AGENDA

1. Call to order

2. IN MEMORIAM:

   David Lynn Atkins, Professor Emeritus of Biology
   Stefan Otto Schiff, Professor Emeritus of Zoology and of Genetics

3. Approval of the minutes of the regular meeting of February 13, 2004, as distributed

4. Resolutions:

   A RESOLUTION TO AMEND THE POLICY ON SCIENTIFIC MISCONDUCT (03/8);
   Professor William J. Briscoe, Chair, Faculty Senate Committee on Research
   (Resolution 03/8 is attached)

5. Introduction of Resolutions

6. Annual Report on the College of Professional Studies: Executive Vice President for
   Academic Affairs Donald R. Lehman

7. Update on the School of Public Policy: Vice President Lehman

8. General Business:

   (a) Nominees for election to the Nominating Committee for the Executive
       Committee for the 2004-05 Session: Professor Gary L. Simon (SMHS), Convener;
       Professors Mary M. Cheh (GWLS), Kurt J. Darr (SPHHS), Salvatore F. Divita
       (SBPM), Robert J. Harrington (SEAS), Sylvia A. Marotta (GSEHD), Joseph Pelzman
       (ESIA), and Lilien F. Robinson (CCAS)

   (b) Report of the Executive Committee: Professor Lilien F. Robinson, Chair

9. Brief Statements (and Questions)

10. Adjournment
WHEREAS, The George Washington University has a responsibility to itself and to the federal government and other sponsors of its research to promote and conform to the highest standards of ethical scientific conduct; and

WHEREAS, the Office of Research Integrity (ORI) of the Department of Health and Human Services undertook a review of the University’s “Misconduct in Research Policy” dated February 8, 1991 (amended to agree with Faculty Senate Resolution (90/11) passed February 8, 1991) and determined that the policy does not comply with federal regulation (42 CFR Part 50, Subpart A) and that, in order to remain eligible for PHS funding, the University would need to revise its administrative policy for handling allegations of scientific misconduct within 30 days; and

WHEREAS, a new policy patterned closely after ORI’s model policy was submitted to ORI in November, 2003, with the understanding that it still needed to be approved within the University; and

WHEREAS, ORI responded that the revised policy was an appropriate response and offered only minor changes, which have been incorporated in the draft; NOW, THEREFORE

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

That the Faculty Senate supports the proposed policy, “The George Washington University Policy and Procedures Regarding Allegations of Scientific Misconduct.”

Faculty Senate Committee on Research
February 6, 2004
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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 scientific 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. 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 science 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. **Definitions**

A. *Allegation* means any written or oral statement or other indication of possible scientific misconduct made to a GW official.

B. *Complainant* means a person who makes an allegation of scientific 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 scientific 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 scientific misconduct warrants an investigation.

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

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

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

J. PHS regulation means the Public Health Service regulation establishing standards for GW inquiries and investigations into allegations of scientific 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."

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

L. Scientific misconduct or misconduct in science means fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research or in reporting research results, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. 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.
M. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

N. *Respondent* means the person against whom an allegation of scientific 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.

O. *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 scientific 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**

The 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 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 attempt to 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 by the Assistant Vice President for Research Compliance and Technology Transfer 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, 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.

B. Complainant

The complainant will have an opportunity to be interviewed by and present evidence to the Associate Vice President for Health Research 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 by and present evidence to the Associate Vice President for Health Research during the inquiry and to testify before the investigation committee during the investigation, to review the draft inquiry and investigation reports.

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 scientific misconduct, he or she has the right to receive reasonable GW assistance to address any damage to his or her reputation caused directly by The George Washington University.

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 science to the Associate Vice President for Health Research. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Associate Vice President for Health Research or the Assistant Vice President for Research Compliance and Technology Transfer at (202-994-2995) to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, but do raise other legitimate concerns, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 scientific misconduct with the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer and will be counseled about appropriate procedures for reporting allegations.

B. Protecting the Complainant

The Associate Vice President for Health Research and Assistant Vice President for Research Compliance and Technology Transfer will also be available to receive complaints regarding the treatment of individuals who bring allegations of
scientific misconduct or of inadequate GW response thereto, and those who cooperate in inquiries or investigations. The Associate Vice President for Health Research and Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer.

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 scientific 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 not be permitted to be present at interviews or meetings conducted during an inquiry or investigation unless the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer authorizes such presence in writing.

D. Cooperation with Inquiries and Investigations

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

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and
Technology Transfer 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 scientific misconduct as set forth above.

F. Legal Counsel

The Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer, 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. The respondent may have the advice of counsel, at the respondent’s own expense.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following a preliminary assessment, if the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer determines that the allegation provides sufficient information to warrant an inquiry and falls under the definition of scientific misconduct as set forth above, he or she will promptly initiate an informal inquiry. In initiating the inquiry, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 scientific 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 and or Assistant Vice President
for Research Compliance and Technology Transfer or their designees 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 or Assistant Vice President for Research Compliance and Technology Transfer will consider whether additional expertise, either internal or external, is appropriate to permit a proper evaluation of the relevant evidence in the inquiry. 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 or Assistant Vice President for Research Compliance and Technology Transfer will formulate a recommendation regarding whether there is sufficient evidence of possible scientific 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.

