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RESEARCH MISCONDUCT

I. Introduction*

**Federal law requires Federal agencies sponsoring research to require an awardee institution to have such a policy in place. For instance, Section 215 of the Public Health Service Act 58 Stat.690 (42 U.S.C.216); (Section 1066, Public Health Service Act, 84 Stat. 1507 (42 U.S.C 300a-4); unless otherwise noted (available in the Office of Research and Economic Development), provides that the Secretary, by regulation, require that entities receiving Federal funds for the conduct of research, research training and related research activities submit assurances that these entities have established, based on regulations prescribed by the Secretary, an administrative process to review reports of alleged research misconduct, research training and related research activities, and a mechanism for reporting any investigation of alleged research misconduct to the Secretary.*

A. General Policy

Louisiana State University and Agricultural and Mechanical College (LSU) has a commitment to high ethical standards in research and scholarship, and expects that all personnel serving in any capacity in research will work to ensure the integrity of science and scholarship. In the event of possible deviation from these standards, LSU provides this policy and administrative procedure to review reports of alleged research misconduct conducted under University auspices. The procedures do not create any right or benefit, substantive or procedural, enforceable at law by a party against the institution, its agencies, or employees. Definitions of terms used in this policy are found in section II.

The primary responsibility for detecting, investigating, reporting and resolving allegations of research misconduct rests with the University. If warranted, the University must take whatever action is necessary to ensure the integrity of research; the rights and interests of research subjects, the public, the respondent, and the complainant; and the observance of relevant legal requirements imposed by any involved funding agency.

B. Scope

This policy and its procedures apply to all individuals at LSU engaged in research or scholarship, including any person paid by, under the control of, or affiliated

with LSU, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at LSU, regardless of whether on or off campus.

This policy and associated procedures will normally be followed when an allegation of possible research misconduct is received by an institutional official or when for any reason research misconduct is suspected. Any change from normal procedures must ensure fair treatment to the subject of the inquiry or investigation and to the complainant. Any significant departure from these procedures must be approved in advance by the Chancellor and, where appropriate, University counsel.
Note: violations of regulations concerning human or animal research subjects, biosafety, recombinant DNA, or financial conflicts of interest are addressed in other policies. These policies shall not be applicable to the present policy unless research misconduct is also alleged.

C. Research Misconduct

“Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
(a) Fabrication is making up data or results and recording or reporting them.
(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
(d) Research misconduct does not include honest error or differences of opinion.

A finding of research misconduct requires that--
(a) There be a significant departure from accepted practices of the relevant research community; and
(b) The misconduct be committed intentionally, knowingly, or recklessly; and
(c) The allegation be proven by a preponderance of the evidence.” [1]

D. Time Limitation

The research misconduct must have occurred within six years of the date LSU receives an allegation of research misconduct with the following exceptions:

> “(1) Subsequent use exception. The respondent continues or renews any incident of alleged research misconduct that occurred before the six-year limitation through the citation, republication or other use for the potential benefit of the respondent of the research record that is alleged to have been fabricated, falsified, or plagiarized.

(2) Health or safety of the public exception. If the ORI or LSU, following consultation with ORI, determines that the alleged misconduct, if it occurred, would possibly have a substantial adverse effect on the health or safety of the public." [1]

E. Evidentiary Standards

The following evidentiary standards apply to findings made under this policy:

(a) "Standard of proof. An institutional finding of research misconduct must be proved by a preponderance of the evidence." [1]

(b) "Burden of proof.

(1) LSU 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 LSU 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, or 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.

(2) 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 LSU has carried the burden of proof, the finder of fact shall give due consideration to admissible, credible evidence of honest error or difference of opinion presented by the respondent.

3) 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 administrative actions following a research misconduct proceeding." [1]

F. Responsibility to Report Misconduct

All covered individuals associated with LSU should report observed, suspected, or apparent research misconduct to the Research Integrity Officer (RIO) who is the Vice Chancellor for Research and Economic Development. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may call the Research Integrity Officer at 225-578-5833 to discuss the suspected research misconduct informally. If the circumstances

described by the individual do not meet the definition of research misconduct, the Research Integrity Officer may refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, a covered individual may have confidential discussions and consultations about concerns of possible research misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

G. Cooperation with Inquiries and Investigations

Covered individuals will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations, and they have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on research misconduct allegations.

