

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

POLICY STATEMENT RELATING TO MISCONDUCT OR RESEARCH MISCONDUCT

Policy

The Health Science Center strives to create a research climate that promotes adherence to high ethical standards in the conduct of research without inhibiting the productivity and creativity of persons involved in research. Misconduct or research misconduct is an offense that damages not only the reputation of those involved, but also that of the entire educational community.

Misconduct or research misconduct means fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion. To constitute research misconduct, the behavior must (1) represent a significant departure from accepted practices of the relevant research community; and, (2) be committed intentionally, knowingly, or with reckless disregard for the integrity of the research; and, (3) the allegation is proven by the preponderance of evidence. [Federal Register: September 1, 2005 (Volume 70, Number 169)]

Misconduct or research misconduct is a major breach of the relationship between a faculty or staff member and the institution. In order to maintain the integrity of research projects, every person engaged in research, including faculty, graduate and undergraduate students, postdoctoral fellows, and technicians, must keep a permanent auditable record of all experimental protocols, data, and findings. Co-authors on research reports of any type, including publications, must have had a bona fide role in the research and must accept responsibility for the quality of the work reported.

Scholarly activities which involve faculty/student collaboration are encouraged and may be positively recognized in faculty personnel processes. Issues related to faculty/student collaboration may include matters such as expected contributions of each party, order of authorship, and/or type of citation to be given, and must be addressed early in any scholarly project. Decisions must be congruent with the ethics and scholarly customs of each discipline involved. Specific

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

recognition of the nature and scope of individual student contributions must be made in all published materials.

Any inquiry or investigation of allegations of misconduct or research misconduct must proceed promptly and with due regard for the reputation and rights of all individuals involved.

The University will take all reasonable steps to assure that the persons involved in the evaluation of the allegations and evidence have appropriate expertise; no person involved in the procedures is either biased against the accused person(s) or has a conflict of interest; and, affected individuals will receive confidential treatment to the maximum extent possible.

This policy is based on a model policy from the U.S. Public Health Service (PHS). If funding sources are from other sources than PHS, it may be necessary to follow the policies of that grantor.

Definitions

ALLEGATION: Any written or oral statement or other indication of possible research misconduct made to an institutional official.

COMPLAINANT: A person who makes an allegation of research misconduct.

CONFLICT OF INTEREST: The real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.

DECIDING OFFICIAL: The Vice President for Research is the deciding official who makes final determinations on allegations of research misconduct and any responsive institutional actions.

EMPLOYEE: Any person paid by, under the control of, or affiliated with the Health Science Center, including but not limited to faculty, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

EVIDENCE: Any document, tangible item, or testimony offered or obtained during a research misconduct proceeding that tends to prove or disprove the existence of an alleged fact.

FABRICATION: Making up data or results and recording or reporting them.

FALSIFICATION: 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.

GOOD FAITH ALLEGATION: An allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

INQUIRY: Preliminary information-gathering and fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

INVESTIGATION: The formal development of a factual record and examination and evaluation of all relevant facts to determine if research misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

ORI: The Office of Research Integrity, the office within the U.S. Department of Health and Human Services (HHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service (PHS).

PHS REGULATION: The Public Health Service (PHS) regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 CFR Part 93, entitled "Public Health Service Policies on Research Misconduct".

PLAGIARISM: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

RESEARCH MISCONDUCT: Fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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RESEARCH RECORD: 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 research 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, subject research files.

RESPONDENT: The person against whom an allegation of research misconduct is directed or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

RETALIATION: Any action that adversely affects the employment or other status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of research misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

Requirements for Findings of Research Misconduct

A finding of research misconduct requires that:

1. There be a significant departure from accepted practices of the relevant research community; and,

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

-
2. The misconduct be committed intentionally, knowingly, or recklessly; and,
 3. The allegation be proven by a preponderance of the evidence.
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Evidentiary Standards

The following evidentiary standards apply to findings:

1. Standard of proof. An institutional or Department of Health and Human Services (HHS) finding of research misconduct must be proved by a preponderance of the evidence.
2. Burden of proof.
 - a. The institution or HHS has the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct where the institution or HHS establishes by a preponderance of the evidence that the respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, and maintained the records and failed to produce them in a timely manner and that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community.
 - b. The respondent has the burden of going forward with and the burden of proving, by a preponderance of the evidence, any and all affirmative defenses raised. In determining whether HHS or the institution has carried the burden of proof imposed by this section, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.
 - c. The respondent has the burden of going forward with and proving by a preponderance of the evidence any mitigating factors that are relevant to a decision to impose

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

administrative actions following a research misconduct proceeding.

