

A RESOLUTION TO ENDORSE THE GEORGE WASHINGTON UNIVERSITY POLICY AND PROCEDURES REGARDING ALLEGATIONS OF RESEARCH MISCONDUCT (04/5)

WHEREAS, in Resolution 03/8, adopted on March 12, 2004, the Faculty Senate expressed its support for “The George Washington University Policy and Procedures Regarding Allegations of Scientific Misconduct,” with the understanding that such Policy and Procedures would be adopted on an interim basis until final Policy and Procedures were reported favorably to the Faculty Senate by the Faculty Senate Committee on Professional Ethics and Academic Freedom (PEAF); and

WHEREAS, in adopting Resolution 03/8, the Faculty Senate was advised that the interim Policy and Procedures were required to bring the University’s sponsored research programs into compliance with regulations issued by the Office of Research Integrity (ORI) of the U.S. Public Health Service in 42 Code of Federal Regulations Part 50, Subpart A;

WHEREAS, the PEAF Committee and members of the University Administration have completed their review of the interim Policy and Procedures and have also considered proposed regulations issued by ORI in April 2004 (69 Federal Register 20777), which would make a number of amendments to 42 Code of Federal Regulations Part 50, Subpart A, as well as ORI’s model policy and procedures regarding allegations of research misconduct;

WHEREAS, the PEAF Committee and members of the University Administration have agreed that the final Policy and Procedures should reflect pending amendments proposed by ORI, so that (1) the final Policy and Procedures will be designated as “The George Washington University Policy and Procedures Regarding Allegations of Research Misconduct,” and (2) the nature of the misconduct covered therein will be defined as “research misconduct” rather than “scientific misconduct,” in order that the final Policy and Procedures will apply to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results in all fields of scholarly inquiry; and

WHEREAS, in accordance with views expressed during the Faculty Senate’s discussion of Resolution 03/8, the PEAF Committee and members of the University Administration have agreed that the final Policy and Procedures should provide persons accused of research misconduct (“respondents”) with the right to be fully advised of the nature of the charges against them and the right to be heard in connection with any informal inquiry and/or formal investigation into such charges;

WHEREAS, to provide respondents with the procedural protections referred to in the preceding paragraph, the final Policy and Procedures endorsed by the PEAFC Committee (after consultation with members of the University Administration) provide each respondent with the following additional rights that were not contained in the Interim Policy and Procedures:

- (i) the right to have the respondent's own counsel present at interviews or meetings conducted during an informal inquiry or formal investigation (Part IV.C.);
- (ii) the right to receive written notice of the initiation of an informal inquiry, including a clear identification of each allegation of research misconduct (Part V.A.);
- (iii) the option to require the University to conduct an informal inquiry by appointing a committee of at least three qualified individuals to perform the inquiry in place of the Associate Vice President for Health Research, Compliance, and Technology (Part V.D.);
- (iv) the requirement that Administration officials will consult with the following faculty representatives in designating the members of an informal inquiry committee or a formal investigation committee, and in considering any challenges by the respondent to members of those committees: (i) in all cases, the Chairs of the Faculty Senate Executive Committee and the Faculty Senate Research Committee will be consulted, and (ii) in cases where the suspected or alleged research misconduct involved a field of study in which persons associated with the Medical Center are actively engaged, the Chair of the Basic Science Faculty Assembly of the Medical Center and a faculty member designated in collaboration with the President of Medical Faculty Associates, Inc. will also be consulted (Parts V.D. and VII.C.);
- (v) the right to receive a copy of the charge given by the Associate Vice President for Health Research, Compliance, and Technology to a formal investigation committee (Part VII.D.1.);
- (vi) the requirement that the draft report prepared by a formal investigation committee must provide a detailed description of all testimony and other evidence upon which the committee intends to rely in making its findings (Part VIII.A.1.);
- (vii) the right of a respondent, before submitting comments on the investigation committee's draft report, to obtain copies of all testimonial and documentary evidence referred to in such report (Part VIII.A.1.);