H. Confidentiality

Except as herein provided, maintenance of confidentiality of all aspects of an allegation of research misconduct, and subsequent inquiries and investigations of the allegation, is required of all individuals knowledgeable of the alleged research misconduct or allegation. Complainants must respect the confidentiality of sensitive information and give legitimate institutional procedures an opportunity to function. Should a complainant elect to make a disclosure that violates institutional rules of confidentiality, the institution may thereafter legitimately limit the complainant's access to further information about the case. Disclosures by any participants during the process may make that person subject to institutional action beyond any remedy sought by any person injured by that disclosure.

II. Definitions

A. *Allegation* means "a disclosure of possible research misconduct through any means of communication. The disclosure may be by written or oral statement or other communication to an institutional or HHS official" [1]. The disclosure may also be to other relevant funding agencies.

B. *Complainant* means "a person who in good faith makes an allegation of research misconduct" [1].

C. *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias in these procedures may occur due to prior or existing personal or professional relationships.

D. *Covered individual* means all individuals associated with LSU engaged in research or scholarship, including any person paid by, under the control of, or affiliated with LSU,
such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at LSU, regardless of whether on or off campus.

E. *Deciding Official (DO)* means the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional actions. The Deciding Official for LSU is the Chancellor.

F. *Evidence* means "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" [1].

G. *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.

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

I. *Inquiry Committee* means a committee of three or more senior tenured faculty members (or equivalent) experienced in research, appointed by the Chancellor based upon the recommendations of the Vice Chancellor for Research and Economic Development and the Dean of the College where the alleged research misconduct has occurred. Committee members may be scientists, subject-matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside LSU.

J. *Investigation* means "the formal development of a factual record and the examination of that record leading to a decision not to make a finding of research misconduct or to a recommendation for a finding of research misconduct which may include a recommendation for other appropriate actions, including administrative actions" [1].

K. *Investigative Committee* means a committee of a minimum of six senior tenured faculty members (or other appropriate professionals), at least three of whom have expertise in the research area in question, to be appointed by the Chancellor based upon the recommendation of the Vice Chancellor for Research and Economic Development and the Dean of the College where the alleged research misconduct has occurred. Committee members may be scientists, subject-matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside LSU. Investigative Committee members will

not ordinarily include individuals who served on the Inquiry Committee. An attorney may be named to serve in an advisory capacity, and a recording secretary will be designated to record the proceedings of the meetings.

L. *Office of Research Integrity* means the office to which the US Department of Health and Human Services (HHS) has delegated responsibility for addressing research integrity and misconduct issues related to the US Public Health Service supported activities.

M. *Plagiarism* is “the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit” [1]. It does not include authorship or credit disputes. Plagiarism which takes the form of theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained via privileged communication, such as a grant or manuscript review.

N. *Preponderance of the evidence* means “proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not” [1].

O. *Research* means a systematic experiment, study, evaluation, demonstration or survey designed to develop or contribute to general knowledge (basic research) or specific knowledge (applied research).

P. *Research Integrity Officer* means the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Research Integrity Officer for LSU is the Vice Chancellor for Research and Economic Development, unless otherwise designated by the Chancellor.

Q.Research record means “the record of data or results that embody the facts resulting from scientific inquiry, including but not limited to, research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and any documents and materials provided to HHS or an institutional official by a respondent in the course of the research misconduct proceeding” [1]. It also includes any documents and materials provided to other relevant funding agencies.

R. *Research misconduct* – See definition in section I.C.

S. *Respondent* means the person against whom an allegation of research misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

T. *Retaliation* means any action taken by an institution or an employee that adversely affects the employment or other institutional status of an individual

because that individual (1) has in good faith made an allegation of research misconduct, (2) has cooperated in good faith with an investigation of such allegation, or (3) charges inadequate institutional response to an allegation.

III. Rights and Responsibilities

A. Research Integrity Officer

The Vice Chancellor for Research and Economic Development will serve as the Research Integrity Officer, unless otherwise designated by the Chancellor, and will have primary
responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will recommend to the Chancellor appointments to the Inquiry and Investigative Committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will make every reasonable effort to ensure that confidentiality is maintained.