Reporting

Allegations of misconduct or research misconduct should be placed in writing and brought to the attention of the Vice President for Research. The Vice President for Research will bring such allegations to the attention of the appropriate Dean, Principal Investigator of the research program and any researchers affected by the allegations. The Vice President for Research, with due regard for the reputations of all parties involved, including those who in good faith reported the apparent misconduct, will immediately conduct an assessment of the allegations.

Responding to Allegations

In responding to allegations of research misconduct, the Vice President for Research will make diligent efforts to ensure that the following functions are performed:

1. Any allegation assessment, inquiry, or investigation is 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. Immediate notification is provided to ORI 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;

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

-
- 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; or,
 - f. there is a reasonable indication of a possible federal criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.
4. Interim administrative actions are taken, as appropriate, to protect federal funds and the public health, and to ensure that the purposes of the federal financial assistance are carried out.

Non-Research Misconduct Issues

When the institution's review of the allegation identifies non-research misconduct issues, the Vice President for Research should refer these matters to the proper institutional or federal office for action. Issues requiring referral are described below.

- 1. Potential violation of criminal law under HHS grants and contracts should be referred to the OIG. If the possible criminal violation is identical to the alleged research misconduct (*e.g.*, alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.
- 2. Potential violations of human subject regulations should be referred to the Office of Human Research Protections.
- 3. Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare.
- 4. Potential violations of Food and Drug Administration (FDA) regulated research requirements should be referred to the FDA Office of Regulatory Affairs.
- 5. Potential violations of cost principles or other fiscal irregularities should be referred as follows:

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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- a. For all NIH Agencies--Office of Management Assessment, NIH.
 - b. For all other PHS Agencies--PHS Office of Grants and Contracts.
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Preliminary Assessment into Allegations

Upon receiving an allegation of research misconduct, the Vice President for Research 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 research misconduct. The Office of Regulatory Affairs & Compliance may be requested to assist in the preliminary initial assessment.

Conducting the Inquiry

Following the preliminary assessment, if the Vice President for Research determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of research misconduct, the Vice President for Research will immediately initiate the inquiry process. In initiating the inquiry, the Vice President for Research 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 research misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

The Vice President for Research will determine whether any Health Science Center affiliated organization/institution is also involved in the research thus possibly warranting a joint inquiry. If so, the appropriate institutional official or director of clinical research should be contacted. Factors to be considered in the decision to conduct a joint inquiry would include source of pay for the investigator, presence or absence of joint appointment, presence or absence of "Without Pay" (WOC) appointments at Veteran's Administration (VA) organizations, source of funding for the research, site where the research was conducted,

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

subject population involved, etc. After consideration and discussion of these factors, the decision on whether a joint investigation is indicated would be made. If a joint investigation is warranted, a decision on which organization has the lead should be made. If there is significant involvement of these factors by the South Texas Veteran’s Health Care System, the VA should take the lead because of the additional Federal regulations applying to VA institutions. In most other scenarios with other affiliated organizations, the Health Science Center would be the lead organization.

As soon as practical after the Vice President for Research determines that an inquiry is required, the Vice President for Research will:

1. Secure the relevant research records;
2. Notify the President, the Office of Legal Affairs, the respondent, and ORI;
3. Appoint a person or persons to conduct an initial inquiry; and,
4. Notify ORI if PHS support and any of the conditions listed above under “Responding to Allegations” exist.

The Vice President for Research may consult with ORI at any time regarding appropriate procedures to be followed.

