POLICIES AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

GRAMBLING STATE UNIVERSITY
Grambling, Louisiana 71245

December 1996

GRAMBLING STATE UNIVERSITY
Grambling, Louisiana 71245

Policies and Procedures for Responding to Allegations of Research Misconduct

I. Introduction

Grambling State University endeavors to achieve excellence in post-secondary education through professional activity and creative teaching governed by the principles of academic freedom. Excellence in scholarship requires all members of the University to adhere strictly to the highest standards of integrity and ethical conduct with regard to research, instruction and evaluation. Grambling State University is committed to the ethical conduct of research by its faculty, staff and students. Anyone who applies for a research, research-training, or research-related grant or cooperative agreement under the Public Health Service (PHS) Act is obligated to pursue his/her study in an ethical manner. Grambling State University expects that all researchers will be responsible for the quality of data they report.

Willful misconduct in the pursuit of basic, clinical or applied research at Grambling State University is not acceptable. It is the direct responsibility of all University personnel to maintain the highest standards of ethics and professional integrity in the performance of and in the reporting of research activities whether such research is funded by private, state or federal agencies. Allegations of misconduct will be investigated and appropriate actions will be taken, in accordance with the University and funding agency guidelines, against anyone found guilty of violating this policy. Grambling State University specifically and fully subscribes to Federal Regulations for dealing with possible misconduct in science.[1]

Grambling State University considers an allegation of misconduct to be a very serious charge, so it is expected that any allegations made will have a substantial element of truth. While the University recognizes the value of good faith allegations of possible misconduct in the interest of science, the University and public good at large, frivolous accusations made with reckless disregard for or willful ignorance of facts will not be tolerated and will be grounds for disciplinary action.

The University also recognizes and proposes that free and open scientific discourse must continue at this institution and accordingly, researchers are strongly encouraged to engage in scientific endeavors. Grambling State University's policy, set forth here is to provide an orderly process for dealing with allegations of plagiarism and misconduct in research. It recognizes all requirements, not in conflict with law, imposed by sponsoring organizations.

---

[1]Public Health Service Regulations codified at 42 Code of Federal Regulations 50.101 through 50.105, and National Science Foundation Regulations 689.1 - 689.9

Ethical Conduct in Academic Research and Scholarship

The primary way to encourage appropriate conduct in research and scholarship at the University is for faculty to promote and maintain a climate consistent with high ethical standards. In order to reduce the likelihood of misconduct in research and scholarship, the faculty and administration should facilitate the following:

1. **Encouragement of intellectual honesty.** Because of the importance of a climate of intellectual honesty in a university community, a commitment to the ethical responsibilities of academia by all of its practitioners is essential. We must emphasize the importance of such common practices as submission of work to peer review, avoidance of conflict of interest, scholarly exchange of ideas and data, and self-regulation.

2. **Assurance that quality of research is emphasized.** The faculty member has a responsibility to assure that the highest standards are adhered to in all aspects of research and scholarship.

3. **Acceptance of responsibility by research supervisor.** University policies must define a locus of responsibility for the conduct of research and ensure that the individual(s) charged with the supervision of researchers can realistically execute the responsibility. The supervisors of research should be experienced academicians who serve as mentors in transmitting the ethics and responsibilities underlying scientific and humanistic research. It is also the responsibility of the supervisor to encourage publication of as much primary data as possible.

4. **Establishment of well-defined research procedures.** Well-defined and strictly adhered to research methods are a deterrent to fraud. Bias in data analysis and interpretation will be minimized by following practices common to the disciplines.

5. **Appropriate assignment of credit and responsibility.** Publications should recognize the contributions of others through adequate citation and/or acknowledgment. Publications should also name as authors only those who have had a genuine role in the research and who accept responsibility for the quality of the work being reported.

