Louisiana State University
Health Sciences Center in Shreveport
Policy and Procedures for
Dealing with Allegations of Research Fraud

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I. Introduction

The Louisiana State University Health Sciences Center in Shreveport (LSUHSC-S) seeks excellence in the discovery and dissemination of knowledge. Excellence in scholarship requires all members of the University community to adhere strictly to the highest standards of integrity with regard to research, instruction and evaluation. The principle of academic integrity is integral to membership on the faculty. Each faculty member recognizes the value and special importance of this responsibility, which is linked to accepting an appointment to the faculty.

As scholars and citizens of the University community, all parties must be ever cognizant of the axiom that every increment of authority and discretion brings with it corollary responsibilities to colleagues, students, the University as a whole, the community, and society at large. In addition, Federal regulations impose policies and procedures on the University for dealing with possible misconduct in science.[1]

The faculty is cognizant of the value to the University of calling attention to research misconduct and of the importance of bona fide challenges in assuring and maintaining the integrity of scholarly investigation of this institution.

Should the conduct of research or the collection or reporting of research data and information by a faculty member be challenged on the ground of misconduct, whether by another faculty member, student, staff member, research associate or fellow or a person outside the University, the framework for resolution of the grievance shall involve a process of peer and administrative review. Throughout, responsible and honest discourse, the protection of the individual against public dissemination of unwarranted allegations are the essential ingredients in the process.

Research misconduct, as defined below, carries potential for serious harm to the University community, to the integrity of science and to society as a whole. Accordingly, it is incumbent upon senior faculty members to exercise active leadership in their supervisory roles in collaborating with or directing junior colleagues or students. First, senior faculty must be fully cognizant of the quality of work being done for which they assume responsibility; and second, they must seek to alleviate undue pressure placed upon junior faculty or students which could lead to the publication of any inaccurate, incomplete or falsified data or information. In judging whether misconduct has occurred, it is important to distinguish fraud from honest error and ambiguities that are inherent in the process of scholarly investigation and are normally corrected by further research.

[1] See, e.g., 42 CFR 93.25 et seq. (Public Health Service Policies Research Misconduct).

This policy for handling allegations of misconduct shall apply to all persons who apply, as well as receive, PHS funding, Department of Defense, Department of Energy, Homeland Security, Industrial or foundation funding, including faculty, fellows, postdoctoral trainees, students, technicians and any other staff members, regardless of whether they are faculty.

The procedures described below, which implement the foregoing policy statement, are steps in a academic peer review and fact-finding process, and are not intended or designed to represent rules of a judiciary. Principles of basic fairness and confidentiality shall be observed in these peer review procedures. Any allegations of misconduct must be treated on an individual-case basis.

The Research Integrity Officer shall work closely with the Office of Legal Affairs and Organizational Integrity and the academic administrators and faculty panels involved. We will consult with law, government regulations, University policy, and principles of fairness in each stage of the proceedings set out in this policy. Academic administrators and faculty panels shall keep the Research Integrity Officer fully informed and shall consult him/her as to process before making any final decisions. The Research Integrity Officer shall monitor all procedures and time schedules described in this policy and shall inform the Deciding Official of any failures to comply with such time schedules. The Research Integrity Officer shall not have decision-making responsibility regarding the substance of any allegations. The Research Integrity Officer shall make or supervise all contacts with government agencies or other outside parties, and shall maintain a record of all proceedings.

The Research Integrity Officer shall have oversight responsibility to ensure compliance with the policy. Only the Research Integrity Officer has the authority to modify the various time limits specified in the procedures except that approval by the Chancellor shall be required if for unusual circumstances the Research Integrity Officer recommends an extension of time beyond 270 days for completion of the Inquiry and investigative phases after receipt of the initial report of alleged misconduct.

II. Definitions

A. *Allegation* means any written or oral statement or other communication of possible research misconduct made to an institutional official.

B. *Complainant*[2] means a person who in good faith makes an allegation of research misconduct.

C. *Confidentiality*[3] means that disclosure of the identity of respondents and complainants in research misconduct proceedings is limited, to the extent possible, to those who need to know, consistent with a thorough, competent, objective and fair research misconduct proceeding. LSUHSC-S

will disclose the identity of respondents and complainants to ORI pursuant to an ORI review of research misconduct proceedings. Confidentiality will be maintained for any records or evidence from which research subjects might be identified. Disclosure is limited to those who have a need to know to carry out a research misconduct proceeding.

D. *Deciding Official* means the LSUHSC-S official, the Chancellor, who shall make final determinations on allegations of research misconduct and any responsive LSUHSC-S actions.