Notification of the Respondent

The Vice President for Research will notify the respondent in writing of the opening of the inquiry, or this notification may be sent simultaneously with sequestering of records. See “Sequestration of Research Records” below.

The notification should identify the research project in question and the specific allegations; define research misconduct; identify the PHS funding involved; list the name or names of the person or persons conducting the initial inquiry and expert consultants (if any); explain the respondent's opportunity to challenge the person or persons designated for bias or conflict of interest, to be assisted by legal counsel, to be interviewed, to present evidence to the person or persons designated, and to comment on the inquiry report; address the

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

respondent's obligation as an employee of the institution to cooperate; and, describe the institution's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings.

Potential Respondents

If no specific respondent has been identified at this stage of the process, the Vice President for Research 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.

Sequestration of the Research Records

To the extent it has not already been done at the allegation stage, the institution must, on or before the date on which the respondent is notified or the inquiry begins, whichever is earlier, promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.

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 the institution will be provided access to contract records in the custody of the institution for purposes of reviewing misconduct allegations.

The Vice President for Research should 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 Vice President for Research should obtain the assistance of the respondent's supervisor and legal counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for 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 Vice President for Research may need to sequester records from other individuals, such as co-authors, 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.

A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should 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 should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

The Vice President for Research 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 an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified.

Designation of an Official or a Committee to Conduct the Inquiry

The Vice President for Research is responsible for conducting or designating others to conduct the inquiry. The person or persons designated to conduct the inquiry will obtain the necessary expert and technical advice to consider properly all research issues.

Inquiry

The Vice President for Research will take reasonable steps to ensure that those conducting the inquiry and any expert consultants have no bias or personal or professional conflict of interest with the respondent, complainant, or the case in question. In making this determination, the Vice President for Research will consider whether the individual (or any members of his or her immediate family):

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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1. Has any financial involvement with the respondent or complainant;
 2. Has been a co-author on a publication with the respondent or complainant;
 3. Has been a collaborator or co-investigator with the respondent or complainant;
 4. Has been a party to a scientific controversy with the respondent or complainant;
 5. Has a supervisory or mentor relationship with the respondent or complainant;
 6. Has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or complainant; or,
 7. Falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

The Vice President for Research will notify the respondent of the proposed person or persons to conduct the inquiry within ten (10) days. If the respondent submits a written objection to anyone appointed based on bias or conflict of interest within five (5) days, the Vice President for Research will immediately determine whether to replace the challenged member or expert with a qualified substitute.

The person or persons conducting the inquiry and any expert consultants 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 inquiry they may not discuss the proceedings with the respondent, complainant, witnesses, or anyone not authorized by the Vice President for Research to have knowledge of the inquiry.

The Vice President for Research's Office, in consultation with the legal counsel, will provide staff assistance and guidance to the committee

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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. Additional guidance may be found in the model policy posted on the ORI's web site at <http://ori.hhs.gov/misconduct/>.

Charge

The Vice President for Research will prepare a charge for the person or persons conducting the inquiry that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation, as required by the PHS regulation. The purpose is not to determine whether research misconduct definitely occurred or who was responsible.

The Office of the Vice President for Research and legal counsel will be present or available throughout the inquiry to advise those conducting the inquiry as needed. Additional guidance may be reviewed on the ORI's web site at <http://ori.hhs.gov/misconduct/>

General Approaches to Conducting the Inquiry

1. All necessary steps must be taken to avoid bias or conflict of interest between those conducting the inquiry and expert consultants and the respondent, and complainant.
 2. The Vice President for Research must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy.
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General Approaches to Conducting an Interview

Interviews with the respondent will be transcribed and recorded. Interviews with anyone else will be recorded. 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.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

Witnesses should 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.

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.

If the respondent admits to the misconduct, the respondent should 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 Vice President for Research or the Office of Legal Affairs 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 Vice President for Research as the Deciding Official with recommendations for appropriate institutional sanctions and then submitted to ORI for review. If the respondent admits to the misconduct, the committee should consult with the Office of Legal Affairs immediately.

