

UNIVERSITY OF SOUTH ALABAMA STANDARDS IN THE CONDUCT OF RESEARCH

Policy for Responding to Allegations of Research Misconduct

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Standards in the Conduct of Research

Policy and Procedures for Responding to Allegations of Research Misconduct

I. Introduction

1. Policy

The University of South Alabama recognizes that academic institutions have the responsibility to set standards for ethical behavior in the conduct of research and scholarly activities. The pursuits of University's faculty, research staff, and students will be conducted with integrity and openness on the part of all those engaged in research. The University of South Alabama does not tolerate misconduct in research or scholarly activity and has adopted the definition of misconduct as stated by the Office of Science and Technology Policy (OSTP):

Research misconduct is defined as fabrication, falsification, plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

To constitute research misconduct, the behavior must (1) represent a significant departure from accepted practices of the relevant research community; and, (2) be committed intentionally, or knowingly, or with reckless disregard for the integrity of research; and, (3) the allegation is proven by a preponderance of evidence [Federal Register: May 17, 2005, Vol. 70, No. 94].

The University will undertake diligent efforts to protect the position and reputation of the Complainant and Respondent, and protect their privacy to the extent possible. In addition, the University will protect against retaliation of any kind toward a person who reported or provided information about suspected or alleged misconduct and who has not acted in bad faith in so doing (45 CFR, Part 689, Section 1, and the Office of Research Integrity [ORI] Guidelines for Institutions and Whistleblowers). The University is committed to preventing misconduct in research by supporting good faith efforts to intervene in and remedy such misconduct.

2. Scope

This policy and associated procedures apply to all research activities regardless of funding source. It is to be used by the University and its various schools/colleges and institutes conducting fundamental or applied research as well as other forms of scholarly activities. The following university-wide procedures for addressing allegations of research misconduct apply to

all students, faculty, staff, and employees of the University of South Alabama and its affiliations. This policy is based on a model policy from the U.S. Public Health Service (PHS) Office of Research Integrity. If funding is from sources other than PHS, it may be necessary to follow the policies of that grantor in addition to this University policy. The Research Integrity Officer or designee will determine policies and guidelines applicable to the alleged research misconduct and will apply USA policy and the sponsoring agency policy accordingly:

- Public Health Service (PHS) policy, 42 CFR Parts 50 and 93
- National Science Foundation (NSF) described in Section 930 of the NSF Grant Policy Manual, NSF policy 45 CFR 689
- All other funding sources as applicable to their guidelines

II. Definitions

Allegation- any written or oral statement or other indication of possible research misconduct made to a University official.

Complainant- a person who makes an allegation of research misconduct.

Conflict of interest (as used in this Policy)- when an individual or organization has involvement in multiple interests and one of these interests could possibly corrupt the motivation for an act by the individual or organization in another of the interests.

Deciding Official- the University official, at USA, the Vice President for Research and Economic Development, who makes final determinations on allegations of research misconduct and any responsive University actions. The Deciding Official will not be the same individual as the Research Integrity Officer.

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

Fabrication- making up data or results, or recording or reporting made-up data or results.

Falsification- manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record

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

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

*Inquiry Committee- Ad hoc committee c*harged to perform the inquiry into the allegation of potential research misconduct.

Intentionally - where a person acts with purpose to cause a consequence, and the person is aware,

believes, or hopes the consequence will occur.

Investigation- the formal examination and evaluation of all relevant facts to determine if research misconduct has occurred; and, if so, to determine the responsible person, the seriousness of the research misconduct, and evaluate appropriate action.

Investigation Committee: ad hoc committee charged to perform the investigation of inquiry findings regarding allegations of potential research misconduct.

Knowingly- the circumstance where a person acts with awareness or understanding of the likely consequences of their actions, and the person is aware or understands that those consequences are practically certain to occur.

NSF OIG – The National Science Foundation Office of Inspector General oversees investigations of research misconduct and conducts any NSF inquires and investigations into suspected or alleged research misconduct.

ORI- 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.

Preponderance of the evidence- "evidence which is of greater weight or more convincing than the evidence which is offered in opposition to it; that is, evidence which as a whole shows the fact sought to be proved is more probable than not." (<u>Black's Law Dictionary</u>, 1979, p. 1064) "greater weight of evidence"

Plagiarism- the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Recklessly- the circumstance where a person acts with conscious disregard of a substantial, unjustifiable, and foreseeable risk of consequences that constitute research misconduct.