II. Definitions

a) **Misconduct** is defined as (1) 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; (2) material failure to comply with Federal requirements for protection of researchers, human subjects or the public or for ensuring the welfare of laboratory animals; or (3) failure to meet with other material legal requirements governing research. It does not include honest error, honest differences, interpretations or judgements of data.

b) **Inquiry** is defined as an informal information-gathering and initial fact-finding process to determine whether an allegation of misconduct warrants an investigation.

c) **Investigation** is defined as a formal examination and evaluation of all relevant facts to determine if an instance of misconduct has taken place. If misconduct is confirmed, the investigation should determine the seriousness of the offense and the extent of any adverse effects resulting from the misconduct.

d) **Falsification of data** ranges from fabrication to deceptively selective reporting, including the purposeful omission of conflicting data with the intent to falsify results.

(e) **Plagiarism** is defined as the representation of another person's work as one's own.

(f) **Misappropriation of Other's Ideas** is defined as the unauthorized use of privileged information (such as the violation of confidentiality of peer review), however obtained.

III. Appointments

A. Committee on Research Misconduct

The Provost/Vice President for Academic Affairs at Grambling State University will appoint a Committee on Research Misconduct consisting of seven (7) members. The Committee shall include tenured faculty members and/or senior administrators with one at-large student/trainee or staff member. The Provost shall appoint one member as chairperson.

B Misconduct Policy Officer (MPO)

The Provost shall appoint an individual to serve as the Misconduct Policy Officer. This individual will be responsible for a) working with an individual who wishes to pursue an allegation of research misconduct to develop a specific, formal, written complaint; b) providing staff and other support assistance for inquiries and investigations; c) maintaining records of all allegations and institutional responses; and d) serving **ex-officio** (without vote) on any inquiry or investigative groups considering allegations of misconduct. The Provost shall provide the Misconduct Policy Officer with sufficient resources to carry out the functions of the office.

IV. Guidelines for Handling Allegations of Research Misconduct

1. Whenever an accusation of research or scientific misconduct is brought to the attention of the MPO, the MPO will notify ORI if it is ascertained at any stage of the inquiry or investigation that 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 allegations or the individual(s) who is/are the subject of the allegations and his/her co-investigators and associates, if anv:

d) It is probable that the alleged incident is going to be reported publicly;
e) the allegation involves a public health sensitive issue, e.g., a clinical trial;
f) There is reasonable indication of possible criminal violations, in which event, the University will notify ORI within 24 hours of obtaining that information.

2. Whenever an accusation of research misconduct is brought to the attention of the University, the charges should be directed to the Misconduct Policy Officer. This officer shall work with individuals who have a specific research misconduct allegation against a current or former Grambling State University researcher. The Misconduct Policy Officer will assist the individual in the development of a signed formal complaint for referral to the Committee on Research Misconduct. The Misconduct Policy Officer will ensure that the privacy of individuals making reports in good faith are protected.

3. In case of anonymous allegations, the Misconduct Policy Officer will record the allegation and all preliminary information gathered in connection with the allegation. The Misconduct Policy Officer will consult with a dean/director of the unit involved in the anonymous allegation and will convene a group of no more than three (3) individuals to determine whether the anonymous allegation should be referred to the Committee on Research Misconduct for inquiry.

4. The Misconduct Policy Officer will refer all allegations to the Committee on Research Misconduct within five (5) working days of receipt of the allegation. The Committee on Research Misconduct will determine if there is sufficient information to warrant an initial inquiry.

V. Initial Inquiry

1. Once the Committee determines that an informal inquiry is warranted, the Chairman shall, within three (3) working days of the referral, appoint an Inquiry Board consisting of three (3) members of the Committee on Research Misconduct to conduct the inquiry. No member of the Inquiry Board shall have a primary appointment in the department of the respondent or complainant. The Misconduct Policy Officer (MPO) is an **ex-officio** (without vote) member of the Inquiry Board and is responsible for maintaining the records of the Inquiry Board's deliberations.

2. The Inquiry Board shall notify the respondent immediately, along with the dean/director of the relevant college or unit, that an allegation of research misconduct has been received.

