University of LOUISIANA Monroe

Scientific Research Misconduct Policy

Policy # RE001.1

Responsible Executive: VP for Academic Affairs
Responsible Office: Sponsored Programs & Research
Originally Issued: 05/15/2013
Latest Revision: 01/26/2017
Effective Date: 1/31/2017

I. Policy Statement

It is the policy of the University of Louisiana at Monroe (ULM) to follow the Public Health Service (PHS) requirements and associated procedures for all scientific research regardless of funding source (For the latest from the PHS CFR 42, Chapter 1, Subchapter H, Part 93, See http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title42/42cfr93_main_02.tpl).

ULM will follow this policy if any institutional official receives an allegation of possible misconduct in science. The Director of the Office of Sponsored Programs and Research (OSPR) and the Vice President for Academic Affairs must approve any departures from this policy in advance.

II. Purpose of Policy

ULM is strongly committed to personal and institutional integrity and this is particularly imperative in the sciences. ULM knows that fraudulent or deliberately misapplied science can have severe, immensely costly, and even fatal consequences. In order to protect the public and to continue the progress of science, ULM will practice honesty, integrity, and vigilance.

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III. Applicability

This policy and the associated procedures apply to all individuals at ULM. Of particular concern is research funded by the Public Health Service (PHS). Also please see PHS regulation at 42 C.F.R. Part 50,

Subpart A, which applies to any research, research training, or research related grant or cooperative agreements with PHS.

IV. Definitions

The following definitions are modeled on the "PHS Model Policies for Responding to Allegations of Scientific Misconduct." Anyone with questions should contact the OPSR (telephone 318.342.1039; email OSPR@ulm.edu).

Definitions:

- *Allegations* are any written or oral statements or other indications of possible scientific misconduct made to an institutional official.
- *Conflict of interest* means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to prior or existing personal or professional relationships.
- *Good faith allegation* means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard, malice, or willful ignorance of facts that would disprove the allegation.
- *Inquiry* means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation. The inquiry phase occurs before the investigation, described below.
- *Investigation* means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.
- *PHS* means the U.S. Public Health Service, an operating component of the U.S. Department of Health and Human Services (DHHS).
- *PHS regulation* means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science."
- *PHS support* means PHS grants, contracts, or cooperative agreements or applications.
- *Research record* means any data, document, computer file, computer diskette, hard drive, cloud storage, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct.
- *Retaliation* means any action that adversely affects the employment, academic status, professional reputation, or other institutional status of an individual or his or her family that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation. Direct or veiled threats of psychological or physical harm or of career standing outside of the institution to an individual, family, or friends may be considered retaliation.
- *Scientific misconduct or misconduct in science* means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research, soliciting external funds, or interacting with the public. Intentional deviations from research protocol approved by the Institutional Review Board (IRB) without notification to the Board may constitute misconduct.

Roles:

- *Deciding Official* means the institutional official who makes final determinations about allegations of scientific misconduct and any responsive institutional actions. At the University of Louisiana at Monroe, the Vice President for Academic Affairs is the designated Deciding Official.
- *Inquiry Committee* is a standing committee that formally examines basic evidence and produces a report with their findings of the likelihood of scientific misconduct. The Inquiry Committee must consist of 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.
- *Investigation Committee* is a body that evaluates the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness. The Investigation Committee should consist of at least three members with no conflicts of interest.
- *Office of Research Integrity (ORI)* means the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.
- *Research Integrity Officer (RIO)* means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. The Director of the Office of Sponsored Programs and Research (OSPR) is the designated RIO.
- *Respondent* means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. This may include people who reasonably should have had knowledge of alleged scientific misconduct, but through deliberate action, made sure that they were not aware. There can be more than one respondent in any inquiry or investigation.
- *Sponsor* is an organization or department whether local, state, federal, or non-profit that provides funds for a particular purpose.
- *Whistleblower* means a person who makes an allegation of scientific misconduct. Most often, though not always, identification of allegations of scientific misconduct begins with a within-house whistleblower. Exceptions may occur when members of the public or other extra-institutional professionals raise concern.

V. Policy Procedure

A. Efforts to Prevent Scientific Misconduct

ULM believes that prevention of scientific misconduct is ultimately more effective than after-the-fact efforts. All individuals at ULM who participate in a research project must: 1) complete a relevant course on the Responsible Conduct of Research available through the Collaborative Institutional Training Initiative (CITI) before beginning work on a project and complete a refresher CITI course every two years; and 2) provide documentation of the successful completion of this course to the Office of Sponsored Programs and Research. OSPR will maintain records of all the individuals who have completed ethics training.

B. Response to Allegations of Scientific Misconduct

The response to allegations of scientific misconduct may involve as many as four consecutive phases.