Research Integrity Officer- the individual with primary responsibility for implementation of the institution's policies and procedures on research misconduct and for overseeing inquiries and investigations.

Research misconduct (for the purposes of this document and as defined by the federal Office of Science and Technology Policy) - fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

Research record- any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of research misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs;

laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

Respondent- 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.

Retaliation- any action that adversely affects the employment or other University 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 University response thereto or has cooperated in good faith with an investigation of such allegation.

Sequestration- the collection and segregation of research records, equipment, and other tangible or intangible information for the specific purpose of assessing allegations as part of the research misconduct investigative process. All appropriate rights are accorded to the Respondent in the act of sequestrating research records, as outlined in the Roles and Responsibilities of the Respondent section of this policy.

III. Rights and Responsibilities

1. College/School Deans and Institute Directors

The deans and institute directors shall facilitate implementation of this policy in their respective College/School/Institute, and may report knowledge of allegations of research misconduct to the Vice President for Research, Office of Research Compliance and Assurance, or the Office of Internal Audit. The Dean/Institute Director facilitates cooperation of Respondents and other individuals in his/her respective College/School/Institute in instances of allegations of research misconduct, including, but not limited to, the sequestration of research records and/or other relevant information and documentation relative to the allegations of research misconduct.

2. Research Integrity Officer

The Vice President for Research and Economic Development shall appoint the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer ensures that the University has written policies and procedures for responding to allegations of research misconduct and will report information to external sponsors of research, as required, keeping them apprised of any developments during the course of the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation. The Research Integrity Officer will ensure that the final investigation report, the findings of the Deciding Official, and a description of any pending or completed administrative actions are provided to any relevant sponsor. The Research Integrity Officer will assist ad-hoc (inquiry) committees, the investigation committee, and all University personnel in complying with these procedures and with applicable standards imposed by government or external funding sources.

Upon receipt of a written allegation of research misconduct, the Research Integrity Officer will:

- inform Respondents, Complainants, and witnesses of the procedural steps in the research misconduct process.
- take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct process; including an inventory of the records and evidence and sequestering such records/evidence in a secure manner.
- provide Respondent copies of, or reasonable supervised access to, the research records.
- receive reports of and take appropriate action in the event the Respondent or Complainant has a concern or complaint about the research misconduct process. If necessary, the Research Integrity Officer shall present the issue to the Deciding Official who shall take appropriate action.
- keep the Deciding Official and others who need to know, as described in this policy, apprised of the progress of the review of the allegation of research misconduct.
- assist the Deciding Official in implementing his/her decision to take administrative action against any Complainant, Respondent, witness, or committee member determined by the Deciding Official not to have acted in good faith.
- be available or present throughout an inquiry or investigation process to advise the committee as requested.
- Assist in the preparation of the Inquiry and Investigation committee reports.
- confirm that there are no conflicts of interest in conducting the described duties. If the Research Integrity Officer has a conflict of interest; the Deciding Official shall appoint a qualified administrator or tenured faculty member to conduct the Research Integrity Officer duties described in the policy.

If an investigation is warranted, the Research Integrity Officer will:

- initiate the investigation within 30 calendar days after the determination by the Deciding Official that an investigation is warranted.
- on or before the date on which the investigation begins: (1) notify ORI and/or NSF OIG of the decision to begin the investigation and provide a copy of the inquiry report, if applicable; and (2) notify the Respondent in writing of the allegations to be investigated.
- convene first meeting of the Investigation Committee.
- upon determining that if the investigation cannot be completed within 120 days of its initiation, submit a request for an extension including a statement of the reasons for the extension. If the misconduct is applicable to PHS policy, the Research Integrity Officer will file periodic progress report with the Department of Health and Human Services Office of Research Integrity or other relevant funding agency.
- transmit the draft investigation report to the University counsel for review.
- Submit the report of the Investigation Committee to the Deciding Official.

3. Complainant

The Complainant may have an opportunity to speak before the Ad hoc (inquiry) Committee and the Investigation Committee, and to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony. The Complainant is responsible for making allegations in good faith, and cooperating in good faith with an inquiry or investigation.

4. Respondent

The Respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The Respondent will review the list of individuals proposed for the Inquiry and Investigation Committees. The Respondent will also have the opportunity to be interviewed by and present evidence to both the Inquiry Committee and the Investigation Committee, and to review the inquiry and investigation reports. The Respondent may seek the advice of personal counsel, but counsel may not participate or be present in the ad hoc (inquiry) committee or the investigation committee proceedings.