The Research Integrity Officer will initially assess the allegation, will determine whether to proceed with an inquiry, and will assist appointed Inquiry and Investigative Committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research
Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

B. Complainant

The complainant will be officially informed in writing if an inquiry is opened, and notified of the final determinations, but will not be informed of any recommended or imposed personnel actions taken. He or she will also be officially notified in the event that no inquiry or investigation is initiated. The complainant will have an opportunity to testify before the Inquiry and Investigative Committees, to review and comment on the accuracy of the portions of the inquiry and investigation draft reports containing his or her allegations or testimony, to be informed of the results of the inquiry and investigation, and to be protected from retaliation. If the Research Integrity Officer has determined that the complainant may be able to provide pertinent information on other portions of the draft report, these portions will be given to the complainant for comment.

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

C. Respondent

The respondent will be officially informed in writing of the allegations if an inquiry is opened. The respondent will also have the opportunity to be interviewed by and present evidence to the Inquiry and Investigative Committees, to review summaries of interviews by Inquiry and Investigative Committees, to review the draft inquiry and investigation
reports, and to have the advice of counsel. The respondent will be notified in writing of the final determinations and resulting actions.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of research misconduct, he or she has the right to receive reasonable institutional assistance in restoring his or her reputation.

D. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the complainant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether research misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see section X].

As required by law, or as deemed appropriate, the Deciding Official will keep all relevant external funding agencies apprized as set forth herein of any developments during the course of the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation or that the relevant agency needs to know to ensure appropriate use of external funds and otherwise protect the public interest.

I**V. General Policies and Principles**

A. Protecting the Complainant

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of research misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also the institution will protect, to the maximum extent possible, the privacy of those who report research misconduct in good faith. For example, if the complainant requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and

regulations and state and local laws, if any. The complainant will be advised that if the matter is referred to an Investigative Committee and the complainant's testimony is required, anonymity may no longer be guaranteed. The complainant may bring a personal advisor to interviews or meetings on the case. LSU is required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

B. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) and confidentiality, to the extent possible without compromising
public health and safety or a thorough inquiry or investigation.

Covered individuals accused of research misconduct may consult with legal counsel or other personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case. The presence of a legal counsel representing the respondent during an inquiry or investigation will require the presence of legal counsel representing the University. Counsels will not be permitted to question witnesses or speak before the committee.

C. Preliminary Assessment of Allegations

Upon receiving an allegation of research misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether externally funded support or external support applications are involved, and whether the allegation falls under the definition of research misconduct for the relevant agency. Normally, the preliminary assessment by the Research Integrity Officer will be completed in one month or less. If the Research Integrity Officer deems an inquiry to not be warranted, he or she will so inform the individual who brought the allegation and any others made privy to the information in the course of the assessment.

V. Conducting the Inquiry

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, and falls under the definition of research misconduct, he or she will immediately initiate the inquiry process and so inform the respondent in writing. In initiating the inquiry, the Research Integrity Officer will in writing identify clearly the original allegation and any related issues that should be evaluated and will submit it to the Deciding Official with a recommendation of names to appoint to an Inquiry Committee as defined under section II.I. 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 research misconduct occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of research misconduct, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with the US Public Health Service Office of Research Integrity, if appropriate, for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

After receiving the written recommendation of the Research Integrity Officer, the Deciding Official, if he/she agrees with the recommendation, will appoint an Inquiry Committee and committee chair within 10 calendar days. The Inquiry Committee, as defined under section II.I., will consist of individuals who do not have real or apparent conflicts of interest in the case and are unbiased; they will also have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry.

After approval by the Deciding Official, the Research Integrity Officer will notify the respondent in writing of the allegations, the decision to proceed to inquiry, and the proposed committee membership within 5 calendar days. If the respondent submits a written objection to any appointed member of the Inquiry Committee based on bias or conflict of interest within 5 additional calendar days, the Deciding Official, on recommendation of the Research Integrity Officer, will determine whether to replace the challenged member with a qualified substitute without expanding established time restrictions.

