Case Number, if assigned	Type of Activity	Type of Misconduct			
			Fabrication	Falsification	Plagiarism	Other Serious Deviations
1.	_____	<input type="checkbox"/> Inquiry.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	_____	<input type="checkbox"/> Inquiry.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	_____	<input type="checkbox"/> Inquiry.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Continued on back

Section II. (Continued)

B. (Continued)

2. Activity begun in 2003:

Incident Number	ORI Case Number, if assigned	Type of Activity	Type of Misconduct			
			Fabrication	Falsification	Plagiarism	Other Serious Deviations
1.	_____	<input type="checkbox"/> Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	_____	<input type="checkbox"/> Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.	_____	<input type="checkbox"/> Allegation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Inquiry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/> Investigation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Section II. (Continued)

Official Certifying for Institution:

NAME OF OFFICIAL (Please type)	TITLE
SIGNATURE	DATE
TELEPHONE NUMBER ()	FAX NUMBER ()

E-MAIL ADDRESS OF OFFICIAL:

STATEMENT OF BURDEN

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Hubert H. Humphrey Building, Room 503-H, 200 Independence Avenue, S.W., Washington, D.C. 20201 (Attn: PRA) and to: Office of Management and Budget, Paperwork Reduction Project (0937-0198) Washington, D.C. 20502. *Please do not return this form to either of these addresses.*

RETURN THIS FORM TO:

Assurance Program
Office of Research Integrity
1101 Wootton Parkway, 7th Floor
Rockville, MD 20852

Phone: (301) 443-5300
FAX: (301) 594-0042

E-Mail: DBROWN@OSOPHS.DHHS.GOV

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
OFFICE OF PLANNING AND POLICY MANAGEMENT
225-6816

M E M O R A N D U M

TO: Deputy Secretaries
Program Directors
Division Chiefs
Directors/Superintendents of Facilities
Assistant Superintendents of Facilities
Local Health Officers

FROM: Adele Wilzack, R.N., M.S. *AW 5/31/90*
Secretary

DATE: June 6, 1990

SUBJECT: Investigation and Reporting of Possible Misconduct in Scientific Research

EXECUTIVE SUMMARY

The Public Health Service (PHS) Act requires that each institution or entity that applies for or receives assistance (funds) under the ACT must establish policies and procedures for investigating and reporting instances of alleged or apparent misconduct in research or research training, the application for support of research or research training or related research activities. In addition, each institution or entity that applies for federal assistance must assure the Secretary of Health and Human Services, that the applicant has established policies and procedures that meet the requirements of the Act and supporting Code of Federal Regulations (CFR).

GENERAL POLICY

DEFINITIONS

"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 the practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgements of data."

POLICY

The Department of Health and Mental Hygiene (DHMH), the "institution," shall examine, first by "inquiry" and, if warranted, by "investigation," all allegations of "misconduct" ("misconduct in science") in biomedical or behavioral research projects or programs, when the research projects are conducted by personnel of DHMH, regardless of the source of funds (i.e., Federal, State or other funds) or involve, through participation, patients/clients/students or employees of the DHMH.

The Chairperson of the Institutional Review Board (IRB) shall be the Lead Official of the Department for the inquiry and, if necessary, investigation of any allegation of misconduct in science. The Deputy Secretary for Public Health Service shall become the Lead Official in the absence of the Chairperson of the IRB or in the case of a conflict of interest involving the Chairperson of the IRB.

Allegations of "misconduct in science," from any source, shall be received by the Lead Official.

The requirements that are contained in 42 CFR Part 50, Subpart A, as revised from time to time, shall be the primary requirements in the carrying out of an "inquiry" and, if warranted, an "investigation" of allegations of "misconduct in science."

If you have any questions concerning this policy you may call Mr. Louis W. Miller, Office of Planning and Policy Management, telephone (MAR-COM) 225-6813.