The Respondent has the right to suggest witnesses and present evidence to rebut the testimony and other evidence used against the Respondent before a preliminary determination is made by the Investigation Committee, to be interviewed during the investigation, to have the opportunity to correct the recording (if any) or transcript of that interview, and to have the corrected recording or transcript included in the record of the investigation.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the Respondent is not found to have committed research misconduct, he/she has the right to receive reasonable assistance from the University toward restoring his/her reputation.

5. Deciding Official

The Vice President for Research and Economic Development is the University Deciding Official. The Deciding Official determines the need for an inquiry, appoints the Inquiry committee as described herein, and shall receive the inquiry report and any written comments made by the Respondent on the report. After consulting with the Research Integrity Officer and other University officials, the Deciding Official will determine whether or not an investigation is warranted under the following criteria: there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct based on evidence and/or information gathering and preliminary fact finding from the ad hoc committee as described herein. If research misconduct is found by the Investigation Committee, the Deciding Official, after consultation with other University officials, decides the extent to which the University accepts the findings of the investigation report and determines what administrative actions are appropriate, if any.

IV. General Policies and Principles

1. Responsibility to Report Misconduct

All employees or individuals associated with the University of South Alabama should report observed, suspected, or apparent misconduct in research to his/her immediate supervisor, Vice President for Research, Research Integrity Officer or the Office of Internal Audit. The Office of Internal Audit maintains the University's Whistleblower and Non-Retaliation policy and website, as well as information on alternative methods for reporting. 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 to discuss the suspected misconduct informally. If the circumstances

described by the individual do not meet the definition of research misconduct, the Research Integrity Officer will refer the individual or allegation as necessary to other offices or officials with responsibility for resolving the problem. At any time, an employee may have discussions and consultations about concerns of possible misconduct with their immediate supervisor, college/school dean or institute director, Research Integrity Officer or other University administrative officials. The confidentiality of any of these discussions will be maintained to the extent possible as determined by University needs.

2. Protecting Complainants, Witnesses, and Committee members

Employees or other parties may not threaten, intimidate or retaliate in any way against Complainants, witnesses, or committee members. Any threats or attempts to intimidate or retaliate against Complainants, witnesses or committee members should be promptly reported to the Research Integrity Officer, who shall review the matter and, in consultation with appropriate University officials take reasonable and necessary intervening, and/or corrective or restorative actions. Although efforts will be made to protect the Complainant's identity, anonymity may not be assured. If the matter is referred to an Inquiry Committee or the Investigation Committee, the Complainant's testimony may be required.

3. Protecting the Respondent

As requested and as appropriate, the Research Integrity Officer and other University officials shall make reasonable and practical efforts to protect the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made. Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent(s), and confidentiality of the process will be maintained to the extent possible without compromising public health and safety. Respondents accused of research misconduct may seek advice of legal counsel, or a non-lawyer personal advisor (who is not a principal or witness in the case) The Respondent may not bring counsel or a personal advisor to interviews, meetings, or proceedings on the matter.

4. Cooperation with Inquires and Investigations

Employees and students of the University of South Alabama will cooperate with and have an obligation to provide evidence/information relevant to the research misconduct allegations to the Research Integrity Officer and other University officials in the review of allegations and the conduct of inquiries and investigations.

V. Conducting the Assessment and Inquiry

1. Initiation and Purpose of the Inquiry

To ensure impartiality in the receipt and review of allegations, all research misconduct allegations will be referred to and reviewed by the Deciding Official. If the Deciding Official determines the allegation is credible and there is sufficient cause to warrant an inquiry, and the allegation falls under the definitions of research misconduct set forth in this Policy, he or she will initiate the inquiry process in a timely manner. The Research Integrity Officer may assist in this initial assessment. The purpose of the inquiry will be to conduct an initial review of the available evidence to determine whether to refer the matter for an investigation. An inquiry does not require a full review of all the evidence related to the allegation. In any instance where harm

might have been made to human subject, the Deciding Officials may determine that it is necessary to halt clinical trials.

2. <u>Sequestration of the Research Records</u>

At the time of or before the beginning of an inquiry, the Research Integrity Officer will take all reasonable and practical steps to obtain custody of all research records and evidence needed to conduct the research misconduct process. The Research Integrity Officer will inventory the records and evidence and sequester them in a secure manner. Where appropriate, as determined by the Deciding Official, the Respondent will be provided copies of, or reasonable, supervised access to the research records.

