DHMH POLICY

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OFFICE OF THE SECRETARY – Office of the Inspector General

DHMH POLICY 01.03.04
Effective Date: March 29, 2016

RESPONDING TO ALLEGATIONS OF SCIENTIFIC MISCONDUCT

I. EXECUTIVE SUMMARY

This policy applies to all of the Department of Health and Mental Hygiene's (the "Department") employees and affiliated personnel engaged in research that is supported by or for which support is requested from the Public Health Service. The regulation at 42 C.F.R. Part 93 applies to any research, research training or research-related grant or cooperative agreement with the Public Health Service. This policy applies to any person paid by, under the control of, or affiliated with the Department, including employees, trainees, students, fellows, guest researchers, or collaborators of the Department.

The policy will normally be followed when an allegation of possible misconduct in science is received by a Department official. Particular circumstances in an individual case may dictate variation from the normal procedure when deemed in the best interests of the Department and the Public Health Service. Any change from normal procedures must ensure fair treatment to the subject of the inquiring or investigation. Any significant variation must be approved in advance by the Secretary of the Department.

II. BACKGROUND

The Public Health Service (PHS) Act requires that each institution or entity that applies for or receives funds under the Act must establish policies and procedures for investigating and reporting instances of alleged or apparent misconduct in research or research training, applications for support of research or related research activities. In addition, each institution or entity that applies for federal funds must assure the Secretary of Health and Human Services that the applicant has established policies and procedures that meet the requirement of the Act and supporting Code of Federal Regulations (CFR). The PHS recently revised its regulations and moved the regulations governing scientific misconduct to a new section of the Code of Federal Regulations.

This policy updates the September 30, 1997 version by updating references to the CFR and changing certain terms to conform to the terminology currently used in the CFR. There have been no substantive changes to the September 30, 1997 version of the policy.

III. POLICY STATEMENTS

A. DEFINITIONS

In this policy, the following terms have the meanings indicated.

1. **"Complainant"** means a person who makes an allegation of scientific misconduct.

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

3. **"Deciding official"** refers to the Secretary of the Department of Health and Mental Hygiene, or the Secretary's designee, who shall make final determinations on allegations of scientific misconduct and any responsive Department actions.

4. **"Department"** means the Department of Health and Mental Hygiene.

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

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

7. **"Office of Research Integrity"** means the office within the United States Department of Health and Human Services that is responsible for the scientific misconduct and research integrity activities of the Public Health Service.

8. **"Respondent"** means a person accused of scientific misconduct.

9. **"Scientific misconduct"** means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, performing, or reviewing research, or in reporting results. It does not include good faith error or good faith differences in interpretations of data.

B. STANDARDS

1. All employees or individuals associated with the Department shall report observed, suspected, or apparent scientific misconduct to the Research Integrity Officer. If an individual is unsure of whether a suspected incident falls within the definition of scientific misconduct, he or she shall contact 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 responses by the Department thereto, and those who cooperate in inquiries and investigations. The Research Integrity Officer shall ensure that these persons are not retaliated against in terms and conditions of their employment or other status within the Department 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 and complainant in the course of the inquiry and investigation. However, protection shall not compromise public health and safety or preclude a thorough inquiry or investigation.

4. Department employees shall cooperate with inquiries and investigations conducted by the Department under this policy and by the Public Health Service under relevant federal regulations and policies.

C. INQUIRY

1. Upon receiving an allegation of scientific research misconduct, the Research Integrity Officer shall immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether Public Health Service Support or applications for funding are involved, and whether the allegation falls under the Public Health Service definition of research misconduct found at 42 C.F.R. §93.103.

2. The Research Integrity Officer, following the preliminary assessment, shall determine if the allegation provides sufficient information to allow specific follow-up, involves Public Health Service support, and falls under the definition of scientific misconduct, and if so, shall immediately initiate the inquiry process. The Research Integrity

Officer shall clearly identify the original allegation and any related issues that shall be evaluated.

3. 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 research misconduct to warrant an investigation.

4. The Research Integrity Officer, after determining that an allegation falls within the definition of scientific misconduct, shall ensure that all original research records and materials relevant to the allegation are immediately secured prior to or at the time of beginning an inquiry . The Research Integrity Officer shall consult with the Office of Research Integrity for advice and assistance in this regard.

5. The Research Integrity Officer, in consultation with other Department 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:

(i) Have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry;

(ii) Are unbiased; and

(iii) Do not have real or apparent conflicts of interest in the case; 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 the Department.

6. 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 research misconduct to warrant an investigation as required by Public Health Service regulations. At the committee's first meeting, the Research Integrity Officer shall review the charge with the committee, discuss the allegations and any related issues, go over the appropriate procedures for

conducting the inquiry, assist the committee with organizing a work plan for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer and Department Counsel shall be present or available throughout the inquiry to advise the committee as needed.