D. Charge to the Committee and the First Meeting

After appointment of the Inquiry Committee, the Research Integrity Officer will convene its first meeting within 10 calendar days. The Research Integrity Officer will present a written charge for the Inquiry Committee that describes the allegations and any related issues identified during the allegation assessment and states the purpose of the inquiry as defined under section V.A. A copy of the document will be provided to the respondent. At the committee's first meeting, the Research Integrity Officer will review the charge with the committee; discuss the allegations, any related issues, the appropriate procedures for conducting the inquiry, and the time line for completion of the report; assist the committee with

organizing plans for the inquiry; and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The Inquiry Committee will normally interview the complainant, the respondent, and key witnesses as well as examine relevant research records and materials. All interviews will be tape recorded. The Inquiry Committee will then evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. The Inquiry Committee will reach its determination considering all relevant factors, including, but not limited to: (1) the accuracy and reliability of the source of the allegation of the research misconduct, (2) the seriousness of the alleged research misconduct, (3) the scope of the alleged incident and the context in which it became known, and (4) other information obtained during the inquiry. The Inquiry Committee determination will be based on a majority vote, with the chair voting. The scope of the inquiry does not include deciding whether research misconduct occurred or conducting exhaustive interviews and analyses, nor does it include delving into issues not directly relevant to the allegation.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and position of the respondent(s); the name and title of the committee members and experts, if any; the
allegations; the source of any relevant extramural research support, including grant numbers, grant applications, contracts, and publications listing the extramural research 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 or not; 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; and any dissenting opinions. Institutional counsel will review the report for legal sufficiency.

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

The Inquiry Committee will provide the Research Integrity Officer with a draft report within 40 calendar days following its first meeting. 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 portions of the draft investigation report containing his or her allegations or testimony.

B.1. Confidentiality

The Research Integrity Officer must establish reasonable conditions for review to protect the confidentiality of the draft report.

B.2. Receipt of Comments

Within 8 calendar days of their receipt of the draft report or the appropriate portions thereof, the complainant and respondent will provide their comments, if any, in writing to
the Inquiry Committee. All comments that the complainant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the Inquiry Committee may revise the report as appropriate.

B.3. Time Limit for Completing the Inquiry Report

The Inquiry Committee will normally complete the inquiry and submit its final report in writing to the Research Integrity Officer no more than 55 calendar days following its first
meeting, 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 also will be notified of the extension.

C. Inquiry Decision and Notification

C.1. Decision by Deciding Official

The Research Integrity Officer will transmit the final report and his or her recommendation to the Deciding Official, who will make the final 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 in writing within 5 calendar days of the submission to him or her of the final report. Any extension of this period will be based on good cause and recorded in the inquiry file.

C.2. Notification

The Research Integrity Officer will immediately notify the respondent, the complainant, and the committee 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 respondent and complainant will receive copies of the final report.

VII. Conducting the Investigation

A. Initiation and 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, based on a preponderance of the
evidence, whether research misconduct occurred, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important when the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer 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.

C. Appointment of the Investigative Committee

The Deciding Official, based on a written recommendation of names from the Research Integrity Officer, will appoint an Investigative Committee and committee chair as defined in section II.K. within 10 calendar days of the notification to the respondent that an investigation is planned, or as soon thereafter as practicable. The Investigative Committee will consist of individuals who do not have real or apparent conflicts of interest in the case and are unbiased; they will also have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and
key witnesses, and conduct the investigation.

After approval of the proposed committee membership by the Deciding Official, the Research Integrity Officer will notify the respondent of the proposed committee

membership within 5 calendar days. If the respondent submits a written objection to any appointed member of the Investigative Committee based on bias or conflict of interest within 5 additional calendar days, the Deciding Official, on recommendation from the Research Integrity Officer, will determine whether to replace the challenged member with a qualified substitute without expanding established time restrictions.

D. Charge to the Committee and the First Meeting

The Research Integrity Officer will convene the first meeting of the Investigative Committee within 10 calendar days after appointment of the committee. The Research Integrity Officer will present a written charge for the Investigative Committee that describes the allegations and any related issues identified during the inquiry, defines research misconduct, and states the purpose of the investigation as defined under section VII.A. A copy of the document will be provided to the respondent. The Investigative Committee will also receive the Inquiry Committee's report. At the committee's first meeting, the Research Integrity Officer will review the charge with the committee; discuss the allegations, any related issues, the appropriate procedures for conducting the investigation, and the time line for completion of the report; assist the committee with organizing plans for the investigation; and answer any questions raised by the committee. The need for confidentiality will be emphasized. The Research Integrity Officer and
institutional counsel will be available throughout the investigation to advise the committee as needed.