3. Appointment of the Inquiry Committee

If the allegations appear to have merit and there is evidence of wrongdoing, the Deciding Official will appoint an inquiry committee composed of three (3) persons. The Deciding Official will select the committee members on the basis of scientific expertise that is pertinent to the matter and, prior to selection, shall screen them for any personal, professional, or conflicts of interest with the Respondent, Complainant, potential witnesses, or others involved in the matter. The inquiry committee members selected should not have published any manuscripts or scientific reports or made any joint research support applications with either the accuser or the accused. Any such conflict which a reasonable person would consider to demonstrate potential bias shall disqualify the individual from selection. At least one member of this committee must be a tenured full-time faculty member and the others may be tenured, full-time faculty members or administrators. The inquiry shall be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. If no grounds for misconduct are found by the ad hoc committee, the Deciding Official and the college/school dean or institute director, in consultation with the accused, shall act to protect the reputation of the accused as outlined herein.

Outside the official proceedings of the inquiry, the committee may not discuss the proceedings with the Respondent, Complainant, witnesses, or anyone not authorized by the Deciding Official to have knowledge of the inquiry.

4. Charge of the Inquiry Committee and the First Meeting

The Deciding Official will prepare a charge for the ad-hoc (inquiry) committee that:

- Sets forth the time for completion of the inquiry;
- Describes the allegations and any related issues identified during the allegation assessment:
- States that the purpose of the inquiry is to conduct an initial review of the evidence, including the interviews with the Respondent, Complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
- Informs the ad hoc (inquiry) committee that it is responsible for preparing or directing the preparation of a written report of the committee that meets the requirements of this policy.

The Research Integrity Officer will be present or available throughout the inquiry to advise and facilitate the committee as needed.

5. Inquiry Process

The inquiry committee normally will interview the Complainant, the Respondent, and key witnesses as well as examine relevant research records and materials. Then the committee will evaluate the evidence obtained during the inquiry. The committee will decide whether there is sufficient evidence of possible research misconduct to recommend that an investigation be conducted. The scope of the inquiry does not include deciding whether research misconduct occurred or conducting a full review of the evidence related to the allegation.

VI. The Inquiry Report

1. Elements of an Inquiry Report

Following the inquiry, the inquiry committee must prepare a written report that includes the following information: (1) name and position of Respondent; (2) a description of the allegations; (3) federal support for subject research, if any; (4) the basis for its recommendation regarding an investigation; and (5) any comments on the draft report by the Respondent. The Research Integrity Officer will provide the Respondent with a copy of the draft inquiry report for comment.

2. Comments on the Draft Report

a. Respondent

The Research Integrity Officer will provide the Respondent with a copy of the inquiry report for comment. The Respondent will be allowed ten (10) calendar days to review and comment on the draft report. The Respondent's written comments will be attached to the final report.

b. Complainant

The Research Integrity Officer will provide the Complainant, if he or she is identifiable, and it is deemed appropriate with those portions of the inquiry report that address the Complainant's role and opinions in the investigation for comment.

3. <u>Time Limit for Completing the Inquiry Report</u>

The inquiry, including preparation of the final inquiry report should be completed within 60 calendar days of initiation of the inquiry, unless the Deciding Official determines that circumstances warrant a longer period. If an extension is approved, the inquiry record must include documentation of the reasons for exceeding the 60-day period. The Respondent will also be notified of the extension.

4. Inquiry Decision and Notification

a. Decision by Deciding Official

The Research Integrity Officer will transmit the final report, which will include any written comments, to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to merit an investigation. The inquiry is completed when the Deciding Official makes this determination. The Deciding Official will notify both the Respondent and the Complainant in writing of his/her decision on whether to proceed to an investigation and their obligation to cooperate in the event an investigation is opened. The Deciding Official will also notify all appropriate University officials of his/her decision.

b. Notification to Appropriate Funding Agencies

In the event the Deciding Official determines that an investigation is warranted, the Research Integrity Officer will provide the Office of Research Integrity (ORI) and/or National Science Foundation Office of Inspector General or other identified grantor agency, as appropriate, with the Deciding Official's written decision and a copy of the inquiry report and any comments on the report provided by the Respondent. Such notification will be provided within the grantor agency's prescribed time limit for reporting such findings.