3. Private and separate sessions should be scheduled to hear the accuser, if identified, the respondent, and others who are deemed necessary by the Inquiry Board. All relevant evidence that is produced shall be reviewed and secured. All persons meeting with the Inquiry Board may be accompanied by a representative of their choice.

4. Refusal on the part of the respondent to allow the Inquiry Board to review all necessary documents shall be sufficient to warrant an investigation.

5. An investigation shall be conducted when the inquiry phase uncovers information which tends to support the allegation or which raises questions as to possible misconduct that can only be resolved by formal investigation.

6. The Inquiry Board shall take no more than thirty (30) days from the date the Misconduct Officer was first notified of the allegation to conduct its inquiry and determine whether a formal investigation is warranted. If the inquiry exceeds the thirty (30) day period, the Inquiry Board shall document the reason(s) for the delay.

7. The Inquiry Board shall make a formal report consisting of the allegation, the Inquiry Board's findings, and a recommendation on future actions. The report can recommend that either:

(a) information collected during the inquiry does not substantiate the allegation and a formal investigation is not warranted; or
(b) the allegations have sufficient substance to warrant further investigation.

A copy of the report and recommendations shall be sent to the complainant, respondent, dean/director of the college or unit, and the President through the Provost/Vice President for Academic Affairs. The respondent may comment on the report which will be made a part of the record. Records from the inquiry and any subsequent investigation will be maintained in a secure manner for a period of at least three (3) years after the termination of the inquiry of investigation and will be made available to the Director, ORI.

VI. Formal Investigation

1. If the President agrees with the Inquiry Board's report, appropriate action will be taken. If an investigation is warranted, the Provost will notify the funding agency that an investigation will be initiated within 30 days after receipt of the Board's report to determine if misconduct has occurred. The University will inform ORI of any developments during the course of the investigation, including the status of current funds designated for use by the respondent.

2. The Provost shall appoint an Investigation Committee consisting of no more than five (5) persons including at least one (1) member of the Committee on Research Misconduct and one (1) individual who is not affiliated with the University. The Investigation Committee should include individuals with sufficient expertise and dedication to conduct a thorough investigation. Precautions should be taken to avoid real or apparent conflicts of interests on the part of those involved in the inquiry or investigation. Grambling State University Legal Counsel shall advise the Investigation Committee.

3. The respondent, along with the complainant, shall be notified immediately that a formal investigation will occur. The University, respondent, and the complainant may each be represented by counsel during the investigation, if desired.

4. The investigation must be timely, thorough, and affords the respondents an opportunity to comment on allegations and findings of an investigation.

5. While interviews during the investigation shall be conducted in a non-adversarial manner, they shall be fully recorded by tape recorder or court reporter unless the Investigation Committee is otherwise advised by legal counsel. Each participant shall have an opportunity to review the transcript from his/her interview. The record of the interview will become a part of the investigatory file.

6. Private and separate sessions will be scheduled to hear the respondent, accuser and others as determined necessary by the Investigation Committee. All relevant evidence that is produced shall be reviewed and secured. All necessary support (e.g., clerical, gathering information, organizational, securing witnesses; security, record-keeping, and confidentiality) will be arranged by the Misconduct Policy Officer, who shall serve as an **ex-officio** member (without vote) of the Investigation Committee.

7. The formal investigation shall be completed within 120 days after the completion of the informal inquiry. This includes conducting the investigation, preparing the report of findings, making the report of the investigation available to the respondent(s) for comment, and submitting the report to ORI.

8. The Investigation Committee's report shall set forth the nature of any violation, the severity of the infraction, and the effect of the violation on the particular research project as well as any other research being conducted at the University. The report shall recommend whether corrective measures for information erroneously published or submitted for publication, such as letters of retraction or withdrawal of manuscripts from the publisher, are warranted. Each member of the Investigation Committee shall sign the report or submit a signed dissenting report. If the Investigation Committee determines that it will not be able to complete the investigation within 120 days, it must submit to the President an interim report on the progress to date, submit a written request for an extension, provide an explanation of the reason(s) for the delay, provide an outline of what remains to be done, and indicate an estimated date for completion of the report, including:

a) a finding of misconduct;
b) a finding that no culpable conduct was committed, but serious research errors were discovered;
c) a finding that no fraud, misconduct or serious research error was committed.