E. *Employee* means, for the purpose of these instructions only, any person paid by, under the control of LSUHSC-S, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers.

F. *Good faith allegation* means an allegation made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

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

H. *LSUHSC-S counsel* means the LSUHSC-S Office of Legal Affairs and Institutional Integrity who represents LSUHSC-S during the research misconduct inquiry and investigation and who is responsible for advising the Research Integrity Officer, the inquiry and investigation committees, and the Deciding Official on relevant legal issues. The LSUHSC-S counsel does not represent the respondent, the complainant, or any other person participating during the inquiry, investigation, or any follow-up action, except LSUHSC-S officials responsible for managing or conducting the LSUHSC-S research misconduct process as part of their official duties.

I. *Investigation* means the formal 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.

J. *ORI* means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the research misconduct and research integrity activities of the U.S. Public Health Service.

K. *PHS* means the U.S. Public Health Service, an operating component of the U.S. Department of Health and Human Services.

L. *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of research misconduct, which is set forth at 42 C.F.R. Part 93, Subpart A, entitled "Public Health Services Policies on Research Misconduct."

M. *PHS support* means Public Health Service grants, contracts, or cooperative agreements, or applications therefore.

N. *Preponderance of Evidence*[4] means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.

O. *Research Integrity Officer/Attorney* the LSUHSC-S official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing any inquiries and investigations.

Research Misconduct Proceedings[5] means any actions related to alleged research misconduct taken, including but not limited to, allegation assessments, inquiries, investigations, ORI oversight reviews, hearings and administrative appeals.

P. *Research record* means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of 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 patient research files.

Q. *Respondent* means 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.

R. *Retaliation*[6] means 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.

S. *Research misconduct*[7] or misconduct in research means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting or reviewing research, or in reporting research results. It does not include honest error or honest differences in interpretations or judgments of data.

III. General Procedures and Principles

A. Responsibility to Report Misconduct

LSUHSC-S employees who observe potential research misconduct or receive or learn of an allegation of research misconduct will immediately report the observation or allegation to the Research Integrity Officer for appropriate action. The Research Integrity Officer will promptly engage in an assessment of the allegation to determine whether it falls within the definition of research misconduct, involves PHS support, and provides sufficient information to proceed with an inquiry

B. Protecting the Complainant

LSUHSC-S employees who receive or learn of an allegation of research misconduct 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 LSUHSC-S against retaliation. Employees will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

C. Protecting the Respondent

LSUHSC-S employees who receive or learn of an allegation of research 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 93, Subparts A-E, and these procedures are followed. Employees will report significant deviations from these instructions to the Research Integrity Officer. The Research Integrity

Officer will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Confidentiality[3]

To the extent allowed by law, we shall maintain the identity of respondents and complainants securely and confidentially and shall not disclose any identifying information, except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) ORI as it conducts its review of the research misconduct proceeding and any subsequent proceedings. To the extent allowed by law, any information obtained during the research misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the research misconduct proceeding.

E. Responding to Allegations

In responding to allegations of research misconduct, the Research Integrity Officer and any other LSUHSC-S official with an assigned responsibility for handling such allegations 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.[8]

2. Reasonable precautions are taken to avoid bias and real or apparent personal, professional or financial conflicts of interest on the part of those involved in conducting the inquiry or investigation with the complainant, respondent or witnesses.[8]

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;

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 a reasonable indication of a possible Federal criminal violation. In this instance, LSUHSC-S will 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.

F. Employee Cooperation

LSUHSC-S employees shall cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other LSUHSC-S officials on misconduct allegations. Further, employees will cooperate with ORI in its conduct investigations, its oversight of LSUHSC-S inquiries and investigations, and any follow up actions.

G. Evidentiary Standards

The following evidentiary standards apply to findings of research misconduct.

1. Burden of Proof

LSUHSC-S or HHS has the burden of proof for making a finding of research misconduct.[9]

2. Standard of Proof [10]

Any LSUHSC-S or ORI finding of research misconduct must be proved by a preponderance of the evidence. This means proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.[4]

H. Completion of Process

The Research Integrity Officer is responsible for ensuring that the

inquiry/investigation process and all other steps required by this 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 the institution plans to terminate an inquiry or investigation prior to completion of all the steps required by the PHS regulation, the Research Integrity Officer will notify ORI of the planned termination and the reasons therefore. ORI will review the information provided and advise LSUHSC-S whether further investigation should be undertaken.

J. Referral of Non- Research Misconduct Issues

When LSUHSC-S's review of the allegation identifies non- research misconduct issues, the Research Integrity Officer should refer these matters to the proper LSUHSC-S or Federal office for action. Issues requiring referral are described below.