VII. Conducting The Investigation

1. Purpose of the Investigation

The investigation should begin within thirty (30) calendar days after the determination by the Deciding Official that an investigation is warranted. The investigation should be completed within 120 days from the date the investigation was initiated (180 days if NSF funding is involved). The purpose of the investigation is to thoroughly examine the allegations and available evidence, determine whether misconduct was committed and if so, by whom. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. Any additional considerations would begin at the investigation level. This is particularly important where 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.

2. Sequestration of the Research Records

The Research Integrity Officer in consultation with other appropriate University officials will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. Additional records may be required to aid the institution's decision to investigate additional allegations not considered during the inquiry stage. The Deciding Official and/or the Research Integrity Officer will provide the respondent with a written notification of any new allegation of research misconduct within a reasonable time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

3. Appointment of the Investigation Committee

The Investigation Committee is charged to investigate research misconduct findings at the recommendation of the Deciding Official. The Deciding Official, in consultation with the RIO and other institutional officials as appropriate, will appoint an investigation committee and committee chair. Appointed committee members must have no real or apparent conflicts of interest in a case under consideration, be unbiased, and have the necessary expertise to: a) evaluate the evidence and issues related to the allegations, b) interview the principals and key witnesses, and c) conduct the investigation. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the Respondent of the members of the investigation committee. If the Respondent submits a written objection to any member of the investigation committee based on bias or conflict of interest, the Deciding Official will determine whether to replace the challenged member with a qualified substitute. The Respondent must submit a written objection within five (5) days of notification of the committee membership.

4. Charge to the Investigation Committee and the First Meeting

a. Charge to the Committee

The Deciding Official will prepare a charge for the Investigation Committee defining the subject matter of the investigation that: describes the allegations and related issues identified during the inquiry, provides the definition of research misconduct promoted by this policy, identifies the name of the Respondent, and informs the committee that it must prepare a written investigation report that meets the requirements of this policy and applicable federal, state or grantor requirements. The charge will state that the committee is to evaluate the evidence and testimony/interviews of the Respondent, Complainant, and witnesses to determine whether, based on a preponderance of the evidence, it is more likely than not that research misconduct occurred and, if so, who was responsible and what was the level of seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional Respondent(s), the committee will notify the Research Integrity Officer, who will in turn notify the Respondent of the new subject matter and provide notice to any additional Respondent(s).

b. The First Meeting

At the initial meeting, the committee should begin the development, with assistance of the Research Integrity Officer, of its investigative plan. The investigative plan will include an inventory of all previously secured evidence and testimony, a determination of whether additional evidence needs to be secured, a list of witnesses that may need to be interviewed (including the Complainant, Respondent, and other witnesses with knowledge of the research in question), and anticipated analyses of evidence (scientific, forensic or other).

5. Investigation Process

The Investigation Committee should undertake its investigation within 30 calendar days after notification by the Deciding Official that sufficient basis for an investigation has been found. The investigation normally will involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls or meetings. Whenever possible, the committee should interview the Complainant(s), the Respondent(s), and other individuals who might have information regarding aspects of the allegations. All interviews should be tape recorded and transcribed. Summaries of transcripts/ interviews should be prepared. The transcripts are to be provided to the interviewed party for accuracy and included as part of the investigatory file.

6. Conducting Interviews

The Investigation Committee will adhere to the following procedures:

- Witnesses should have the opportunity to respond to errors in any recordings/transcripts
- Prepare and review in advance all relevant documents and research data that are in possession of committee.
- If significant questions arise during an interview that requires committee deliberation, a short recess in the interview to discuss the issues should be taken. No discussions amongst committee members or deliberations of the committee are to be recorded.
- The committee will conduct interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.
- A transcript of the interview will be provided to the Complainant, Respondent and witnesses for review and correction of errors.
- Maintain confidentiality throughout the proceedings by discussing the matter on a *need to know* basis only.

During the course of the interview process, if the Respondent admits to the research misconduct, the Respondent will be asked to write and sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and that the Respondent was advised of his/her right to seek advice of counsel. The Investigation Committee may consult University Counsel for guidance. The Investigation Committee may ask the Vice President for Research or the Research Integrity Officer to consult with the DHHS Office of Research Integrity (or NSF OIG as applicable) or other funding agency when deciding if an admission of research misconduct has adequately addressed all the relevant issues such that the investigation can be considered complete. The investigation will not be considered closed until the Respondent has the opportunity to comment on the investigation report as provided below.