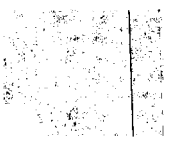
9. If misconduct is confirmed, the President, upon the recommendation of the Committee on Research Misconduct and the appropriate dean(s) and Vice President(s), shall impose appropriate sanctions against the respondent.

10. Upon the receipt of an unfavorable report and recommendation from the Committee on Research Misconduct, but prior to a final determination by the President of Grambling State

University, the respondent may petition the Committee in writing no later than ten (10) calendar days after receipt of the Committee's report. Upon conclusion of the process, the Committee's report shall be forwarded to the President for consideration. The decision of the President shall be final.

1 The Committee's final report should include the following in detail

a. investigation policies and procedures,
b. source(s) of information relevant to the investigation,
c. the investigation findings,
d. basis for the findings,
e. evidence(s) of research misconduct, and
f. actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct, as well as a description of any sanctions taken by Grambling State University.



12. If misconduct is not proven, it should be recorded in the final report. The University shall make every effort to restore the reputation of the respondent. GSU will also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations of scientific misconduct. Any person making frivolous accusations made with reckless disregard for or willful ignorance of facts will be disciplined by the University.

Policy Dissemination

It is the intent and desire of Grambling State University that this policy statement receives as broad and intense dissemination as is appropriate; specifically, that all faculty members be made aware of and conversant with the University's position, policy and procedures relative to allegations of scientific misconduct. To that end, a brief statement will be incorporated into the Faculty Handbook, referring interested persons to the complete policy document. This document will be distributed to all Vice Presidents and Deans. The Deans will be asked in turn to provide a copy of this document to each of their Department Heads, from whom persons (faculty, graduate students, undergraduate students, etc.) undertaking research efforts may obtain the complete policy statement.

General Procedures and Principles

A. Responsibility to Report Misconduct

All Grambling State University employees who receive or learn of an allegation of scientific misconduct in any research project supported by the Public Health Service (PHS) should immediately report the allegation to the Misconduct Policy Officer (MPO) for appropriate action. The Misconduct Policy Officer will promptly engage in an assessment of the allegation to determine whether it falls within the definition of scientific misconduct, involves PHS support, and provides sufficient information to proceed with an inquiry.

B. Protecting the Complainant

Grambling State University employees who receive or learn of an allegation of scientific misconduct for an Inquiry or Investigation will treat the complainant with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the complainant and other individuals who cooperate with the institution against retaliation. Employees will immediately report any alleged or apparent retaliation to the Misconduct Policy Officer.

C. Protecting the Respondent

Grambling State University employees who receive or learn of an allegation of scientific misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 C.F. R., Part 50, Subpart A are followed. Employees will report significant deviations from these instructions to the Misconduct Policy Officer. The Misconduct Policy Officer will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Confidentiality

Grambling State University employees who make, receive, or learn of an allegation of scientific misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the complainant, the respondent, and other affected individuals. The Misconduct Policy Officer should establish reasonable conditions to ensure the confidentiality of such information for Inquiry and Investigation.

E. Responding to the Allegations

In responding to allegations of scientific misconduct, the Misconduct Policy Officer and the Grambling State University Vice President for Academic Affairs will make diligent efforts to ensure that the following functions are performed:

1 Allegation assessments, inquiries, or investigations are conducted in a timely, objective, thorough, and competent manner.

2. Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation.

3. Interim administrative actions are taken, as appropriate, during Inquiries and Investigations to protect Federal funds and the public health and to ensure that the purposes of the Federal financial assistance are carried out.