After consultation with the Vice President for Research and the Office of Legal Affairs, the persons designated to conduct the inquiry will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

Inquiry Report

A written inquiry report must be prepared that states the name and title of the person or persons conducting the inquiry and expert consultants, if any; the allegations; the PHS support; 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, their determination as to whether an investigation is

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

recommended and whether any other actions should be taken if an investigation is not recommended. The Office of Legal Affairs will review the report for legal sufficiency. All relevant dates should be included in the report.

The Vice President for Research will provide the respondent with a copy of the draft inquiry report for comment and rebuttal.

1. Confidentiality

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

2. Receipt of Comments

Within ten (10) calendar days of their receipt of the draft report, the respondent will provide their comments, if any, to those conducting the inquiry. Any comments that the 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.

The person or persons conducting the inquiry will transmit the final report and any comments to the Vice President for Research, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. The inquiry is completed when the Vice President for Research makes this determination.

The Vice President for Research will notify both the respondent and the complainant in writing of their 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 institution must provide the respondent an opportunity to review and comment on the inquiry report.

If the allegations warrant an investigation and PHS funding is involved, then the institution must provide ORI, within thirty (30) days, with the

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

written findings and a copy of the inquiry report, and the respondent's comments.

The report to ORI must include the following:

1. The name and position of the respondent;
2. A description of the allegations of research misconduct;
3. The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
4. The basis for recommending that the alleged actions warrant an investigation; and,
5. Any comments on the report by the respondent or the complainant.

The institution must provide the following information to ORI on request:

1. The institutional policies and procedures under which the inquiry was conducted;
2. The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and,
3. The charges for the investigation to consider.

If the institution makes a decision not to investigate, the institution must keep sufficiently detailed documentation of inquiries to permit a later assessment by ORI of the reasons why the institution decided not to conduct an investigation. The institutions must keep these records in a secure manner for at least seven (7) years after the termination of the inquiry, and upon request, provide them to ORI of other authorized HHS personnel.

The institution must complete the inquiry within sixty (60) calendar days of its initiation unless circumstances clearly warrant a longer period. If

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

the inquiry takes longer than sixty (60) days to complete, the inquiry record must include documentation of the reasons for exceeding the sixty (60) day period.

The institution must notify ORI and other PHS agencies, as relevant, of any special circumstances that may exist. Examples of special circumstances are:

1. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
2. HHS resources or interests are threatened.
3. Research activities should be suspended.
4. There is reasonable indication of possible violations of civil or criminal law.
5. Federal action is required to protect the interests of those involved in the research misconduct proceeding.
6. The institution believes the research misconduct proceeding may be made public prematurely so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved.
7. The research community or public should be informed.

Referral to Other Officials or Agencies

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

Conducting the Investigation

The investigation should begin thirty (30) days after determining that an investigation is warranted, and all aspects of the investigation completed within 120 days from when the investigation started.

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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.

The Vice President for Research will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution'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. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

The Vice President for Research will notify the respondent as soon as reasonably possible after the determination is made to open an investigation. The notification should include:

1. A copy of the inquiry report;
2. The specific allegations;
3. The sources of PHS funding;
4. The definition of scientific misconduct;
5. The procedures to be followed in the investigation, including the appointment of the investigation committee and experts;
6. The opportunity of the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report;

7. The fact that ORI will perform an oversight review of the report regarding PHS issues; and,
8. An explanation of the respondent's right to request a hearing before the HHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition.

The Vice President for Research is responsible for conducting or designating others to conduct the investigation. In complex cases, the Vice President for Research will normally appoint a committee of three or more persons to conduct the investigation.

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 Vice President for Research may choose to conduct the investigation directly or designate another qualified individual to do so. In such cases, the investigation official will nevertheless obtain the necessary expert and technical advice to consider properly all scientific issues.

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

Appointment of the Investigation Committee

If an investigation committee is to be appointed, the Vice President for Research will use the following procedures:

- The Vice President for Research, in consultation with other institutional officials as appropriate, will appoint the investigation committee and the committee chair within ten (10) days of the notification to the respondent or as soon thereafter as practicable. The investigation committee should 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

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

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. Individuals appointed to the investigation committee may also have served on the inquiry committee.