- (viii) the requirement that the investigation committee's final report must provide a detailed description of the testimony and other evidence supporting the committee's findings (Part VIII.B.);
- (ix) the requirement that the Associate Vice President for Health Research, Compliance, and Technology must provide a copy of the University's final decision to the respondent (Part VIII.D.);
- (x) the requirement that any disciplinary actions taken by the University against a respondent must be consistent with the Faculty Code or the Manual of Personnel Policies for the Use of Supervisory Staff or, in the case of a student, the Guide to Student Rights and Responsibilities (Part XI);
- (xi) the requirement that, if the University finds no misconduct and ORI concurs: (A) the Administration will consider appropriate efforts, in consultation with the respondent, to address concerns relating to the respondent's reputation and public knowledge of the inquiry and/or investigation conducted by the University, including the University's publication of the final outcome in scholarly and professional journals and other appropriate forums, and (B) upon request from elected faculty representatives or other University officials, the Administration will consider additional measures to address the respondent's concerns, including consideration of interim support (ordinarily not to exceed one year) for the respondent's ongoing research activities (Part XII.B.); **NOW, THEREFORE**

BE IT RESOLVED BY THE FACULTY SENATE OF THE GEORGE WASHINGTON UNIVERSITY:

- (1) That the Faculty Senate endorses the "The George Washington University Policy and Procedures Regarding Allegations of Research Misconduct," in the form attached to this Resolution as Exhibit A; and
- (2) That the Faculty Senate understands and expects that any proposed future amendments to the attached Policy and Procedures will be presented to the Faculty Senate for its review and endorsement in keeping with the procedures leading to the adoption of Resolution 03/8 and this Resolution.

Faculty Senate Committee on Professional Ethics and Academic Freedom
January 10, 2005

Adopted, with the underlying document as amended, January 21, 2005

Adopted, as amended, January 21, 2005 pursuant to
Faculty Senate Resolution 04/5

The George Washington University
Policy and Procedures Regarding Allegations of Research Misconduct

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I. Introduction

A. General Policy

The research mission of The George Washington University is to create and synthesize knowledge at the frontiers of our understanding and to use that knowledge to address issues of increasing complexity in our world, while strengthening the necessary ties between teaching and research. In pursuing this mission, the University attempts to promote and to conform to the highest standards of ethical research and scholarly conduct.

B. Scope

This policy and the associated procedures apply to all individuals at GW engaged in research, research-training or research-related grant or cooperative agreements. More specifically, this policy applies to any person paid by, under the control of, or affiliated with GW, such as faculty, scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at or with GW.

This policy and associated procedures will normally be followed when an allegation of possible misconduct in research is received by a GW official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interests of GW and any applicable outside agency. Any change from normal procedures will maintain fair treatment to the subject of the inquiry or investigation. Any significant variation from the normal procedure set forth in this policy requires the approval of the Associate Vice President for Health Research.

II. Definition of Terms Used in this Document

- A. *Allegation* means any written or oral statement or other indication of possible research misconduct made to a GW official.
- B. *Complainant* means a person who in good faith makes an allegation of research misconduct.
- C. *Conflict of interest* means the real or apparent interference of one person's outside interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- D. *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 made with reckless disregard for, or willful ignorance of, facts that would

disprove the allegation.

- E. *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of research misconduct has substance and warrants an investigation.
- F. *Investigation* means the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a finding of research misconduct or other appropriate remedies, including administrative actions.
- G. *Investigators* means any person paid by, under the control of, or affiliated with GW, such as faculty, scientists, trainees, technicians, and other staff members, students, fellows, guest researchers, or collaborators at or with GW.
- H. *MFA Representative* means the President of Medical Faculty Associates, Inc. or, if that person is not a faculty member, a faculty member designated jointly by the President of Medical Faculty Associates, Inc. and the Associate Vice President for Health Research, Compliance, and Technology Transfer.
- I. *Medical Center-related case* means a case involving suspected or alleged research misconduct occurring in a field of study in which persons associated with the Medical Center are actively engaged.
- 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 GW 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," or as amended.
- M. *PHS support* means PHS grants, contracts, or cooperative agreements or applications therefor.
- N. *Preponderance of the evidence* means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