F. Employee Cooperation

Grambling State University (GSU) employees will cooperate with the Misconduct Policy Officer and other GSU officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Misconduct Policy Officer or other GSU officials on misconduct allegations. Further, employees will cooperate with ORI in its conduct of inquiries and investigations, its oversight of institutional inquiries and investigations, and any follow up actions.

G. Evidentiary Standards

The following evidentiary standards apply to findings of scientific misconduct made under the PHS regulation.

Burden of Proof

The burden of proof for making a finding of scientific misconduct is on the institution. If ORI adopts GSU's finding of scientific misconduct or makes an ORI finding, the burden of proof is on ORI for purposes of its finding and administrative actions.

2. Standard of Proof

Any GSU or ORI finding of scientific misconduct will be established by a preponderance of the evidence. This means that the evidence shows that it is more likely than not that the respondent committed scientific misconduct.

H. Completion of Process

The Misconduct Policy Officer is responsible for ensuring that the inquiry/investigation process and all other steps required by the instruction and the PHS regulation are completed even in those cases where the respondent leaves the institution after allegations are made.

I. Early Termination

If GSU plans to terminate an inquiry or investigation prior to completion of all the steps required by the PHS regulations, the Misconduct Policy Officer will notify ORI of the planned termination and the reasons thereof. ORI will review the information provided and advise GSU whether further investigation should be undertaken.

J. Referral of Non-Scientific Misconduct Issues

When the institution's review of the allegation identifies non-scientific misconduct issues, the Misconduct Policy Officer will refer these matters to the Office of Academic Affairs or Federal office for action. Issues that will be referred are as follows:

HHS Criminal Violation

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

2. Violation of Human and Animal Subject Regulations

Potential violation of human or animal subject regulations will be referred to the Office for Protection from Research Risks, National Institutes of Health, 6100 Executive Boulevard, MSC 7507, Rockville, MD 20892-7507, telephone (301) 496-7005.

3. Violation of FDA Regulations

Potential violations of Food and Drug Administration regulated research requirements will be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, Room 12A41, Rockville, MD 20857, telephone (301) 443-2390.

4. Fiscal Irregularities

Potential violations of cost principles or other fiscal irregularities will be referred as follows: For all NIH Agencies--Office of Management Assessment, NIH, Building 31, Room 1B05, Bethesda, MD 20892, telephone (301) 496-6630.

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

K. Requirements for Reporting to ORI

1. GSU's decision to initiate an investigation will be reported in writing to the Director of ORI on or before the date the investigation begins. The notification will include the name(s) of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS application 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 the institutional policies and procedures will be explained in any reports submitted to ORI.

2. If GSU plans to terminate an inquiry or investigation for any reasons without completing all relevant requirements of the PHS regulation, the Misconduct Policy Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

3. If GSU determines that it will not be able to complete the investigation in 120 days, the Misconduct Policy Officer will submit to ORI a written request for an extension that explains the delay, report on the progress to date, estimate the date of completion of the report, and describe other necessary steps to be taken. If the request is granted, the Misconduct Policy Officer will file periodic progress reports as requested by the ORI.

4. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Misconduct Policy Officer will contact ORI for consultation and advice.

5. The Misconduct Policy Officer will notify ORI at any stage of the inquiry or investigation if:

   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 of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any,

   d. it is probable that the alleged incident is going to be reported publicly; or

   e. the allegation involves a public health sensitive issue, e.g., a clinical trial; or

f. there is a reasonable indication of possible criminal violation. In this instance, GSU will inform ORI within 24 hours of obtaining that information.

IX. Preliminary Assessment of Allegations

A. Allegation Assessment

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

1. PHS Support

Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support. If the allegation does not involve PHS support, it will be handled under GSU's own definition of scientific misconduct and procedures (**if applicable**) without regard to the PHS regulation at 42 C.F.R. Part 50, Subpart A.