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. Any proceedings against additional respondents will be instituted *de novo* with respect to processes defined in this policy.

E. Investigation Process

The Investigative Committee will be appointed and the investigative process initiated within 30 calendar days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, e-mail, proposals,
manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee will interview the complainant(s), the respondent(s), and other individuals who might have information regarding

aspects of the allegations. An investigation may consist of a combination of activities including but not limited to: (1) review of readily available documents; (2) review and copying of data or other pertinent documents of the University or elsewhere; (3) inspection of laboratory or clinical facilities and/or materials at the University; (4) interviews of parties and witnesses who may have been involved in or have knowledge about the case; (5) review of scientific publications; (6) invitations to outside consultants to participate in an investigation, either as site visitors to the University or in some other capacity; (7) review of any documents or evidence provided by or properly obtainable from parties, witnesses or other sources; (8) cooperation with other Federal agencies; (9) provision of opportunities for the subject of the allegations to be heard; and (10) full adjudicatory hearings or other formal proceedings as warranted. When relevant expertise is not available locally, the University will secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence. All interviews will be tape recorded. The Investigative Committee determination will be based on a majority vote, with the chair voting.

VIII. The Investigation Report

A. Elements of the Investigation Report

The final report must state the name and position of the respondent; name and title of the committee members and experts, if any; the allegations; the source of any relevant extramural research support; a summary of the inquiry process used; a list and summary of the research records reviewed, including any relevant records and evidence not taken into custody and why; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate the basis for the findings; the findings for each separate allegation, and any dissenting opinions. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in research misconduct as well as a description of any recommended sanctions and administrative actions.

B. Comments on the Draft Report

The Investigative Committee will provide the Research Integrity Officer with a draft report within 60 calendar days following its first meeting. The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal and will provide the complainant, if he or she is identifiable, with portions of the draft investigation report containing his or her allegations or testimony. The respondent will be given a copy of, or supervised access to, evidence on which the report is based.

B.1. Confidentiality

The Research Integrity Officer must establish reasonable conditions for review to protect the confidentiality of the draft report. For example, the Research Integrity Officer may request that the recipient sign a confidentiality statement or come to his or her office to review the report.

B.2. Receipt of Comments

Within 10 calendar days of their receipt of the draft report or the appropriate portions thereof, the complainant and respondent will provide their comments, if any, in writing to
the Investigative Committee. Any comments that the complainant or respondent submits on the draft report will become part of the final investigation report and record. Based on the comments, the Investigative Committee may revise the report as appropriate.

C. Institutional Review and Decision

C.1. Decision by Deciding Official

The Research Integrity Officer will transmit the final report and his or her recommendation to the Deciding Official. Institutional counsel will review the report for legal sufficiency. 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 institutional actions. If this determination varies from that of the Investigative Committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigative Committee. The Deciding Official's explanation should be consistent with the definition of research misconduct, the University's policies and procedures, and the evidence reviewed and analyzed by the Investigative Committee. The Deciding Official may also return the report to the Investigative Committee with a request for further fact finding or analysis. The Deciding Official's written determination, together with the Investigative Committee's report, constitutes the final investigation report. The Deciding Official's determination will be made in writing within 10 calendar days of the submission of the final report from the Investigative Committee. Any extension of this period will be based on good cause and recorded in the investigation file and report.

C.2. Notification

When a final decision on the case has been reached, the Research Integrity Officer will provide copies of the final report to the respondent and the complainant; committee members will be provided an opportunity to view the final report. In addition, in the event of a finding of research misconduct, the Deciding Official will determine whether professional societies, professional licensing boards, editors of journals in which falsified reports may have been published,

collaborators of the respondent in the work, law enforcement agencies, or other relevant parties should be notified of the outcome of the case, and will initiate appropriate disciplinary action. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 100 calendar days of its initiation, with the initiation being defined as the first meeting of the Investigative Committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the respondent and complainant for comment, and submitting the report to the Deciding Official for approval. The Research Integrity Officer may approve 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 also will be notified of the extension.

IX. Requirements for Reporting to US Public Health Service Office of Research Integrity

The US Public Health Service has specific reporting requirements for alleged research misconduct involving Public Health Service research funding, as specified below. Other agencies may likewise in the future also develop similar guidelines, with which the University will comply.