- The Vice President for Research will notify the respondent of the proposed committee membership within five (5) days. If the respondent submits a written objection to any appointed member of the investigation committee or expert based on bias or conflict of interest, the Vice President for Research will immediately determine whether to replace the challenged member or expert with a qualified substitute.
- Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. 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 Vice President for Research to have knowledge of the investigation.

Charge to the Committee and the First Meeting

The Vice President for Research will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines research misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, complainant, and key witnesses to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

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 Vice President for Research, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

The Vice President for Research, with the assistance of legal counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed 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 these instructions and, where PHS funding is involved, the PHS regulation.

Developing an Investigation Plan

At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the complainant, respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and, a plan for the investigative report.

General Approaches to Conducting the Investigation

During the investigation, the committee will take the following steps:

- All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, complainant, and witnesses.
 - The Vice President for Research must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy.
 - The Vice President for Research and the Office of Legal Affairs should be consulted throughout the investigation on compliance with these procedures and PHS regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The Vice President for Research and Office of Legal Affairs will be present or available throughout the investigation to advise the committee.
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HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

Reviewing the Evidence

The investigation committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed. Also, the committee should pursue diligently all significant issues and leads discovered that are determined relevant to the investigation.

Conducting Interviews

The investigation committee will conform to the following guidelines:

- The investigation committee will conduct the interviews as described in this policy, except that at the investigative stage interviews should be in depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.
 - The investigation committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to discuss the issues. Committee deliberations should never be held in the presence of the interviewee.
 - The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.
 - Any interview with the respondent will be transcribed or recorded. Interviews with anyone else will be recorded. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.
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HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The committee should consult with the Office of Legal Affairs on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. The committee may ask the Vice President for Research or Office of Legal Affairs to consult with ORI when deciding whether an admission has adequately addressed all the relevant issues such that the investigation can be considered completed. The investigation should not be closed unless the respondent has been appropriately notified and given an opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the Vice President for Research as the Deciding Official with recommendations for appropriate institutional actions and then to ORI for review.

**Committee
Deliberations**

In reaching a conclusion on whether there was scientific misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence.

The committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific community at the time the actions were committed.

The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden of proving misconduct by a preponderance of the evidence. The committee will also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that research misconduct cannot be proven by a preponderance of the evidence.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

The Investigation Report

The final institutional investigation report must be in writing and include:

1. Allegations. Describe the nature of the allegations of research misconduct.
2. PHS Support. Describe and document the PHS support, including, for example, any grant numbers, grant applications, contracts, and publications listing PHS support.
3. Institutional charge. Describe the specific allegations of research misconduct for consideration in the investigation.
4. Policies and procedures. If not already provided to ORI with the inquiry report, include the institutional policies and procedures under which the investigation was conducted.
5. Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.
6. Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so:
 - a. Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or in reckless disregard;
 - b. Summarize the facts and analysis which support the conclusion and consider the merits of any reasonable explanation by the respondent;
 - c. Identify the specific PHS support;
 - d. Identify whether any publications need correction or retraction;
 - e. Identify the person(s) responsible for the misconduct; and,

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

f. List any current support or known applications or proposals for support that the respondent has pending with non-PHS Federal agencies.

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

8. Maintain and provide records. Maintain and provide to ORI upon request all relevant research records and records of the institution's research misconduct proceeding, including results of all interviews and the transcripts or recordings of such interviews.

Documenting the Investigative File

The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

The purpose of the documentation is to substantiate the investigation's findings. After completion of a case and all ensuing related actions, the Vice President for Research will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Vice President for Research. The Vice President for Research will keep the file for seven (7) years after completion of the case to permit later assessment of the case. ORI or other authorized HHS personnel will be given access to the records upon request.