1. HHS Criminal Violations

Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General, telephone (202) 619-3148, paffairs@oig.hhs.gov. 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. Violation of Human and Animal Subject Regulations

Potential violations of human subject regulations should be referred to the Office of Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Phone: 240-453-6900, or 866-447-4777. Email: ohrp@osophs.dhhs.gov.

Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare, National Institutes of Health, 6705, Rockledge Drive, RKL1, MSC 7982, Bethesda, MD 20892, Phone: 301-496-7163.

3. Violation of FDA Regulations

Potential violations of Food and Drug Administration regulated research

requirements should be referred to the FDA Office of Regulatory Affairs, Bioresearch Monitoring Operations, US Custom House, 200 Chestnut Street, Room 900, Philadelphia, PA, 19106, telephone 215-717-3003, anne.johnson@fda.hhs.gov.

4. Fiscal Irregularities

Potential violations of cost principles or other fiscal irregularities should be referred as follows:

a. For all NIH Agencies--Office of Management Assessment, telephone (301) 496-1873, omainfo@nih.gov

b. For all other HHS Agencies—US Department of Health and Human Services, 200 Independence Avenue, SW, Washington DC 20201, telephone 1-877-696-6775

If there are any questions regarding the proper referral of non- research misconduct issues, the Research Integrity Officer may call the ORI Division of Investigative Oversight at telephone 240-453-8800 to obtain advice.

K. Requirements for Reporting to ORI

LSUHSC-S's decision to initiate an investigation will be reported in writing to the Director, ORI, on or before the date the investigation begins.[11] At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of research misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[12] Any significant variations from the provisions of the LSUHSC-S policies and procedures should be explained in any reports submitted to ORI.

1. If LSUHSC-S plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

2. If LSUHSC-S determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the

progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.[13]

3. When PHS funding or applications for funding are involved and an admission of research misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, LSUHSC-S cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

4. The Research Integrity Officer will notify ORI immediately at any stage of the inquiry or investigation if: [14]

   a. health or safety of the public is at risk, including an immediate need to protect human or animal subjects;

   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 violation of civil or criminal law. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

5. Other Procedures to be reported to the Research Integrity Officer shall include allegations of misconduct in projects funded by Department of Defense, Department of Energy, Homeland Security or any industrial or foundation funded projects.

LSUHSC-S shall cooperate fully and on a continuing basis with ORI during

its oversight reviews of this institution and its research misconduct proceedings and during the process under which the respondent may contest ORI findings of research misconduct and proposed HHS administrative actions. This includes providing, as necessary to develop a complete record of relevant evidence, all witnesses, research records and other evidence under our control, or in the possession of, or accessible to, all persons that are subject to our authority.

LSUHSC-S will report to ORI any proposed settlements, admissions of research misconduct, or LSUHSC-S findings of misconduct that arise at any stage of a misconduct proceeding, including the allegation and inquiry stages.

IV. Preliminary Assessment of Allegations

A. Allegation Assessment

Promptly after receiving an allegation of research misconduct, defined as a disclosure of possible research misconduct through any means of communication, the Research Integrity Officer shall assess the allegation to determine if,

a. it meets the definition of research misconduct in 42 CRF Section 93.103 (copy attached)

b. it involved either the PHS supported research, applications for PHS research support, or research records specified in 42 CFR Section 93.102 (b) (copy attached)

c. the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

1. PHS Support

Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support.

2. PHS Definition

The allegation should 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 Research Integrity Officer should consult with LSUHSC-S counsel or ORI on whether the allegation falls within the PHS definition of research 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 should 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 research 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 should be referred to the appropriate PHS or DHHS office. See section III-J.

V. Conducting the Inquiry[15]

A. Initiation and Purpose of the Inquiry[16]

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of research misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity 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 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.

If it is determined that an inquiry (i.e., an initial review of the evidence to determine if the criteria for conduction of an investigation have been met)

is warranted, LSUHSC-S personnel shall complete the inquiry, including preparation of the inquiry report and giving the respondent a reasonable opportunity to comment on it, within 60 calendar days of its initiation, unless circumstances warrant a longer period.[17] If the inquiry takes longer than 60 days to complete, the Research Integrity Officer shall include documentation of the reasons for the delay in the inquiry record and notify the respondent and complainant of the extension.

B. First Steps if an Inquiry Is Necessary

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

1. secure the relevant research records;

2. notify the department head, institutional counsel, the respondent, and 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 III.E.3 of these procedures are present.

The Research Integrity Officer or LSUHSC-S counsel may consult with ORI at any time regarding appropriate procedures to be followed.