7. The Inquiry Committee shall interview the complainant, respondent, and key witnesses as well as examine relevant research records and materials. All testimony shall be recorded or transcribed. If testimony is transcribed, the person giving testimony shall be given the opportunity to review the transcription and make edits. The Inquiry Committee shall evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and Department Counsel, the Inquiry Committee shall decide whether there is sufficient evidence of possible scientific research misconduct to recommend further investigation.

8. The Inquiry Committee shall issue an Inquiry Report, which shall contain the following elements:

a. The name and title of each committee member;

b. The name and title of any experts consulted during the inquiry;

c. The name and position of the respondent;

d. A description of the allegations of scientific misconduct;

e. The Public Health Service support, including, for example, grant numbers, grant applications, contracts, and publications listing Public Health Service support;

f. A summary of the inquiry process;

g. A list of research records reviewed and persons interviewed;

h. Summaries of any interviews conducted; and

i. A description of the evidence in sufficient detail to demonstrate whether or not an investigation is warranted.

9. Department Counsel shall review the Inquiry Report for legal sufficiency.

10. The Research Integrity Officer shall provide the respondent with copy of the Inquiry Report for comment and rebuttal and shall provide the complainant, if identifiable, with those portions of the Inquiry Report that address the complainant's opinions and role in the investigation.

a. Within 15 days of their receipt of the draft report, the respondent and the complainant shall provide their comments, if any to the Inquiry Committee.

b. The comments of the respondent and complainant 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 respondent and complainant.

11. The Research Integrity Officer shall transmit the final Inquiry Report including all comments by the respondent and complainant to the Deciding Official, who shall make a determination within 60 days of the first meeting of the Inquiry Committee as to whether the findings from the inquiry provide sufficient evidence of possible scientific research misconduct to warrant an investigation. Any extension to this period will be based on good cause and recorded in the inquiry file.

12. The Research Integrity Officer shall notify the respondent and the complainant in writing of the Deciding Official's decision 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 Department officials of the Deciding Officer's decision.

13. Within thirty 30 of a determination that an investigation is warranted, the Research Integrity Officer shall forward a copy of the final Inquiry Report, including all comments by the respondent or complainant, to the Office of Research Integrity.

D. INVESTIVATION

1. The purpose of the investigation shall be to explore the allegations in detail, examine the evidence in depth, and determine specifically whether scientific misconduct has been committed, by whom, and to what extent.

2. 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.

3. If the Deciding Official determines that an investigation is necessary, 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.

4. An Investigation Committee shall be appointed and the investigation process initiated within 30 days of the completion of any inquiry where a determination is made that there is a sufficient basis for conducting an investigation.

5. The Research Integrity Officer, in consultation with other Department officials as appropriate, shall appoint an Investigation Committee and a committee chairman within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable.

a. The Investigation Committee shall consist of at least 3 individuals who:

(i) Have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry;

(ii) Are unbiased; and

(iii) Do not have real or apparent conflicts of interest in the case; and

b. The Investigation Committee members shall be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the Department.

c. The Research Integrity Officer may appoint individuals who served on the Inquiry Committee to serve on the Investigation Committee.

6. The Research Integrity Officer shall notify the respondent of the proposed committee membership within 5 days. Any objection to a

proposed committee member or expert shall be submitted in writing within 5 days of receipt of the notification of proposed committee membership. The Research Integrity Officer shall make the final determination on whether to replace the challenged member or expert with a qualified substitute.

7. The Research Integrity Officer shall define the subject matter of the investigation in a written charge to the Investigation Committee that describes the allegations and related issues identified during the inquiry, defines scientific research 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, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific research misconduct occurred, and if so, to what extent, who was responsible, and to what degree.

8. 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. A copy of this policy and procedure document will be provided to the committee members. In the event that Public Health Service funding is involved, a copy of the Public Health Service Regulations will also be provided.

9. If additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the Investigation 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.

10. The findings of the investigation shall be set forth in an Investigation Report.

11. The final Investigation Report must include:

a. Allegations. Describe the allegations of scientific research misconduct;

b. Public Health Service support. Describe and document the Public Health Service support including, for example, grant numbers, grant applications, contracts, and publications listing Public Health Service support;

c. Institutional Charge. Describe the specific allegations of scientific misconduct for consideration in the investigation;

d. Policies and procedures. Describe the policies and procedures under which the investigation was conducted, or include a copy of those policies and procedures as part of the report.

e. Sources of Evidence. Describe how and from whom information relevant to the investigation was obtained;

f. Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed;

g. Statement of findings. For each separate allegation of scientific misconduct identified during the investigation, provide a finding as to whether scientific misconduct did or did not occur, and if so:

i. Identify whether the scientific misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;

ii. Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;

iii. Identify the specific Public Health Service support, if any;

iv. Identify whether any publications need correction or retraction;

v. Identify the person(s) responsible for the scientific misconduct; and

vi. List any current support or known applications or proposals for support that the respondent has pending with non-Public Health Service Federal or State agencies.

h. Comments. Include and consider any comments made by the respondent and complainant on the draft investigation report; and

i. Sanctions. Describe any sanctions imposed and administrative actions taken by the Department.