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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer, with a summary of the inquiry findings for comment.

1. Confidentiality
The Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer will transmit the final report with his or her recommendations to the Executive Vice President for Academic Affairs, who will make a determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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. 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or the Assistant Vice President for Research Compliance and Technology Transfer, in consultation with other GW officials as appropriate, 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 or the Assistant Vice President for Research Compliance and Technology Transfer will ordinarily notify the respondent of the proposed committee membership within five (5) business days of its appointment. If the respondent submits a written objection to any appointed member of the investigation committee or expert within five (5) business days of receipt of notification of composition of the committee, the Executive Vice President for Academic Affairs will determine whether to replace the challenged member or expert with a qualified substitute within five (5) days of 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 scientific 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, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer will provide the respondent with a copy of the draft investigation report for comment. The respondent will be permitted fourteen (14) business days from receipt 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 or Assistant Vice
President for Research Compliance and Technology Transfer 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, to the respondent and complainant, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to address such confidentiality. The recipient(s) of the draft report 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, state the findings, and explain the basis for the findings. A finding of scientific 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 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 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 scientific 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 or Assistant Vice President for Research Compliance and Technology Transfer will notify both the respondent and the complainant in writing. 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 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.

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 scientific 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 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer will 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 Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer 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. GW Administrative Actions

GW will take appropriate administrative actions against individuals when an allegation of scientific 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 or Assistant Vice President for Research Compliance and Technology Transfer. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific 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;

- restitution of funds as appropriate.

XI. 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 scientific 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
If the respondent refuses to participate in the process after resignation, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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, after consulting with the respondent, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer will undertake reasonable efforts to address any damages to the respondent's reputation caused directly by GW. Depending on the particular circumstances, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from 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.

C. Protection of the Complainant and Others

Regardless of whether GW or ORI determines that scientific misconduct occurred, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer will undertake reasonable efforts to protect complainants 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 investigation, the Executive Vice President for Academic Affairs will determine, after consulting with the complainant, what steps, if any, appropriate to protect the position or reputation of the complainant. The Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer will be responsible for coordinating such steps, in consultation with the Executive Vice President for Academic Affairs. The Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 or Assistant Vice President for Research Compliance and Technology Transfer will determine whether the complainant’s allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 and ensure that the purposes of the Federal financial assistance are carried out.

XII. Record Retention

After completion of a case and all ensuing related actions, the Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer 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 the investigation committee. The Associate Vice President for Health Research and Technology or Assistant Vice President for Research Compliance and Technology Transfer will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request, for cases related to PHS funding.

Resources:

- PHS Regulations—42 CFR 50.101 et seq.
THE GEORGE WASHINGTON UNIVERSITY
SCIENTIFIC MISCONDUCT POLICY
(PROCESS FOR CONDUCTING INQUIRY/INVESTIGATION)

1. **Allegation of misconduct reported to AVPHR***
2. AVPHR makes preliminary assessment of allegation
3. AVPHR elects to initiate informal inquiry
4. **INQUIRY PROCESS**
   - All records secured in confidential manner
   - AVPHR/designees review all records and interview key witnesses
   - AVPHR requests consultation, if appropriate, from internal/external experts
   - AVPHR formulates recommendation whether to commence investigation
   - AVPHR prepares Inquiry Report; respondent (and complainant, if appropriate) have 14 days to comment
5. EVPAA makes determination whether to commence investigation
6. **INVESTIGATION**
   - If investigation not warranted, EVPAA may elect to take other actions or may take no further action
   - AVPHR notifies respondent, complainant

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**AVPHR** refers to Associate Vice President for Health Research or Assistant Vice President for Research Compliance and Technology Transfer

**If inquiry takes longer than 60 days, circumstances warranting longer period must be documented and included in Inquiry Report**

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**AVPHR** designates

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**EVPAA** designates
THE GEORGE WASHINGTON UNIVERSITY
SCIENTIFIC MISCONDUCT POLICY
(PROCESS FOR CONDUCTING INQUIRY/INVESTIGATION)

AVPHR appoints Investigation Committee of = 3 individuals

Within 30 days of completion of Inquiry

EVPAA makes determination whether to accept Investigation Report

AVPHR convenes first meeting of Committee

120 DAYS*

INVESTIGATION PROCESS

Committee reviews records, interviews relevant witnesses

Committee prepares draft Investigation Report; respondent submits comments within 14 days

Committee finalizes report and submits to EVPAA

Accepts findings/recommendations of Investigation Report

Alters findings/recommendations of Investigation Report; provides written explanation of basis for decision

Decides to return Investigation Report to Committee for further fact-finding, analysis, and finalization of Report

AVPHR notifies respondent, complainant, and other parties as determined by EVPAA

Respondent submits written objections, if any, to composition of Committee

AVPHR notifies respondent of appointment of Committee

EVPAA decides whether to replace challenged Committee member

Within 30 days of completion of Inquiry

5 days

5 days

5 days

* Extension of time may be requested from Office of Research Integrity
POLICY ON MISCONDUCT IN RESEARCH

The George Washington University
Amended to agree with Faculty Senate Resolution (90/11) Passed February 8, 1991

As a recipient of federal funds, the University is required to file an annual assurance regarding procedures for dealing with and reporting possible misconduct in science. The following statements are reaffirmed by The George Washington University in fulfillment of these requirements. Faculty and staff are urged to bear in mind the importance of compliance with the relevant policies and procedures.