2. PHS Definition

The allegation will be carefully reviewed to determine whether it potentially constitutes fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices for proposing, conducting, or reporting research. In case of doubt, the Misconduct Policy Officer will consult with the GSU's counsel or ORI on whether the allegation falls within the PHS definition of scientific misconduct.

3. Sufficient evidence to proceed

There is not always sufficient evidence or information to permit further inquiry into the allegation. For example, an allegation that a scientist's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, an effort will be made to obtain more information before initiating an inquiry. This information may be sought from any reasonable source, including the complainant, if known.

B. Referral of Other Issues

Regardless of whether it is determined that a scientific misconduct inquiry is warranted, if the allegation involves PHS support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation will be referred to the appropriate PHS or DHHS office.

X. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Misconduct Policy Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Misconduct Policy Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, 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. First Steps if an Inquiry is Necessary

As soon as practicable after the Misconduct Policy Officer determines that an inquiry is required, he or she will:

1. secure the relevant research records;

2. notify the Vice President for Academic Affairs, institutional counsel, the respondent, or ORI (if the request to open the inquiry originated from ORI);

3. appoint and charge the inquiry committee; and

4. notify ORI if any of the conditions listed in section VIIIE.3 of these procedures are present.

The Misconduct Policy Officer or institutional counsel may consult with ORI at any time regarding appropriate procedures to be followed.

C. Sequestration of the Research Records

1. Immediate Sequestration

If the relevant research records have not been obtained at the assessment stage, the Misconduct Policy Officer will immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of records.

2. Institutional Access

Research records produced under PHS grants and cooperative agreements are the property of the institution, and employees cannot interfere with the institution's right of access to them. Under contracts, certain research records may belong to PHS, but GSU will be provided access to contract records in the custody of GSU for purposes of reviewing misconduct allegations.

3. Original Records

The documents and materials to be sequestered will include all the original items (or copies if originals cannot be located) that may be relevant to the allegations. These include, but are not limited to, research records as defined in this document.

4. Sequestration of the Records from the Respondent

The Misconduct Policy Officer will notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with location and identification of the research records. The Misconduct Policy Officer will obtain the assistance of the respondent's supervisor and GSU counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent will not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification. In addition to securing records under the control of the respondent, the Misconduct Policy Officer may need to sequester records from other individuals, such as coauthors, collaborators, or complainants. As soon as practicable, a copy of each sequestered record will be provided to the individual from whom the record is taken if requested.

5. Inventory of the Records

A dated receipt must be signed by the sequestering official and the person from

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

6. Security and Chain of Custody

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

D. Notification of the Respondent

1. Contents of Notification

The Misconduct Policy Officer will notify the respondent in writing of the opening of the inquiry. The notification should identify the research project in question and the specific allegations; define scientific misconduct; identify the PHS funding involved; list the names of the members of the inquiry committee (if appointed) and experts (if any); explain the respondent's opportunity to challenge the appointment of a member of the committee or expert for bias or conflict of interest, to be assisted by counsel, to be interviewed, to present evidence to the committee, and to comment on the inquiry report; address the respondent's obligations as an employee of GSU to cooperate; describe the GSU's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings; and indicate that GSU will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed.

2. Potential Respondents

If no specific respondent has been identified at this stage of the process, the Misconduct Policy Officer will notify each potential respondent that an inquiry will be undertaken, e.g., each co-author on a questioned article or each investigator on a questioned grant application. The Misconduct Policy Officer must consult with the GSU's counsel on the proper notification under the circumstances.

E. Designation of an Official or a Committee to Conduct the Inquiry

The Misconduct Policy Officer is responsible for conducting or designating others to conduct the inquiry.

1. Use of an Inquiry Committee

In complex cases, the Misconduct Policy Officer will normally appoint a committee of three or more persons to conduct the inquiry, following the procedures set forth.

2. Use of an Inquiry Official

In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the Misconduct Policy Officer may choose to conduct the inquiry directly or designate another qualified individual to do so. In such cases, the inquiry official will nevertheless obtain the necessary expert and technical advice to consider properly all scientific issues.