VIII. The Investigation Report

1. Elements of the Investigation Report

The final report will: describe the allegations; describe sources of external funding, if any; describe the specific allegations of research misconduct considered in the investigation; describe the policies and procedures under which the investigation was conducted; describe how and from

whom information relevant to the investigation was obtained; and state the findings of the investigation with an explanation of the basis for the findings. Each statement of findings must:

- Determine a finding of research misconduct; a finding of no culpable conduct, but serious research error; or a finding of no misconduct and no serious research error.
- If a finding of research misconduct is made:
 - o Summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the Respondent;
 - State whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
 - o Identify whether any publications require correction or retraction;
 - o Identify the person(s) responsible for the research misconduct;
 - o List any current support of known applications or proposals for support that the Respondent has pending with PHS or non-PHS federal agencies.
 - o Make recommendations to the Deciding Official on appropriate University administrative actions

2. Comments on the Draft Report

a. Respondent

The Research Integrity Officer will provide the Respondent with a copy of the Investigation Committee's report for comment. The Respondent will be allowed 30 calendar days to review and comment on the report. The Respondent's written comments will be attached to the final report.

b. Complainant

The Research Integrity Officer will provide the Complainant, if applicable, if he or she is identifiable, with those portions of the Committee's investigation report that address the Complainant's role and opinions in the investigation.

c. University Counsel

The investigation report of the Investigation Committee will be transmitted to University Counsel for procedural review.

3. University Review and Decision

The Deciding Official will make the final determination whether to accept the Committee's draft investigation report, its findings, and the recommended University actions. Unless it was determined that errors or biases influenced the Committee's report, the Deciding Official will accept the determination. 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 University's letter transmitting the report to any external sponsors. The explanation should be consistent with the federal definitions

of research misconduct, the University'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. Furthermore, a request to meet with the Respondent and/or the Investigation Committee may be initiated prior to making a final decision. The Deciding Official's determination, together with the Investigation Committee's report, constitutes the final investigation report for the purposes of University and federal review. When this final report on the case has been issued, the Deciding Official will notify both the Research Integrity Officer and the Respondent in writing.

4. <u>Transmittal of the Final Investigation Report to ORI, NSG OIG and/or Other to Relevant Entities</u>

After comments have been received, and the necessary changes have been made to the draft report, the Research Integrity Officer should transmit the final report with attachments and any appeals, including the Respondent's comments, to the Department of Health and Human Services Office of Research Integrity or other required federal agency within the required timeframe. The Research Integrity Officer shall transmit a copy of the Report with attachments to any external sponsors as required.

Additionally, 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.

5. Time Limit for Completing the Investigation Report

An investigation ordinarily should be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the Investigation Committee following notification by the Deciding Official that sufficient basis for investigation is found. This 120 day time period includes time required for conducting the investigation, preparing the draft report of the findings, making the draft report available to the Complainant for comment, submitting the Investigation Committee's report to the Deciding Official for approval, and submitting the final report to any external sponsor. If at any point it is determined that the investigation cannot be completed within 120 days of its initiation, the Investigation Committee may request an extension from the Deciding Official and applicable federal agency including a statement of the reasons for the extension.

IX. University Administrative Actions

The University 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/she, after consultation with other University officials, will decide on the appropriate action(s) to be taken. Actions may include, but are not limited to, the following:

- o withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- o notification of professional societies, professional licensing boards, editors of journals, collaborators of the respondent in the work, or other relevant individuals or organizations;

- o 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;
- o restitution of funds as appropriate;
- o notification of law enforcement agencies;
- o completion of appropriate training, specified by the Deciding Official;
- o unacceptable academic/employment performance combined with research misconduct could be a cause for an adverse employment action, up to and including dismissal;
- other action appropriate for cases involving students, including but not limited to referral for possible charges of academic misconduct under the Student Academic Conduct Policy or possible charges of non-academic misconduct under the Student Code of Conduct; and
- o other actions as appropriate to remedy the research misconduct and to prevent it the future.

X. Appeals

The Respondent may appeal findings of research misconduct in writing to the Senior Vice President for Academic Affairs or the Vice President for Medical Affairs or the Director, Mitchell Cancer Institute, as applicable given the academic appointment of Respondent within ten (10) business days of such finding. The appellate Vice President or Director will review the grounds for an appeal. This review is limited to the adequacy of the procedures followed and the appropriateness of the disciplinary action taken. All parties will be notified in writing of the appeal decision within ten (10) business days with the option of an extension if the appellate, vice president, or director chooses to meet with the Respondent and/or representative of the Investigation Committee as part of the appeal process. The decision is final and no further appeal is allowed.