C. Maintenance and Custody of Research Records and Evidence

LSUHSC-S shall take the following specific steps to obtain, secure, and maintain the research records and evidence pertinent to the research misconduct proceeding:

1. Either before or when we notify the respondent of the allegation, we shall promptly take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct proceedings, inventory those materials, and sequester them in a secure manner, except in those cases where the research records or evidence encompass research instruments shared by a number of uses, 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. 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.

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

2. Where appropriate, give the respondent copies of, or reasonable, supervised access to the research records.

3. Notify the respondent that an inquiry is being initiated simultaneously with the custody of research records so that the respondent can assist with location and identification of the research records. The Research Integrity Officer should obtain the assistance of the respondent's supervisor and LSUHSC-S counsel in this process, as necessary. If the respondent is not available, custody may begin in the respondent's absence. The respondent should not be notified in advance of the custody 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 Research Integrity 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.

4. Inventory of the Records

   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.

5. Security and Chain of Custody

   The Research Integrity 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 an LSUHSC-S 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 LSUHSC-S counsel.

D. Notification of the Respondent

1. Contents of Notification

The Research Integrity 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 research 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 obligation as an employee of LSUHSC-S to cooperate; describe LSUHSC-S's policy on protecting the complainant against retaliation and the need to maintain the complainant's confidentiality during the inquiry and any subsequent proceedings

2. Potential Respondents

If no specific respondent has been identified at this stage of the process, the Research Integrity Officer will notify each potential respondent that an inquiry will be undertaken, e.g., each coauthor on a questioned article or each investigator on a questioned grant application.

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

The Research Integrity Officer is responsible for conducting or designating others to conduct the inquiry.

1. Use of an Inquiry Committee

In complex cases, the Research Integrity Officer will normally

appoint a committee of three or more persons to conduct the inquiry, following the procedures set forth in section V.F.

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 Research Integrity Officer may choose to conduct the inquiry.

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 Research Integrity Officer will use the following procedures:

1. Committee Membership

The Research Integrity Officer, in consultation with other LSUHSC-S officials as appropriate, will appoint the committee and committee chair within 10 days of the initiation of the inquiry. The inquiry 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 allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of LSUHSC-S.

2. Experts

The Research Integrity 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 provide a strictly advisory function to the committee; they do not vote and generally do not interview witnesses. The experts chosen may be from inside or outside of LSUHSC-S.

3. Bias or Conflict of Interest

The Research Integrity Officer will take reasonable steps to ensure that the members of the committee and experts have no bias or personal, professional or financial conflict of interest with the respondent, complainant, or the case in question. In making this determination, the Research Integrity 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 coauthor on a publication with the respondent or complainant;

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

d. has been a party to a research 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 other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

4. Objection by Respondent

The Research Integrity 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 Research Integrity 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 Research Integrity Officer to have knowledge of the inquiry.

6. Provision of Assistance

The Research Integrity Officer, in consultation with LSUHSC-S 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 Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, complainant, and key witnesses to determine whether there is sufficient evidence of possible 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.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, 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 Research Integrity Officer and LSUHSC-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 or Conflict of Interest

All necessary steps must 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 Research Integrity Officer 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. See section III.E.3 and III.J.

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 should not attempt to speculate about what happened or might have happened or put words in the witnesses' mouths. Also, the committee should 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 should 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 should be given an opportunity to supplement the record in writing or in another interview. The witness should be informed that his or her cooperation and truthful answers are expected.

3. Confrontation

Witnesses should not be told at this stage whether other testimony conflicts with theirs, although questions may be asked for purposes of clarifying the testimony. 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. Any 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 by a certified court reporter, or equivalent. 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 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.

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 should interview, if possible, the complainant, key witnesses, and the respondent. Witnesses should 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 should attempt to obtain as much additional evidence regarding 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 should 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 research judgment occurred, he or she should provide any evidence to support that 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 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 Research Integrity Officer or LSUHSC-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 Deciding Official 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 Research Integrity Officer and LSUHSC-S counsel, the committee members 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.

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

J. Interim Protective Actions

1. At any time during a research misconduct proceeding, we shall take appropriate interim actions to protect public health, federal funds and equipment, and the integrity of the PHS supported research process. The necessary actions that may be necessary include delaying the publication of research results, providing for closer supervision of one or more researchers, requiring approvals for actions relating to the research that did not previously require approval, auditing pertinent records or taking steps to contact other institutions that may be affected by an allegation of research misconduct.