1. Preliminary assessment of allegations by the Research Integrity Officer.
    a. Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.
    b. Throughout the process, the RIO will be responsible for maintaining files of all evidence and for the confidentiality and the security of the files.
    c. In the case of allegations of misconduct where there is PHS funding, the RIO will initially report to ORI, as required by federal regulation. He/she will also notify PHS to ensure appropriate use of federal funds and otherwise protect the public interest. In cases of allegation of misconduct involving funding sources other than PHS, the RIO will make a preliminary report to the relevant funding agencies.
    d. If, as a result of the preliminary assessment of allegations, the RIO decides that there is sufficient evidence to warrant an inquiry, he or she will refer the case to the Inquiry Committee.

2. Inquiry Committee evaluation of evidence and testimony.
    a. The Inquiry Committee is a standing committee led by the Chair of the Research Council. Other members include the: 1. Chair of the Graduate Council, 2. Chair of the Institutional Review Board, 3. Chair of the Animal Institutional Review Board, and 4. two other members with scientific research expertise appointed by the Vice President for Academic Affairs for a one year tenure.
    b. After consultation with the RIO and, as necessary, institutional counsel, the Inquiry Committee will formally examine basic evidence to determine whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The purpose of the inquiry is not to decide whether misconduct occurred nor to conduct exhaustive interviews and analyses.
    c. At the conclusion of its review, the Inquiry Committee will submit a draft Inquiry Report to the RIO that states: 1) the name and title of the committee members and experts, if any; 2) the allegations; 3) the PHS support, if any; 4) a summary of the inquiry process used; 5) a list of the research records reviewed; 6) summaries of any interviews; 7) a description of the evidence in sufficient detail to demonstrate whether and investigation is warranted or not; 8) the committee's determination as to whether an investigation is recommended; and 9) whether any other actions should be taken if an investigation is not recommended.
    d. The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal. If a whistleblower is involved, the RIO will provide him or her with portions of the draft inquiry report that address the whistleblower's role and opinions in the investigation. The respondent and whistleblower may provide comments to the Inquiry Committee within 14 business days of their receipt of the draft report.
    e. The Inquiry Committee will produce a final report that incorporates any comments made on the draft report by the respondent and the whistleblower. This report will: a) state what evidence was reviewed, b) summarize relevant interviews, c) include the conclusions of the inquiry, and d) state whether its findings provide sufficient evidence of possible scientific misconduct to justify conducting an investigation.

f. The respondent will be given a copy of the report of inquiry. If the respondent comments on that report, those comments will be made part of the record.
g. 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 scientific misconduct to justify conducting an investigation.
h. 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.
i. The Research Integrity Officer will notify both the respondent and the whistleblower 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 Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

3. Conducting the investigation of potential scientific misconduct.
   a. If the Deciding Official determines that there may be a likelihood of scientific misconduct, then the Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an Investigation Committee and the committee chair within ten business days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable.
   b. 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. As an alternative, the institution may appoint a standing committee authorized to add or reuse members or use consultants when necessary to evaluate specific allegations.
   c. The Research Integrity Officer will notify the respondent of the proposed committee membership within five business days of forming the committee. If the respondent submits a written objection to any appointed member of the Investigation Committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.
   d. 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 scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.
   e. 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.

f. The Deciding Official will report to ORI as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential DHHS funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

g. An investigation should ordinarily be completed within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the ORI. If they can be identified, the person(s) who raised the allegation should be provided with those portions of the report that address their role and opinions in the investigation. If the institution determines that it will not be able to complete the investigation in 120 days, it must submit to the ORI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. Any consideration for an extension must balance the need for a thorough and rigorous examination of the facts versus the interests of the subject(s) of the investigation and the PHS in a timely resolution of the matter. If the request is granted, the institution must file periodic progress reports as requested by the ORI. If satisfactory progress is not made in the institution's investigation, the ORI may undertake an investigation of its own.

h. 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 investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the Investigation Committee in the institution's letter transmitting the report to ORI. The explanation should be consistent with the PHS definition of research misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The 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.

4. Institutional administrative actions

   a. When a final decision on the case has been reached, the RIO will notify both the respondent and the whistleblower in writing. In addition, the Deciding Official will determine whether other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

   b. 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:

      1) Withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found;
      2) 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, revocation of tenure, or termination of employment; and/or
      3) restitution of funds as appropriate.

c. ULM is responsible for notifying the Sponsor if it ascertains at any stage of the inquiry or investigation, that any of the following conditions exists: 1) an immediate health hazard; 2) an immediate need to protect Federal funds or equipment; 3) 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; 4) a probability that the alleged incident is going to be reported publicly; and/or 5) a reasonable indication of possible criminal violation. With regard to the fifth point, ULM must inform the Sponsor within 24 hours of obtaining that information.