- O. *Research misconduct or misconduct in research* ~~means~~ includes, without limitation, fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research or in reporting research results. A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research or scholarly community; that the research misconduct be committed intentionally, knowingly, or recklessly; and that the allegation be proven by a preponderance of the evidence. It does not include honest error or honest differences in interpretations or judgments of data.
- 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.
 - Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
- P. *Research record* means any data or results that embody the facts resulting from scholarly inquiry including, but 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. "Data or results" shall be interpreted broadly to encompass all forms of scholarly information about the research at issue without regard to the type of recording or storage media, including, but not limited to, raw numbers, field notes, interviews, notebooks and folders, laboratory observations, computers and other research equipment, CD-ROMs, hard drives, floppy disks, Zip disks, back-up tapes, machine counter tapes, research interpretations and analyses, tables, slides, photographs, charts, gels, individual facts, statistics, tissue samples, reagents, and documented oral representations of research results.
- Q. *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, and, if there are multiple respondents, all references in this policy to "respondent" shall also be read in the plural as appropriate.
- R. *Retaliation* means any action that adversely affects the employment or other GW or professional status of an individual that is taken by an institution or another individual (e.g., respondent) because the first individual has in good faith made an allegation of research misconduct or of inadequate GW response thereto or has

cooperated in good faith with an investigation of such allegation.

III. Rights and Responsibilities

A. Associate Vice President for Health Research, Compliance, and Technology Transfer

The Associate Vice President for Health Research, Compliance, and Technology Transfer (hereinafter “Associate Vice President for Health Research”) will have primary responsibility for implementation of the procedures set forth in this document. The Associate Vice President for Health Research is a GW official who is qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Associate Vice President for Health Research will conduct the inquiry (except as provided in Part V.D.) and oversee the investigation committee, with consideration that necessary and appropriate expertise may be appropriate to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Associate Vice President for Health Research will maintain the confidentiality of the proceedings, consistent with this policy and other applicable policies and law. The Associate Vice President for Health Research may, in his or her discretion, be assisted in fulfilling these responsibilities.

The Associate Vice President for Health Research will assist the investigation committee and GW personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Associate Vice President for Health Research is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Associate Vice President for Health Research will be responsible for making reports and providing information to research funding sponsors in accordance with applicable laws, regulations, and research funding agreements. In particular, the Associate Vice President for Health Research will, to the extent and in the manner required by applicable law and regulations, report to ORI and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

In the event that the Associate Vice President for Health Research is unable to fulfill any of the responsibilities set forth herein for any reason, such

responsibilities will be fulfilled by the Associate Vice President for Research and Graduate Studies.

B. Complainant

The complainant will have an opportunity to be interviewed and present evidence during the inquiry and to testify before the investigation committee during the investigation, 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 Associate Vice President for Health Research has determined that the complainant may be able to provide pertinent information on any portions of the draft report; these portions will be given to the complainant for comment.

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

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed and present evidence during the inquiry and to testify before the investigation committee during the investigation, to review the draft inquiry and investigation reports and to submit comments before those documents are issued in final form.

The respondent is responsible for answering an inquiry or investigation truthfully and in good faith, maintaining confidentiality and cooperating with the conduct of an inquiry or investigation, and not retaliating against any individual. If the respondent is not found guilty of research misconduct, he or she has the right to request GW's consideration of reasonable steps to address any concerns regarding his or her reputation , as provided in Part XII(B).

D. Executive Vice President for Academic Affairs

The Executive Vice President for Academic Affairs will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Executive Vice President for Academic Affairs will consult with the Associate Vice President for Health Research or other appropriate officials and will determine whether to conduct an investigation after receipt of an inquiry report, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions.

IV. General Policies and Principles

A. Responsibility to Report Misconduct

All employees or individuals associated with The George Washington University (GW) should report observed, suspected, or apparent misconduct in research to the Associate Vice President for Health Research. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Associate Vice President for Health Research at (202-994-2995) to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of research misconduct, but do raise other legitimate concerns, the Associate Vice President for Health Research will refer the individual or allegation to other offices or officials with responsibility for addressing the concerns.

At any time, an employee may have confidential discussions and consultations about concerns of possible research misconduct with the Associate Vice President for Health Research and will be counseled about appropriate procedures for reporting allegations. The Associate Vice President for Health Research, upon request, will arrange for University counsel to provide information to employees regarding the provisions of this policy and applicable laws and regulations.

B. Protecting the Complainant

The Associate Vice President for Health Research will also be available to receive complaints regarding the treatment of individuals who bring allegations of research misconduct or of inadequate GW response thereto, and those who cooperate in inquiries or investigations. The Associate Vice President for Health Research will communicate that such persons should not be retaliated against in the terms and conditions of their employment or other status at the institution and will be available to review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Associate Vice President for Health Research.