2. Notifying ORI of Special Circumstances that may Require Protective Actions

   At any time during a research misconduct proceeding, we shall notify ORI immediately if we have reason to believe that any of the following conditions exist:

   a. Health or safety of the public is at risk, including an immediate need to protect human or animal subjects

   b. HHS resources or interest are threatened

   c. Research activities should be suspended.

   d. There is a reasonable indication of violations of civil or criminal law.

   e. Federal action is required to protect the interests of those involved in the research misconduct proceeding.

f. We believe 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.

g. We believe the research community of public should be informed.

VI. The Inquiry Report[18]

A. Elements of the Inquiry Report[19]

A written inquiry report must 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 an investigation is not recommended. LSUHSC-S counsel will review the report for legal sufficiency. All relevant dates should be included in the report.

B. Comments on the Draft Report by the Respondent and the Complainant[20]

The Research Integrity 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 a summary of the inquiry findings for comment.

1. Confidentiality

The Research Integrity 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 Research Integrity 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 research 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 Research Integrity 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 notice must include a copy of the inquiry report and include a copy of or refer to this part and LSUHSC-S's policies and procedures.[21]

The Research Integrity Officer will also notify all appropriate institutional 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 Research Integrity Officer no more than 60 calendar days following its first meeting,[17] unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity 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.

VII. ORI Oversight

A. Decision to Investigate

If the Deciding Official decides that an investigation will be conducted, the Research Integrity Officer will notify ORI and will forward a copy of

the final inquiry report and LSUHSC-S's policies and procedures for conducting investigations to ORI. [22]

On or before the date on which the investigation begins (the investigation must begin within 30 calendar days of our finding that an investigation is warranted), we shall provide ORI with the written finding by the Deciding Official and a copy of the inquire report containing the information required by 42 CFR Section 93.309 (a) (copy attached). Upon a request from ORI we shall promptly send them

1. A copy of LSUHSC-S 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.

3. The charges for the investigation to consider

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 Research Integrity 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 LSUHSC-S 's determination not to proceed to an investigation, the Research Integrity 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 Research Integrity Officer will keep all records secure until ORI makes its final decision on its oversight of the LSUHSC-S inquiry or investigation.

LSUHSC-S will keep all records relating to the inquiry in a secure manner for at least seven years after the termination of the inquiry, and, upon request, provide them to ORI or other authorized HHS personnel.[23]

VIII. Referral to Other Agencies

Information obtained during the inquiry regarding allegations other than research misconduct involving PHS funds should be referred to the responsible LSUHSC-S officials or government agencies. See section III.J.

IX. Conducting the Investigation[24]

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.

The investigation must begin within 30 days after determining that an investigation is warranted.[25]

B. Maintenance of Custody of the Research Records and Evidence

The Research Integrity Officer will immediately sequester and maintain custody of any additional pertinent research records that were not previously sequestered during the inquiry. This maintenance of custody should occur before or at the time the respondent is notified that an investigation has begun. The need for additional custody 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 custody during the investigation are the same procedures that apply during the inquiry. See section V.C.

C. Notification of the Respondent

The Research Integrity Officer will notify the respondent as soon as reasonably possible after the determination is made to open an

investigation, but before the investigation begins[26]. The notification should include: a copy of the inquiry report; the specific allegations; the sources of PHS funding; the definition of research misconduct; the procedures to be followed in the investigation, including the appointment of the investigation committee and experts; the opportunity of the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report; the fact that ORI will perform an oversight review of the report regarding PHS issues; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition.

D. Designation of an Official or a Committee to Conduct the Investigation

The Research Integrity Officer is responsible for conducting or designating others to conduct the investigation.

1. Use of an Investigation Committee

In complex cases, the Research Integrity Officer will normally appoint a committee of three or more persons to conduct the investigation, following the procedures set forth in section IX

. 2. Use of an Investigation 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 Research Integrity Officer 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 research issues.

3. Investigation Process

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

E. Appointment of the Investigation Committee

If an investigation committee is to be appointed, the Research Integrity Officer will use the following procedures:

1. Committee Membership

The Research Integrity Officer, in consultation with other LSUHSC-S officials as appropriate, will appoint the investigation committee and the committee chair within 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 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.

2. Experts

Experts may be appointed as noted in section V.E.2-3 (or carried over from the inquiry) to advise the committee on research or other issues.

3. Bias or Conflict of Interest

The Research Integrity Officer will take reasonable steps to ensure that the members of the committee and he experts have no bias or personal, financial or professional conflict of interest with the respondent, complainant, or the case in question. See section V.F.

4. Objection to Committee or Experts by Respondent

The Research Integrity Officer will notify the respondent of the proposed committee membership within 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 Research Integrity 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 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 Research Integrity Officer to have knowledge of the investigation

F. Charge to the Committee and the First Meeting

The Research Integrity Officer 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 Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

The Research Integrity Officer, with the assistance of LSUHSC-S 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.