3. Inquiry Process

The inquiry, whether conducted by a committee or an individual, will follow each procedural step set forth below.

F. Appointment of the Inquiry Committee

If an inquiry committee is to be appointed, the Misconduct Policy Officer will use the following procedures.

1. Committee Membership

The Misconduct Policy Officer, in consultation with the Vice President for Academic Affairs, will appoint the committee chair within 10 days of the initiation of the inquiry. 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 evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

2. Experts

The Misconduct Policy Officer, in consultation with the committee, will

determine whether additional experts other than those appointed to the committee need to be consulted during the inquiry to provide special expertise to the committee regarding the analysis of specific evidence. In this case, the experts will provide a strictly advisory function to the committee; they do not vote and generally do not interview witnesses. The experts may be from internal or external to GSU.

3. Bias or Conflict of Interest

The Misconduct Policy Officer will take reasonable steps to ensure that the members of the committee and experts have no bias, personal or professional conflict of interest with the respondent, complainant, or the case in question. In making this determination, the Misconduct Policy Officer will consider whether the individual (or any members of his or her immediate family):

a. has any financial involvement with the respondent or complainant;

b. has been a co-author on a publication with the respondent or complainant;

c. has been a collaborator with the respondent or complainant;

d. has been a party to a scientific controversy with the respondent or complainant;

e. has a supervisory or mentor relationship with the respondent or complainant;

f. has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or complainant; or

g. falls within any circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

4. Objection by Respondent

The Misconduct Policy Officer will notify the respondent of the proposed committee membership within 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Misconduct Policy Officer will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality

Members of the committee and experts will agree in writing to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the Misconduct Policy Officer to have knowledge of the inquiry.

6. Provision of Assistance

The Misconduct Policy Officer, in consultation with the institutional counsel, will provide staff assistance and guidance to the committee and the experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report.

G. Charge to the Committee and the First Meeting

The Misconduct Policy Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment. The charge will state that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation, as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Misconduct Policy Officer will review the charge with the committee, discuss the allegation, any related issues, and the appropriate procedures for conducting the inquiry; assist the committee with organizing plans for the inquiry; and answer any questions raised by the committee. The Misconduct Policy Officer and GSU's counsel will be present or available throughout the inquiry to advise the committee, as needed.

H. General Approaches to Conducting the Inquiry

During the inquiry, the committee will take the following steps.

1. Avoid Bias of Conflict of Interest

All necessary steps will be taken to avoid bias or conflict of interest between the committee and experts and the respondent, complainant, and witnesses.

2. Refer Other Issues

The Misconduct Policy Officer must be advised of any necessary interim actions to protect the research funds, human and animal subjects, or other steps required by regulation or policy.

I. General Approaches to Conducting an Interview

1. Purpose of the Interview

The purpose of an interview at the inquiry stage is to allow each respondent, complainant, or witness to tell his or her side of the story. The committee will not attempt to speculate about what happened or might have happened or put words in the witnesses' mouths. Also, the committee will not disclose information obtained from others interviewed unless this is necessary and can be done without identifying the source of the information.

2. Issues to Cover

Before an interview, the committee will provide each witness with a summary of the matters or issues intended to be covered at the interview. If the committee raises additional matters, the witness will be given an opportunity to supplement the record in writing or in another interview. The witness will be informed that his or her cooperation and truthful answers are expected.

3. Confrontation

Witnesses will not be told at this stage whether other testimony conflicts with theirs, although questions may be asked for purposes of clarifying the testimony. The questioners will avoid leading questions such as, "You must have made a mistake and thought it was actually this way, right?"

4. Using Experts

The committee may request that experts attend or participate in interviews to assist in its evaluation of the allegations and related issues. If the committee determines that such participation is not appropriate, it may ask an expert to prepare questions for the committee to use at the interview. An expert retained to assist the committee may read the transcripts or summaries of the interviews.