GW is also committed to protecting the privacy of those who report misconduct in good faith to the maximum extent possible. If a complainant requests anonymity, GW will make an effort to honor the request during the allegation assessment or inquiry; however, if the matter is referred to an investigation committee and the complainant's testimony is required, anonymity will no longer be available.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that is designed to provide fair treatment to the respondent(s) in the inquiry or investigation and

confidentiality to the extent possible without compromising public health and safety or the thoroughness of the inquiry or investigation.

Individuals accused of research misconduct may, at their own expense, consult with legal counsel or a non-lawyer personal adviser (who is not a witness or University official involved or to be involved in the case) in an advisory capacity. Legal counsel and advisors will be permitted to be present at interviews or meetings conducted during an inquiry or investigation.

D. Cooperation with Inquiries and Investigations

GW Investigators have an obligation to provide relevant evidence to the Associate Vice President for Health Research or other GW officials in the conduct of inquiries or investigations into misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Associate Vice President for Health Research will promptly assess the allegation to determine whether there is sufficient evidence to warrant an inquiry and whether the allegation falls under the definition of research misconduct as set forth above.

F. Legal Counsel for University Officials and Entities

The Associate Vice President for Health Research, an informal inquiry committee (if requested by the respondent), an investigation committee, and all other University officials and entities may seek the advice and/or representation of University-provided legal counsel on any and all aspects and at any stages of this policy.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following a preliminary assessment, if the Associate Vice President for Health Research determines that the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified and falls under the definition of research misconduct as set forth above, he or she will promptly initiate an informal inquiry. The Associate Vice President for Health Research will provide written notice of the inquiry to the respondent. In initiating the inquiry, and in providing notice to the respondent, the Associate Vice President for Health Research will clearly identify the original allegation and any related issues. 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 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 will be set forth in an inquiry report.

B. Sequestration of the Research Records

After initiating an inquiry, the Associate Vice President for Health Research will ordinarily attempt promptly to secure all original research records and materials relevant to the allegation in a confidential manner.

C. Inquiry Process

The Associate Vice President for Health Research will interview the complainant, the respondent and key witnesses as well as examining relevant research records and materials. The Associate Vice President for Health Research will consider whether additional expertise, either internal or external, is appropriate to permit a proper evaluation of the relevant evidence in the inquiry. The respondent may also request that additional outside expertise be consulted. If internal or external expertise is deemed warranted, individuals with such expertise will only include those without any real or apparent conflicts of interest in the subject matter of the inquiry or any participants involved in the inquiry. The Associate Vice President for Health Research will formulate a recommendation regarding whether there is sufficient evidence of possible research misconduct to warrant further investigation. The scope of an inquiry will not include a determination of whether misconduct occurred or conducting exhaustive interviews and analyses.

D. Appointment of Inquiry Committee at the Option of the Respondent

Upon the written request of the respondent, which must be filed within five (5) business days after the respondent's receipt of notice of the inquiry, the Associate Vice President for Health Research will consult with the following: the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative, and will appoint a committee to perform the informal inquiry described in this Part V and to prepare the inquiry report described in Part VI. The Associate Vice President for Health Research will designate one member of the inquiry committee to act as the chair. The inquiry committee will 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 conduct the informal inquiry. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and

they may be from inside or outside the institution.

The Associate Vice President for Health Research will ordinarily notify the respondent of the proposed inquiry committee membership within five (5) business days of its appointment. If the respondent objects to one or more members of the inquiry committee, the respondent will submit a written objection to the Associate Vice President for Health Research, the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative. Such objection shall be submitted within five (5) business days of receipt of notification of composition of the committee. The Executive Vice President for Academic Affairs, after considering the views of the Associate Vice President for Health Research, the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative, will determine whether to replace the challenged member with a qualified substitute within five (5) business days after receipt of the written objection.

If an inquiry committee is appointed, the committee (under the direction of its chair) will be responsible for taking each of the actions related to the informal inquiry and for preparing the inquiry report that the Associate Vice President for Health Research would otherwise be required to take under Part V(C) and Parts VI(A), VI(B), VI(C)(1), and VI(D). The inquiry committee may request advice from the Associate Vice President for Health Research in carrying out its responsibilities.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report will be prepared by the Associate Vice President for Health Research that states the specific allegations, the identity of each expert or consultant who participated in the inquiry; the PHS support, if any; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in appropriate detail; and a recommendation as to whether an investigation should be conducted, and whether any other actions should be taken if an investigation is not recommended.