G. 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 (research, forensic, or other); and a plan for the investigative report.

In conducting all investigations, we shall:

1. Use diligent efforts to ensure that the investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of the allegations.

2, Interview each respondent, complainant and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of investigation.

3. Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of additional instances of possible research misconduct, and continue the investigation to completion.

4. Otherwise comply with the requirements for conducting an investigation in 42 CFT Section 93.310 (copy attached)

H. General Approaches to Conducting the Investigation

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

1. Avoid Bias or Conflict of Interest

   All necessary steps must 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 Research Integrity Officer 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. See section III.E.3 and III.J.

3. Consult with the Research Integrity Officer and LSUHSC-S counsel The Research Integrity Officer and LSUHSC-S counsel 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 Research Integrity Officer and LSUHSC-S counsel will be present or available throughout the investigation to advise the committee.

I. 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.

J. Conducting Interviews

The investigation committee will conform to the following guidelines:

1. Conducting the Interviews

The investigation committee will conduct the interviews as described in section V.I., 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.

2. Preparing for Interviews

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.

3. Objectivity

The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

4. Transcribing Interviews

Any interview with the respondent and all other witnesses will be transcribed by a qualified court reporter or equivalent. A transcript 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 will only be made to correct factual errors.

5. Recording Admissions

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 LSUHSC-S counsel 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 Research Integrity Officer or LSUHSC-S counsel 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 Deciding Official with recommendations for appropriate institutional actions and then to ORI for review.

K. Committee Deliberations

1. Burden and Standard of Proof

In reaching a conclusion on whether there was research misconduct and who committed it, the burden of proof[9] is on LSUHSC-S to support its conclusions and findings by a preponderance of the evidence[4]. See section III.G.

` 2. Definition of Research Misconduct

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 research community at the time the actions were committed.

3. Sufficient Evidence

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.

X. The Investigation Report

A. Outline for an Investigation Report

The following annotated outline may prove useful in preparing the Investigation Report required by the Office of Research Integrity (42 CFR. Part 93.313), except when special factors suggest a different approach.

We shall prepare the draft and final institutional investigation reports in writing and provide the draft report for comment as provided elsewhere in these policies and procedures and 42 CFR Section 93.312. (copy attached)

The final investigation report shall include:

1. Background

   Include sufficient background information to ensure a full understanding of the issues that concern the PHS under its definition of research misconduct. This section should detail the facts leading to the institutional inquiry, including a description of the research at issue, the persons involved in the alleged misconduct, the role of the complainant, and any associated public health issues. All relevant dates should be included.

2. Allegations

   List all the allegations of research misconduct raised by the complainant and any additional research misconduct allegations that arose during the inquiry and investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a complainant requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

3. PHS Support

   For each allegation of research misconduct under the PHS definition, identify the PHS support for the research or report (e.g., publication) at issue or the application containing the falsification/fabrication or plagiarism.

4. Research Records and Evidence Reviewed

   Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody, but not reviewed. The report should also describe any relevant records and evidence not taken into custody and explain why.

5. Institutional Inquiry: Process and Recommendations
   Summarize the inquiry process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the

evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

6. LSUHSC-S Investigation: Process

Summarize the investigation process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

7. LSUHSC-S Investigation: Analysis

For each allegation:

Background

Describe the particular matter (e.g., experiment or component of a clinical protocol) in which the alleged misconduct occurred and why and how the issue came to be under investigation.

Analysis

The analysis should:

Take into account all the relevant statements, claims (e.g., a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (e.g., laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).

Note any use of additional expert analysis (forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures).

Summarize or quote relevant statements, including rebuttals, made by the complainant, respondent, and other pertinent witnesses and reference/cite the appropriate sources.

Summarize each argument that the respondent raised in his or her defense against the research misconduct allegation and cite the source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

Be consistent with the terms of PHS definition of research misconduct. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Describe any evidence that shows that the respondent acted with intent, that is, any evidence that the respondent knowingly engaged in the alleged falsification, fabrication, plagiarism, or other conduct that constitutes a serious deviation from commonly accepted practices.

Similarly, describe the evidence supporting the possibility that honest error or differences of research opinion occurred with respect to the issue.

Conclusions

a. Findings of Misconduct or No Misconduct

Concisely state the investigation committee's finding for each identified issue. The investigation report should make separate findings as to whether or not each issue constitutes research misconduct, using the PHS definition. A finding of research misconduct should be supported by a preponderance of the evidence.

If the investigation committee finds research misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly in the research community). The report should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the

laboratory or project in which the misconduct occurred.