Comments on the Draft Investigation Report

The draft investigation report will be reviewed as follows:

1. Respondent: The Vice President for Research will provide the respondent with a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the respondent on the draft report, if any, must be submitted within thirty (30)

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

days of the date on which the respondent received the draft investigation report.

2. Complainant: The complainant may be kept apprised of the status of the investigation if requested (ongoing, completed, etc.)
3. Legal Counsel: The draft investigation report will be transmitted to the Office of Legal Affairs for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.
4. Confidentiality: In distributing the draft report, or portions thereof, to the respondent the Vice President for Research will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

Institutional Review and Decision

Based on a preponderance of the evidence, the Vice President for Research will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Vice President for Research will explain in detail the basis for rendering a decision different from that of the investigation committee. The Vice President for Research's explanation should be consistent with the PHS definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The findings of the investigation committee and the Vice President for Research's final determination regarding the report will be provided to the President of the Health Science Center. The President will determine the consequences for the respondent if the determination of research misconduct was made. The President could also request additional fact-finding or analysis. The Vice President for Research's determination on the misconduct committee report together with the report and the President's determination of any consequences for the respondent constitutes the final investigation report for purposes of ORI review.

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

When a final decision on the case has been reached, the Vice President for Research will notify the respondent in writing. In addition, the Vice President for Research 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 Vice President for Research is responsible for ensuring compliance with all notification requirements of ORI, funding or sponsoring agencies, other relevant agencies, e.g., FDA.

Transmittal of the Final Investigation Report to ORI for PHS Funded Research

After comments have been received and the necessary changes have been made to the draft report, the Vice President for Research should transmit the final report with attachments and any appeals, including the respondent's comments, to ORI. In addition, the final institutional action must:

1. State whether the institution found research misconduct, and if so, who committed the misconduct.
 2. State whether the institution accepts the investigation's findings.
 3. Describe any pending or completed administrative actions against the respondent.
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Time Limit for Completing the Investigation Report

The final investigation report will be submitted to ORI within 120 days of the first meeting of the investigation committee, unless the institution requests a written request for extension and ORI grants the extension.

Institutional Administrative Actions

The Health Science Center will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the President determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken with regard to the respondent, after consultation

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

with the department Chair, Dean, and/or Vice President for Research. The actions may include:

1. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.
2. If there is substantial evidence to support the truth of the allegations and that hearing procedures to discipline or terminate the accused person(s) should be commenced pursuant to the established due process procedures of the University and the Board of Regents of the University of Texas System. The hearing procedures must begin within thirty (30) days after the conclusion of the inquiry. An attorney from the University of Texas System Office of General Counsel will be available to represent the University in the hearing.

Other Considerations

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Vice President for Research will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Vice President for Research 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 research misconduct was previously publicized, or expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

actions to restore the respondent's reputation must first be approved by the President.

Regardless of whether the institution or ORI determines that research misconduct occurred, the Vice President for Research will undertake reasonable efforts to protect complainants who made allegations of research misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the President will determine what steps, if any, are needed to restore the position or reputation of the complainant. The Vice President for Research is responsible for implementing any steps the President approves. The Vice President for Research will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the complainant.

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

Institutional 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.

ORI Review of the Investigation Report and Follow-up

ORI reviews the final investigation report, the supporting materials, and the institution's determinations to decide whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness, and competence. After completing its review, ORI either closes the case without a finding of research misconduct, or makes findings of research misconduct and proposes and obtains HHS approval of administrative actions based on the record of the research proceedings and any other information obtained by ORI during its review; or, recommends that HHS seek to settle the case.

Records Retention

The Vice President for Research will keep the complete file on all misconduct inquiries and investigations regardless of funding, including the records of any inquiry or investigation and copies of all documents and other materials furnished, for at least seven (7) years after

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	June 2000
Section 7.6	Research Fraud/Misconduct Policy	Revised:	May 2007
Policy 7.6.1	Policy Statement Relating to Misconduct or Research Misconduct	Responsibility:	Vice President for Research

completion of the case, or if ORI has advised the institution in writing that it no longer needs to retain the records. ORI or other authorized HHS personnel will be given access to the records upon request.