B. Comments on the Draft Report by the Respondent and the Complainant.

The Associate Vice President for Health Research will provide the respondent with a copy of the draft inquiry report for comment, and will provide the complainant, if he or she is identifiable and if deemed appropriate by the Associate Vice President for Health Research, with a summary of the inquiry findings for comment.

1. Confidentiality

The Associate Vice President for Health Research will establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

The complainant and respondent will provide their comments, if any, to the Associate Vice President for Health Research promptly (usually within fourteen (14) calendar days of their receipt of the draft report). Any comments that the complainant or respondent submits regarding the draft report will become part of the final inquiry report and record. Based on any timely received comments, the Associate Vice President for Health Research will revise and finalize the draft report accordingly.

C. Inquiry Decision and Notification

1. Decision by Executive Vice President for Academic Affairs

The Associate Vice President for Health Research will transmit the final report with his or her recommendations to the Executive Vice President for Academic Affairs. The Executive Vice President for Academic Affairs will make a determination of whether findings from the inquiry provide probable cause to believe that research misconduct has occurred in order to justify conducting an investigation and/or whether other actions are appropriate. The inquiry is completed when the Executive Vice President for Academic Affairs makes this determination.

2. Notification

The Associate Vice President for Health Research will notify both the respondent and the complainant in writing of the decision of the Executive Vice President for Academic Affairs as to whether to proceed to an investigation. The Associate Vice President for Health Research will also notify all appropriate GW officials of the decision.

D. Time Limit for Completing the Inquiry Report

The Associate Vice President for Health Research and Technology should ordinarily complete the inquiry and submit his or her report in writing to the Executive Vice President for Academic Affairs in no more than sixty (60) calendar days following the initiation of the inquiry, unless circumstances warrant a longer period. The respondent may request such an extension for good cause. If an inquiry takes longer than 60 days, the circumstances warranting a longer period will be entered into the records of the case and the inquiry report.

VII. Conducting an Investigation

A. Purpose of an Investigation

The purpose of an 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

If there are any additional pertinent research records that were not previously secured during the inquiry, the Associate Vice President for Health Research should promptly secure such records in a confidential manner. The need for additional sequestration of records may occur for any number of reasons, including GW'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.

C. Appointment of the Investigation Committee

The Associate Vice President for Health Research will consult the following: the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative, and will appoint an investigation committee and the committee chair following notification to the respondent that an investigation is planned. The investigation committee will consist of at least three individuals who do not have real or apparent conflicts of

interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The Associate Vice President for Health Research will ordinarily notify the respondent of the proposed committee membership within five (5) business days of its appointment. If the respondent objects to one or more members of the investigation committee, the respondent will submit a written objection to the Associate Vice President for Health Research, the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative. Such objection shall be submitted within five (5) business days of receipt of notification of composition of the committee. The Executive Vice President for Academic Affairs, after considering the views of the Associate Vice President for Health Research, the Associate Vice President for Research and Graduate Studies, the Chairs of the Executive Committee and Research Committee of the University Faculty Senate, and (in any Medical Center-related case) the Chair of the Basic Science Faculty Assembly of the Medical Center and the MFA Representative, will determine whether to replace the challenged member with a qualified substitute within five (5) business days after receipt of the written objection.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Associate Vice President for Health Research will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines 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, 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. The Associate Vice President for Health Research will provide the respondent with a copy of the charge to the committee.

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 Associate Vice President for Health Research, who will provide the respondent with

notice of any new subject matter of the investigation and will determine whether it is necessary to notify additional respondents of the commencement of an inquiry as to possible research misconduct by them.

2. The First Meeting

The Associate Vice President for Health Research will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the 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 this policy and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will ordinarily be appointed and the investigation process initiated within thirty (30) days of the completion of the inquiry by the Executive Vice President for Academic Affairs, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all relevant documentation including, as applicable, but not necessarily limited to, research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee will interview the complainant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should ordinarily be tape recorded or transcribed. All other interviews should ordinarily be transcribed, tape recorded, or summarized. For major witnesses, 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.