12. The Research Integrity Officer shall provide the respondent with copy of the Investigation Report for comment and rebuttal and shall provide the complainant, if identifiable, with those portions of the investigation report that address the complainant's opinions and role in the investigation.

a. Within 7 days of their receipt of the draft report, the respondent and the complainant shall provide their comments, if any to the Inquiry Committee.

b. The comments of the respondent and complainant shall become part of the final Investigation Report and record.

c. The Investigation Committee shall revise the report as appropriate, based on the comments received from the respondent and complainant.

13. The Research Integrity Officer shall provide Department counsel with a copy of the draft Investigation Report for a review of its legal sufficiency.

14. The Research Integrity Officer shall require all recipients of the draft investigation report to sign a nondisclosure agreement.

15. After the draft Investigation Report has been reviewed by Department counsel, the Research Integrity Officer shall forward the Investigation Report to the Deciding Official for a final determination.

a. 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.

b. If the Deciding Officials 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 Department's letter transmitting the report to the Office of Research Integrity.

c. The Deciding Official's explanation shall be consistent with the Public Health Service definition of research misconduct, Department policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee.

d. The Deciding Official may also return the report to the Investigation Committee with a request for further fact-finding or analysis if necessary.

e. The Deciding Official's determination, together with the Investigation Committee's report, shall constitute the final investigation report for purposes of Office of Research Integrity review.

16. The Research Integrity Officer shall notify both the respondent and the complainant in writing when a final decision has been rendered.

17. The Deciding Official shall also 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.

18. An investigation shall be completed within 120 days of the first meeting of the Investigation Committee. This includes conducting the investigation, preparing the Investigation Report, making the draft investigation report available to the respondent and the complainant for comment, providing a copy of the Investigation Report to Department Counsel for review, submitting the report to the Deciding Official for a final decision, and submitting the report to the Office of Research Integrity.

19. The general requirements for reporting to the Office of Research Integrity on the status of the inquiry and investigation processes are:

a. The decision to initiate an investigation shall be reported in writing to the director of the Office of Research Integrity on or before the date the investigation begins. The notification shall include the name of the respondent against whom allegations have been made, the general nature of the allegations as the relate to the Public Health Service definition of research misconduct, and the Public Health Service applications or grant numbers involved. The Office of Research Integrity must also be notified of the final outcome of the investigation and must be provided with a copy of the final Investigation Report. Any significant variations from the provisions of Department policies

and procedures shall be explained in any reports submitted to the Office of Research Integrity.

b. If the Department plans to terminate an inquiry or investigation for any reason without completing all the relevant requirements of Public Health Service regulations, the Research Integrity Officer shall submit a report of the planned termination to the Office of Research Integrity that includes a description of the reasons for the termination.

c. If the Department determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer shall submit to the Office of Research Integrity a written request for an extension that explains the reason for the delay, reports on the progress to date, estimates the date of completion of the final Investigation Report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer shall file periodic progress reports as request by the Office of Research Integrity.

d. When Public Health Service funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer shall contact the Office of Research Integrity 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 Public Health Service funds, the Department may not accept an admission of scientific misconduct as a basis for closing a case or not undertaking a full investigation without prior approval from the Office of Research Integrity.

20. The Research Integrity Officer shall notify the Office of Research Integrity 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 respondent who is the subject of the allegations, or of the co-investigators and associates of the respondent, if any;

d. It is probably that the alleged incident is going to be reported publicly;

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 Department shall inform the Office of Research Integrity within 24 hours of obtaining that information.

21. The Deciding Official shall take appropriate administrative actions against individuals when an allegation of scientific misconduct has been substantiated as governed by Department 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 the scientific research misconduct was found;

b. Disciplinary action; and

c. Restitution of funds as appropriate.

22. Termination of the respondent's employment, either by resignation or otherwise and whether before or after an allegation of possible scientific research misconduct has been reported, will not preclude or terminate the misconduct procedures. In the even the respondent refuses to participate in the process after resignation, the Investigation Committee shall 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.

23. If the Department finds no misconduct and the Office of Research Integrity concurs, after consulting with the respondent, the Research Integrity Officer shall undertake reasonable efforts to restore the respondent's reputation.

24. Regardless of whether the Department or the Office of Research Integrity determines that scientific research misconduct occurred, the Research Integrity Officer shall undertake reasonable efforts to protect the complainant who made allegations of scientific research misconduct in good faith and others who cooperate in good faith with inquiries and investigation of such allegations. Upon completion of an inquiry or an

investigation, the Deciding Official shall determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant and the appropriate means of implementing those actions. The Research Integrity Officer shall monitor this process and report to the Deciding Official on its status.

25. If it is determined that an allegation was not made in good faith, the Deciding Official shall determine whether any administrative action will be taken against the complainant.

26. 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.

27. 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 7 years after completion of the case to permit later assessment of the case. The Office of Research Integrity or any other authorized United States Department of Health and Human Services personnel shall be given access to the records upon request.

IV. REFERENCES

- 42 U.S.C. Part 93
  https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

APPROVED:

Van T. Mitchell, Secretary

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