5. Transcribing Interviews

Interviews with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or information. Changes to the transcript or summary will be made only to correct factual errors.

6. Confidentiality of Interviews

Witnesses will be advised that the proceedings are confidential and that they should not discuss the inquiry or their interview with anyone else other than their counsel or adviser.

7. Access to Counsel

Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or witness in the case. However, the counsel or adviser may only advise the witness and may not participate directly in the interview. Witnesses will respond directly to the interview questions.

8. Order of Interviews

The inquiry committee will interview, if possible, the complainant, key witnesses, and the respondent, in that order. Witnesses will be asked to provide, in advance if possible, any relevant evidence, including their own notes, manuscripts, research records, or other documents that were not sequestered previously but are relevant to the allegation.

9. Interviewing the Complainant

In interviewing the complainant, the inquiry committee will attempt to obtain as much additional evidence regarding the substance of the allegation as possible and to determine the complainant's view of the significance and impact of the alleged misconduct. However, it is not the complainant's responsibility to prove his or her allegations.

10. Interviewing the Respondent

The respondent will be asked to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of scientific judgement occurred, he or she should provide any evidence to support the claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

11. Recording Admissions

If the respondent admits to the misconduct, the respondent will be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is a sufficient basis to proceed directly to an investigation. However, the admission may not be a sufficient basis for closing a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made, the Misconduct Policy Officer or GSU's counsel may seek advice from ORI in determining whether there is a sufficient basis to close a case, after the admission is fully documented and all appropriate procedural steps are taken. If the case is closed, the report should be forwarded to the President of GSU with recommendations for appropriate institutional sanctions and then submitted to ORI for review.

12. Committee Deliberations

The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Misconduct Policy Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducted exhaustive interviews and analyses.

Committee deliberations will never be held in the presence of the interviewee. During the interview, the committee members will not debate among themselves or with witnesses over possible scientific interpretations. These questions will be reserved for private discussions among the inquiry committee members and expert consultants.

XI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report will be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken, if any investigation is not recommended. GSU's counsel will review the report for legal sufficiency. All relevant dates will be included in the report.

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

The Misconduct Policy Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with those portions of the draft report that address the complainant's role and opinions in the investigation.

1. Confidentiality

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

2. Receipt of Comments

Within 10 calendar days of their receipt of the draft report, the complainant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the complainant or respondent submits on the draft report will become part of the final report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

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

2. Notification

The Misconduct Policy Officer will notify both the respondent and the complainant in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Misconduct Policy Officer will also notify all appropriate GSU officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will complete the inquiry and submit its report in writing to the Misconduct Policy Officer no more than 60 calendar days following the first meeting, unless the Misconduct Policy Officer approves an extension for good cause. If the Misconduct Policy Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent will also be notified of the extension.

ORI Oversight

A. Decision to Investigate

If the Deciding Official decides that an investigation will be conducted, the Misconduct Policy Officer will notify ORI and will forward a copy of the final inquiry report and the institution's policies and procedures for conducting investigations to ORI.

B. Decision Not to Investigate

If the Deciding Official decides not to proceed to an investigation and the inquiry was begun at the request of ORI or if ORI requests a copy, the Misconduct Policy Officer will send a copy of the final inquiry report and the institutional decision to ORI. Otherwise, the case may be closed without notice to ORI.

C. Access to Evidence

If ORI is performing an oversight review of the institution's determination not to proceed to an investigation, the Misconduct Policy Officer, if so requested, will provide ORI with the report and the inquiry file, including, but not limited to, sequestered evidence, analyses, and transcripts of interviews. The Misconduct Policy Officer will keep all records secure until ORI makes its final decision on its oversight of the institutional inquiry or investigation.

Referral to Other Agencies

Information obtained during the inquiry regarding allegations other than scientific misconduct involving PHS funds should be referred to the responsible institutional officials or government agencies.

XIV. Conducting the Investigation

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.