VIII. The Investigation Report

A. Comments on the Draft Report

1. Respondent

The Associate Vice President for Health Research will provide the respondent with a copy of the draft investigation report for comment. The draft investigation report will provide a detailed description of all testimony and other evidence upon which the investigation committee intends to rely in making its findings. Within four (4) business days after

receipt of the draft report, the respondent may submit a written request for copies of summaries or transcripts of testimony and copies of other documentary evidence cited in the draft report. The respondent will be permitted fourteen (14) business days from receipt of the draft investigation report or ten (10) business days from the receipt of requested copies of summaries or transcripts of testimony and/or copies of other documentary evidence, whichever is later, 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 will take into account the respondent's comments in addition to all the other evidence.

2. Complainant

The Associate Vice President for Health Research will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant's role and opinions in the investigation. The report will take into account, as appropriate, the complainant's comments.

3. Confidentiality

In distributing the draft report, or portions thereof, or copies of testimony or other evidence referred to therein, to the respondent and complainant, the Associate Vice President for Health Research will inform the recipient of the confidentiality under which the draft report and all such evidence are made available and may establish reasonable conditions to address such confidentiality. The recipient(s) of the draft report and all evidence made available may be requested to sign a confidentiality statement or to comply with other measures to protect the confidentiality of the draft report.

B. Elements of the Investigation Report

The final report, to be submitted to ORI only when PHS funding is involved, will describe the policies and procedures, under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, provide a detailed description of the testimony and other evidence supporting the investigation committee's findings, state the findings, and explain the basis for the findings. A finding of research misconduct requires that: (1) there be a significant departure from accepted practices of the relevant research community; and (2) the misconduct be committed intentionally, or knowingly, or recklessly; and (3) the allegation be proven by a preponderance of the evidence. 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 recommendations

for actions to redress the consequence of the misconduct, if demonstrated, in accordance with the provisions of the **Faculty Code or the Manual of Personnel Policies for the Use of Supervisory Staff** or, in the case of a student, the Guide to Student Rights and Responsibilities.

C. Transmittal of the Final Investigation Report to Executive Vice President for Academic Affairs

After comments have been received and the necessary changes have been made to the draft report, the investigation committee ~~should~~ will transmit the final report with attachments, including the respondent's and complainant's comments, to the Executive Vice President for Academic Affairs.

D. GW Review and Decision

The Executive Vice President for Academic Affairs will make the final determination whether to accept the investigation committee's report, its findings, and any recommendations, including any recommendations for actions to redress the consequence of the misconduct in accordance with the **Faculty Code** or the **Manual of Personnel Policies for the Use of Supervisory Staff** or, in the case of a student, the **Guide to Student Rights and Responsibilities**. If this determination varies from that of the investigation committee, the Executive Vice President for Academic Affairs will explain the basis for rendering a decision different from that of the investigation committee in the letter that GW will transmit with the report to ORI in cases of PHS-funded research. The explanation of the Executive Vice President for Academic Affairs will be consistent with the definition of research misconduct set forth above, the policies and procedures of GW, and the evidence reviewed and analyzed by the investigation committee. The Executive Vice President for Academic Affairs may also return the report to the investigation committee with a request for further fact-finding or analysis. The determination of the Executive Vice President for Academic Affairs, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Associate Vice President for Health Research will notify both the respondent and the complainant in writing. The Associate Vice President for Health Research shall provide a copy of the final written decision to the respondent. In addition, the Executive Vice President for Academic Affairs 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 Associate Vice President for Health Research is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

E. Time Limit for Completing the Investigation Report

An investigation ~~should~~ shall ordinarily be completed within one hundred and twenty (120) days of 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 Executive Vice President for Academic Affairs for final decision, and submitting the report to the ORI when PHS funding is involved. The Executive Vice President for Academic Affairs ~~should~~ shall ordinarily issue a final decision within thirty (30) days after receiving the investigation report.