If the investigation committee determines that the respondent committed research misconduct by seriously deviating from "other commonly accepted practices," the report should thoroughly document the commonly accepted practice of the relevant research community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publications, standards of the institution or relevant professional societies, State and Federal regulations, expert opinion, and other sources should be described and cited as the basis for the commonly accepted practice. The serious deviation therefrom should be described in detail, indicating why the alleged act was a serious deviation.

b. A finding of research misconduct made under this part requires that:

i. there be a significant departure from accepted practices of the relevant research community, and

ii. the misconduct be committed intentionally, knowingly, or recklessly, and

iii. the allegation be proven by a preponderance of the evidence. [27]

c. Misconduct under LSUHSC-S's Policies

The investigation committee may determine that an action that does not constitute research misconduct under the PHS definition is, nevertheless, research misconduct under LSUHSC-S's own definition (e.g., clinical protocol deviations or other violations of human subjects protection; documented animal welfare concerns; substandard data management practices; deficient mentoring of trainees). Any issue that the investigation committee determines to be research misconduct solely under the institution's own definition should be identified as such. These findings are not subject to ORI's jurisdiction if ORI agrees that they do not meet the PHS definition or jurisdictional basis.

8. Recommended Institutional Actions

Based on its findings, the investigation committee should recommend administrative actions that it believes the institution should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, termination, etc. The institution should also identify any published research reports or other sources of research information (such as data bases) that should be retracted or corrected and take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

Attachments

Copies of all significant documentary evidence that is referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and complainant responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments."

It is useful to identify allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc., on a copy of the page or section of the questioned document (e.g., a page from a research notebook). A side-by-side comparison with the actual data or material that is alleged to have been plagiarized is helpful.

B. Standard Format of the Investigation Report [28]

The following outline should be used in preparing the Investigation Report, except when special factors suggest a different approach. The report should incorporate all of the elements described in section 42 CFR 93.313.

1. Background

- Chronology of events

- Include public health issues

2. Allegations

3. PHS Support or Application(s) (by allegation)

4. LSUHSC-S Inquiry: Process and Recommendations

- Composition of committee

- Individuals interviewed

- Evidence sequestered and reviewed

5. LSUHSC-S Investigation: Process

- Composition of committee

- Individuals interviewed

- Evidence sequestered and reviewed

6. Institutional Investigation: Analysis

For each allegation:

- Background

- Analysis of all the relevant evidence and specific identification of evidence supporting the finding

- Conclusion: research misconduct or no research misconduct

- Effect of misconduct (e.g., potential harm to research subjects, reliability of data, publications that need to be corrected or retracted, etc.)

7. Recommended LSUHSC-S Actions

8. Attachments

C. Documenting the Investigative File

1. Index of Evidence

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 analysis.

2. Purpose of Documentation

The purpose of the documentation is to substantiate the investigation's findings.

3. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for seven years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request[29].

D. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 working days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Complainant

The Research Integrity Officer will provide the complainant, if he or she is identifiable, with those portions of the draft investigation report that address the complainant 's role and opinions in the investigation. The report should be modified, as appropriate, based on the complainant's comments.

3. LSUHSC-S Counsel

The draft investigation report will be transmitted to LSUHSC-S counsel 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 and complainant, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

E. LSUHSC-S Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended LSUHSC-S actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in LSUHSC-S's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of research misconduct, LSUHSC-S's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the complainant in writing. In addition, the Deciding Official 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 Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

F. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent' and complainant 's comments, to the Deciding Official, through the Research Integrity Officer.

G. 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[30], unless LSUHSC-S requests a written request for extension and ORI grants the extension. All attachments to the final report should be submitted with the report. The Research Integrity Officer should maintain all other evidence and materials for possible ORI review.

XI. LSUHSC-S Administrative Actions

Louisiana State University Health Sciences Center – Shreveport will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

A. withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found.

B. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

C. restitution of funds as appropriate.

XII. Other Considerations

A. Termination of LSUHSC-S Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's LSUHSC-S 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.

B. Restoration of the Respondent's Reputation

If LSUHSC-S finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer 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 LSUHSC-S actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Complainant and Others

Regardless of whether LSUHSC-S or ORI determines that research misconduct occurred, the Research Integrity Officer 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 Deciding Official will determine, after consulting with the complainant, what steps, if any, are needed to restore the position or reputation of the complainant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the Inquiry and investigation to prevent any retaliation against the complainant.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official 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 Deciding Official will determine whether any administrative action should be taken against the complainant.

E. Interim Administrative Actions

LSUHSC-S 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.