d. The respondent may appeal the decision rendered by the Deciding Official regarding the investigation if: 1) a procedural error has occurred; 2) new evidence has been secured (this evidence must be supported by affidavits or other supporting documentation which will be reasonably reviewed by the committee); 3) the penalty is disproportionate to the violation (clear and convincing reasons must be given to show that the penalty does not meet the test of reasonableness and fairness); and/or 4) the decision is unsupported. The respondent's appeal must be made in writing to the University President within five business days of receiving the decision of the Deciding Official regarding the investigation. The University President will form a committee of at least three individuals who were not involved in previous reviews of the case to hear the appeal. The committee will make its recommendations to the President. The University President will make the final decision on the appeal and communicate this to the respondent within sixty days of receiving the appeal.

e. Regardless of the outcome of the appeal, in each case where PHS funding is involved, the Deciding Official and Research Integrity Officer will continue contact and involvement with the ORI. This appeal process will not obviate the Deciding Official and Research Integrity Officer of their obligation for full cooperation with ORI and other relevant federal, state, and private agencies.to the University President regarding matters of fact within five business days of receiving the decision of the Deciding Official regarding the investigation. However, regardless of the outcome of the appeal, in each case where PHS funding is involved, the Deciding Official and Research Integrity Officer will continue contact and involvement with the ORI. This appeal process will not obviate the Deciding Official and Research Integrity Officer of their obligation for full cooperation with ORI and other relevant federal, state, and private agencies.

f. Institutions are expected to carry their investigations through to completion, and to pursue diligently all significant issues. If an institution 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 such planned termination, including a description of the reasons for the proposed termination to ORI, which will then decide whether further investigation should be undertaken.

C. The Respondent: Obligations and Rights

ULM realizes that it must conduct a fair and objective evaluation to protect the respondent from unfair accusations, misunderstandings, and other cases where allegations of scientific misconduct are unfounded. Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

The respondent will be informed of any allegations in writing. The respondent will have the opportunity to present evidence to the inquiry and investigation committees, and to review the draft inquiry and investigation reports. As allowed by Louisiana law, anyone accused of scientific misconduct may consult with legal counsel or a non-lawyer 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.

In cases where the respondent is a student, he or she has the right to a neutral representative appointed by the President of the ULM Student Government Association.

The termination of the respondent's institutional employment, by resignation or involuntarily before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures. If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will 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.

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 scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D. Whistleblower Reporting

This section applies both to whistleblower reporting and to reporting retaliation against whistleblowers.

All individuals associated with the ULM should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer or to their appropriate supervisor or academic Dean. To the extent possible, any report or complaint should be factual and contain as much specific information as possible setting forth all of the information about which the person has knowledge. In conducting the investigation, ULM may retain outside legal or accounting expertise.

Reports of suspected violations may be made confidentially and/or anonymously. Whistleblowers have assurance that the institution will attempt to protect the privacy of those who report misconduct in good faith and to the maximum extent possible. ULM will not seek information beyond which the whistleblower is willing to furnish unless the event involves the possibility of an imminent harm to someone, as defined by Louisiana and federal law. ULM defers to state or federal law on all matters of misconduct and/or whistleblower protection.

The Research Integrity Officer has primary responsibility for taking whistleblower testimony. Whistleblowers who wish to remain anonymous may call the Misconduct Hotline (at 318.342.1478) or send a confidential email to the Gmail address (ULMresearchinquiries@gmail.com) posted on the OSPR web page. This makes the user's ISP routinely untraceable to all but Federal Court order. Services to assist in sending a more completely anonymous email through a free service can be found at numerous places on the internet, such as http://theanonymousemail.com or www.5ymail.com.

ULM will vigorously protect the rights and monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or

investigations. The RIO will ensure that these persons will not be retaliated against. The Louisiana Whistleblower Protection for Public Employees Freedom from Reprisal for Disclosure of Improper Acts LSA-R.S.42:1169 protects public employees who report information (See http://ethics.la.gov/Pub/Laws/1169.pdf).

On an annual basis, the RIO will provide a summary of all actions under this policy to the Vice President of Academic Affairs.

VI. Enforcement

The Vice President for Academic Affairs at ULM is responsible for enforcing all policy provisions.

VII. Policy Management

Any questions regarding applicable procedures should be directed to the Vice President for Academic Affairs or to the Executive Director of the Office of Sponsored Programs and Research.

VIII. Exclusions

None.

IX. Effective Date

January 31, 2017

X. Adoption

This policy is hereby adopted on this 26th day of January, 2017.

Dr. Eric Pani, Vice President for Academic Affairs

XI. Appendices, References and Related Materials

1. The Office of Research Integrity, Handling Misconduct – Reg SubPart A, 42 C.F.R. Part 50, Subpart A. https://ori.hhs.gov/reg-sub-part-a

2. The Office of Research Integrity, Model Policy for Responding to Allegations of Scientific Misconduct. https://ori.hhs.gov/documents/model_policy_responding_allegations.pdf

XII. Revision History

Initial approval date of the policy: May 15, 2013

Revised: January 26, 2017