IX. Requirements for Reporting to ORI

- A. When PHS funding is involved, GW's decision to initiate an investigation will be reported in writing to the Director of the ORI, on or before the date of the first meeting of the investigation committee. At a minimum, the notification will 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 definition of research misconduct set forth above, and the PHS applications or grant number(s) involved. ORI will also be notified of the final outcome of the investigation and will be provided with a copy of the investigation report. Any significant variations from the provisions of GW's GW policies and procedures will be explained in any reports submitted to ORI.
- B. ~~If~~ In the event that GW plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Associate Vice President for Health Research will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.
- C. In the event that GW determines that it will not be able to complete the investigation relating to PHS-funded research in one hundred and twenty (120) days, the Associate Vice President for Health Research will 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 Associate Vice President for Health Research will file periodic progress reports as requested by the ORI.
- D. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Associate Vice President for Health Research 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.

- E. The Associate Vice President for Health Research 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 that could be addressed by PHS 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, GW will ordinarily inform ORI within 24 hours of obtaining that information.

X. Requirements for Reporting to Other Agencies

The Associate Vice President for Health Research will be responsible for making reports and providing information to research funding sponsors other than DHHS in accordance with applicable laws, regulations, and research funding agreements.

XI. GW Administrative Actions

GW will take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated. If the Executive Vice President for Academic Affairs 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 Associate Vice President for Health Research. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment, provided such actions are consistent with the **Faculty Code** or **the Manual of Personnel Policies for the Use of Supervisory Staff** or, in the

case of a student, the **Guide to Student Rights and Responsibilities**;

- restitution of funds as appropriate.

XII. Other Considerations

A. Termination of GW Employment or Affiliation Prior to Completing Inquiry or Investigation

The termination of the respondent's GW employment or affiliation, 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 Associate Vice President for Health Research or the investigation committee, as appropriate, will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If GW finds no misconduct, and, after an investigation, ORI concurs, the Associate Vice President for Health Research will consider appropriate efforts, in consultation with the respondent, to address any concerns relating to the respondent's reputation and any public knowledge of the inquiry and/or investigation conducted by GW. Depending on the particular circumstances, the Associate Vice President for Health Research should consider such actions as notifying those individuals aware of or involved in the inquiry and/or investigation of the final outcome, publicizing the final outcome in forums in which the allegation of research misconduct was previously publicized or in other forums reasonably requested by the respondent (including relevant scholarly journals and publications of relevant academic or professional organizations) , and including clear reference to findings of no research misconduct in the respondent's official personnel file. Any GW actions to address the respondent's reputation may be discussed with the Executive Vice President for Academic Affairs. In response to reasonable requests from elected faculty representatives or other University officials, the Executive Vice President for Academic Affairs will give careful consideration to additional measures to address concerns of the respondent relating to the consequences of the inquiry and/or investigation conducted by GW, including consideration of interim support (ordinarily not to exceed one year) for the respondent's ongoing research activities.

C. Protection of the Complainant and Others

Regardless of whether GW or ORI determines that research misconduct occurred, the Associate Vice President for Health Research will undertake reasonable efforts to protect complainants who made allegations 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 Executive Vice President for Academic Affairs will determine, after consulting with the complainant, what steps, if any, are appropriate to protect the position or reputation of the complainant. The Associate Vice President for Health Research will be responsible for coordinating such steps, in consultation with the Executive Vice President for Academic Affairs. The Associate Vice President for Health Research will also take appropriate steps during the inquiry and investigation to prevent any known or reasonably suspected retaliation against the complainant.

D. Allegations Not Made in Good Faith

If relevant, the Associate Vice President for Health Research will determine whether the complainant's allegations of research misconduct were made in good faith. If an allegation was not made in good faith, the Associate Vice President for Health Research will determine whether any administrative action should be taken against the complainant.

E. Interim Administrative Actions

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

XIII. Record Retention

After completion of a case and all ensuing related actions, the Associate Vice President for Health Research will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to ~~the~~ him or her or to the investigation committee. The Associate Vice President for Health Research ~~and Technology~~ will keep the file for seven years after completion of the case or the completion of any PHS proceeding involving the research misconduct allegation, whichever is later. ORI or other authorized DHHS personnel will be given access to the records upon request, for cases related to PHS funding.

Resources:

- Federal Policy on Research misconduct—www.ostp.gov/html/001207_3.htm
- Model Policy for Responding to Allegations of Research misconduct –<http://ori.dhhs.gov>
- PHS Regulations—42 CFR 50.101 et seq.
- PHS Proposed Rules, Federal Register, Vol. 69, No. 74