XIII. ORI Review of the Investigation Report and Follow-up

A. Purpose of ORI Review

ORI reviews the final investigation report, the supporting materials, and the Deciding Official's determinations to decide whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness, and competence. Based on its review, ORI may:

1. request additional information from LSUHSC-S;

2. accept all the findings and conclusions of the report;

3. accept all or part of the factual findings of the report and make its own conclusions;

4. request additional investigation by LSUHSC-S;

5. reject the report and conduct its own investigation;

6. impose administrative actions on the respondent beyond those recommended by LSUHSC-S;

7. refer the case to the Division of Policy and Education, ORI, for a review of LSUHSC-S’s regulatory compliance; or

8. take any other action deemed to be in the public interest and within ORI's authority.

ORI will attempt to complete its review of LSUHSC-S’s report within 180 days of its receipt, except where additional follow up activities are required, such as an ORI request for additional information or analysis or where further investigation is necessary.

B. Cooperation with ORI Review

ORI is authorized by statute and PHS regulations to review institutional reports on allegations of research misconduct. In reviewing an institution's report, ORI may request additional information or other assistance from the Research Integrity Officer or other LSUHSC-S officials. If the LSUHSC-S official receiving the ORI request is unsure how to respond, he or she should consult with the Research Integrity Officer or LSUHSC-S counsel. LSUHSC-S counsel may consult with ORI counsel prior to advising the LSUHSC-S official on how to respond.

C. Request for Additional Documents and Information

The Research Integrity Officer will cooperate with any ORI request for additional documents and information by responding to all requests in a timely and responsive fashion. The Research Integrity Officer may consult with LSUHSC-S counsel for advice as needed.

D. Notification of ORI Determination

1. ORI Concurrence

If ORI concurs with LSUHSC-S 's findings, ORI will notify the respondent and appropriate LSUHSC-S officials in writing and will send the respondent and appropriate LSUHSC-S official a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of research misconduct, the respondent will be notified of his or her opportunity to appeal to the DHHS Departmental Appeals Board (DAB). See 42 CFR 93.500

2. ORI Non-concurrence

If ORI does not concur with LSUHSC-S's findings, ORI will notify the appropriate LSUHSC-S official of the basis for that decision. If ORI does not concur with a finding of no misconduct, LSUHSC-S may be requested to conduct a further investigation, either with the same or a different investigation committee, or ORI may conduct its own investigation. In the latter instance, ORI will notify the appropriate individuals of its investigation.

E. Cooperation in Appealed Cases

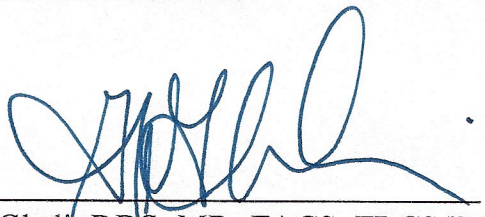
For cases in which ORI concurs with LSUHSC-S's findings of research misconduct under the PHS definition or makes its own finding of research misconduct, ORI will request LSUHSC-S employees to cooperate in presenting ORI findings of misconduct before the DAB if the respondent appeals the findings.

Cooperation includes providing evidence, testimony, or any other information needed to assist in the preparation and presentation of ORI's case before the DAB. LSUHSC-S employees may consult with the Research Integrity Officer or LSUHSC-S counsel in responding to ORI's request for cooperation.

XIV. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer of Committees. The Research Integrity Officer will keep the file for at least seven years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

Revision of October 2008, Model Procedures for Responding to Allegations of Misconduct.
Revised December 2017



G.E. Ghali, DDS, MD, FACS, FRCS(Ed)
Chancellor and Dean

XV. References

1. 42 CFR 25 et seq.
2. 42 CFR 93.203
3. 42 CFR 93.108
4. 42 CFR 93.219
5. 42 CFR 93.223
6. 42 CFR 93.226
7. 42 CFR 93.103
8. 42 CFR 93.300 (b)
9. 42 CFR 93.106 (b)
10. 42 CFR 93.106 (a)
11. 42 CFR 93.310 (b)
12. 42 CFR 93.313
13. 42 CFR 93.311(b)
14. 42 CFR 93.318)
15. 42 CFR 93.307
16. 42 CFR 93.307 (c)
17. 42 CFR 93,307 (g)
18. 42 CFR 93.307 (e)
19. 43 CFR 93.309
20. 42 CFR 93.307 (f)
21. 42 CFR 93.308

22. 42 CFR 93.309 (a)

23. 42 CFR 93.309 (c)

24. 42 CFR 93.310

25. 42 CFR 93.310

26. 42 CFR 93.310 (c)

27. 42 CFR 93.104

28. 42 CFR 93.313

29. 42 CFR 93.317 (b)

30. 42 CFR 93.311 (a)