1. The terms "misconduct" or "misconduct in research" mean 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.

2. An allegation of misconduct in research will be referred to the Associate Vice President for Research and Graduate Studies, who will review the allegation and conduct an informal inquiry. An "inquiry" consists of information-gathering and preliminary fact-finding to determine whether an allegation or apparent misconduct warrants an investigation. This inquiry shall include discussion with the complainant and the investigator accused of misconduct. The initial inquiry shall be held confidential, but the Associate Vice President for Research and Graduate Studies shall consult appropriate advisors and/or review committees concerning accepted standards of practice. The privacy of a person who in good faith reports apparent misconduct shall be protected. An inquiry into allegation of misconduct in research shall 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. To the maximum extent possible the affected individual(s) will be afforded confidential treatment, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

3. When, on the basis of the initial inquiry, a determination is made that an investigation is warranted, and to the extent required by federal law and regulation, the Associate Vice President for Research and Graduate Studies shall notify the Director, Office of Scientific Integrity (OSI), a component of the Office of the Director of the National Institutes of Health, and such other parties as may be required by the funding agency. In addition, when PHS funding is involved, the Associate Vice President for Research and Graduate Studies is responsible for notifying OSI at any stage of the inquiry or investigation if any of the following conditions exist:
   a. There is an immediate health hazard involved;
   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 other individual(s) who is the subject of the allegations as well as his/her co-investigators, if any;
   d. It is probable that the alleged incident is going to be reported publicly;
There is a reasonable indication of possible criminal violation. In that instance, the Associate Vice President for Research and Graduate Studies must inform OSI within 24 hours of obtaining that information, and OSI will immediately notify the Office of the Inspector General.

4. In the event the initial inquiry does not support an allegation of misconduct, the Associate Vice President for Research and Graduate Studies will counsel the complainant and the investigator concerned, and the issue will be closed. The finding(s) and the reason(s) not to request formal investigation shall be documented. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry.

5. If the initial inquiry warrants a formal investigation, the Associate Vice President for Research and Graduate Studies will inform the Vice President for Academic Affairs of the complaint and request formal investigation. The investigation will commence within 30 days of the completion of the inquiry. An "investigation" is a formal examination and evaluation of relevant facts to determine whether misconduct has taken place and to assess its extent and consequences to determine appropriate action. If federal funding is involved, the Associate Vice President for Research and Graduate Studies shall notify OSI, and shall keep the OSI apprised of any developments during the course of the investigation as required.

6. The Vice President for Academic Affairs will immediately appoint an ad hoc committee including members with appropriate expertise to conduct the investigation or refer the matter to an existing committee with established procedures for responding to misconduct in science concerning the use of humans or animals and will ensure that requirements of the sponsor for notification and reporting are addressed. In appointing such committee, the Vice President for Academic Affairs will take appropriate precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

7. The committee will act expeditiously to investigate the alleged misconduct, with appropriate consideration given to providing adequate opportunity for the investigator accused of misconduct to develop a full response to the allegation. The committee may solicit the advice of appropriate intramural and external consultants. During the course of the investigation, the researcher accused of misconduct may be advised, but not represented by legal counsel.

8. At the conclusion of the investigation, the committee will prepare a report for submission to the Vice President for Academic Affairs. The report should ordinarily be issued within 120 days of the initiation of the investigation. This includes conducting the investigation, preparing the report and the findings, making the report available for comment by the subjects of the investigation, and submitting the report to the OSI, if required. The report will address the circumstances of the complaint, the findings of the investigation and make recommendations for actions to redress the consequence of the misconduct, if demonstrated, on accordance with provisions of the Faculty Code or the Manual of Personnel Policies for the Use of Supervisory Staff. A copy of the report will be provided to the investigator accused of misconduct and to OSI if federal funding is involved. If they can be identified, the person(s) who raised the allegation will be provided with those portions of the report that address their role and opinions in the investigation. The documentation prepared to substantiate the investigation's findings will be maintained in a secure location for a period of at least three years after the terminations of the investigation, or longer if required by law or regulation.

9. Further, the University will impose the appropriate sanctions on individuals when the allegation of
misconduct has been substantiated.

10. Appropriate interim actions will be taken to protect federal funds and insure that the purposes of the federal financial assistance are carried out.

11. Where the investigator accused of misconduct is a registered student, and the alleged misconduct is associated with work contributing to the formal academic program of the student, the issue will also be addressed in accordance with University policies relating to academic dishonesty and student conduct.

12. The University will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.