A. For research funded by the US Public Health Service, an institution's decision to initiate an investigation must be reported in writing to the Director, Office of Research Integrity, on or before the date the investigation begins. The notification should include the written finding by the Deciding Official and a copy of the inquiry report.

The Office of Research Integrity must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report, including supporting documentation and a copy of this policy. The notification should indicate whether research misconduct was found, whether the institution accepts the findings of the investigation; and a description of pending or completed administrative actions against the respondent. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to the Office of Research Integrity. Reporting requirements for other outside funding agencies will likewise be followed to the extent that such policies exist.

B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the Public Health Service regulation, the

Research Integrity Officer will submit a report of the planned termination to the Office of Research Integrity, including a description of the reasons for the proposed termination.

C. If the institution determines that it will not be able to complete the investigation in the time period specified by federal regulations (120 days), the Research Integrity Officer
will submit to the Office of Research Integrity 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 Office of
Research Integrity.

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

E. The Research Integrity Officer will notify the Office of Research Integrity at any stage of the inquiry or investigation if:

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. LSU 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.” [1]

X. Institutional Administrative Actions

Louisiana State University will take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated by determination of the Deciding Official.

If the Deciding Official determines that the alleged research 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.

XI. Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

If the respondent, without admitting to the research 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, or is terminated by the institution for other reasons, 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 the institution finds no research misconduct and any appropriate outside funding agency 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, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official and respondent.

C. Protection of the Complainant and Others

Regardless of whether the institution or any outside funding agency 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 cooperated 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

During any and all phases of an inquiry or investigation, 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.

XII. 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. Appropriate agency officials of the relevant funding agency may request access to the documents through the Deciding Official. After seven years the records will be destroyed.

References

1. Public Health Services Policies on Research Misconduct; Final Rule, Department of Health and Human Services, Federal Register – 42 CFR Part 93 – June 2005.
   http://www.ori.hhs.gov/policies/fed_research_misconduct.shtml.

Appendix

The following list is a combined flowchart and time line for the handling of allegations of research misconduct. The reader is referred to the full policy for more detailed explanations. All references to days refer to calendar days.

I. Initial evaluation

Allegation of research misconduct received and evaluated by RIO; if inquiry indicated, RIO recommends and DO appoints Inquiry Committee and chair within 10 days of RIO's recommendation.

II. Inquiry

1. Appointment of committee

Within 10 days of recommendation, DO appoints committee

Within 5 days of appointment, RIO informs respondent

Within 5 days of being informed, respondent reports any objections

Within 10 days of finalizing committee, RIO convenes first meeting, which initiates the inquiry

2. Committee inquiry

Committee conducts inquiry

Within 40 days of first committee meeting, draft report to RIO, respondent, appropriate portions to the complainant for comment and rebuttal

Within 8 days of receiving report, respondent and complainant provide any written comments on draft

Within 55 days of first committee meeting, final report due to RIO

3. Deciding official

RIO forwards report and recommendations to DO

Within 5 days of receiving report, DO makes determination and sends written decision to respondent, comlainant, and committee

If sufficient evidence exists for investigation, DO appoints Investigative Committee within 10 days of receiving report

If insufficient evidence is found, all reasonable efforts are made to restore respondent's reputation

Total days from initiation of inquiry to notification of respondent: 60

III. Investigation

1. Appointment of committee (note overlap of II.1. above)

Within 10 days of recommendation, DO appoints committee and chair

Within 5 days of appointment, RIO informs respondent

Within 5 days of being informed, respondent reports objections

Within 10 days of finalizing committee, RIO convenes first meeting, which initiates the investigation

2. Investigation

Committee conducts investigation

Within 60 days of first committee meeting, draft report due to RIO, respondent, appropriate portions to complainant for comment and rebuttal

Within 10 days of receiving report, respondent and complainant provide any written comments on draft

Within 90 days of first committee meeting, final report due to RIO

3. Deciding Official

Within 10 days of receiving report, DO makes a final written determination of whether to accept report, its findings, and recommended institutional actions, and RIO immediately provides respondent and complainant copies of final report and informs committee of the determination

If finding of research misconduct is not made, all reasonable efforts are made to restore the respondent's reputation

Total days from initiation of investigation to notification of respondent: 100

Any extension of these periods must be approved by the RIO, and will be based on good cause and recorded in the inquiry or investigation file and report.