XI. Specific Requirements for Reporting to ORI or OIG When PHS or NSF Funding is Involved

- 1. A decision by the University to initiate an investigation regarding PHS or NSF funded research must be reported in writing by the Research Integrity Officer to the applicable federal agency(ies) on or before the date the investigation begins. At minimum, the notification should include the name of the person(s) against whom the allegation(s) has been made, the general nature of the allegation(s) as it relates to the definition of research misconduct, and the PHS/NSF application(s) or grant number(s) involved. ORI/NSF must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of University policies and procedures should be explained in any reports submitted to ORI/NSF.
- 2. If the University plans to terminate an inquiry for any reason other than that an investigation is not warranted or an investigation for any reason without completing all relevant requirements of the PHS/NSF regulation, the Research Integrity Officer will submit a report of the planned termination to the applicable federal agency(ies), including a description of the reasons for the proposed termination.

If the University determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to the applicable federal agency(ies) a written request for 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 and/or NSF OIG. When PHS funding or other federal agency applications for funding are involved and an admission of research misconduct is made, the Deciding Official or Research Integrity Officer will contact the applicable office(s) for consultation. 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, the University cannot accept an admission of research misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

The Research Integrity Officer will notify ORI, and/or NSF OIG immediately and at any stage of the inquiry or investigation if:

- there is an immediate health or safety hazard involved, including the immediate need to protect human or animal subjects;
- there is an immediate need to protect Federal resources, reputations or other interests;
- 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;
- it is probable that the alleged incident is going to be reported publicly;
- the research activities should be suspended; or
- there is reasonable indication of possible violation of civil or criminal law.

3. NSF Funded Activities (45 CFR 689)

Where NSF funds are involved, the requirements at 45 CFR 689 must be met by the University. Possible actions to be taken by OIG (including initiation of its own Investigation) are identified in 45 CFR 689, and should be noted.

If NSF conducts a formal Investigation, prompt written notice will be made to the individual or institutions to be investigated, unless notice would prejudice the Investigation, or unless a criminal Investigation is underway or under active consideration. In the case of consideration of a criminal Investigation by the Department of Justice, FBI etc., the OIG will determine what information may be disclosed to the subject of the Investigation.

XII. Other Considerations

1. <u>Termination of University Employment or Resignation Prior to Completion of an Inquiry or Investigation</u>

The termination of the Respondent's employment with the University, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the misconduct procedures set forth herein.

If the Respondent, without admitting to the misconduct, elects to resign his/her position prior to the initiation of the inquiry, but after an allegation has been made, or during an inquiry or investigation, the inquiry or investigation will proceed. If the Respondent refuses to participate in the process after resignation, the ad hoc (inquiry) committee, and, if necessary, the Investigation Committee will use its best efforts to reach a conclusion concerning the allegation(s), noting in its report the Respondent's failure to cooperate and its affect on the review of all the evidence.

2. Restoration of the Respondent's Reputation

Upon receiving the report from the ad hoc (inquiry) committee and/or Investigation Committee, if the Deciding Official determines that the Respondent is exonerated of research misconduct and, where relevant, if ORI/NSF or other federal agencies concur, reasonable action(s) will be taken to preserve or restore the Respondent's reputation. Any such actions will be taken by and at the discretion of the Deciding Official, after consultation with the Respondent and appropriate University officials. Those actions may include, but are not limited to 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 from the Respondent's personnel file.

3. Protection of the Complainant and Others

During the pendency, and upon completion of research misconduct proceedings, regardless of whether the University, ORI, NSF OIG, or other federal agencies determine that research misconduct occurred, University officials and the Inquiry and the Investigation committees will make reasonable efforts to protect from retaliation, Complainants who made allegations of research misconduct in good faith, and individuals 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 other University officials, what steps, if any, are needed to restore the position or reputation of the Complainant.

4. Allegations Not Made in Good Faith

The Deciding Official will determine whether the Complainant's allegations of research misconduct were made in good faith. If a determination is made that an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the Complainant.

XIII. Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a), for seven years after completion of the proceeding, or any ORI or DHHS proceeding under Subparts D and E of 42 CFR Part 93, or as required by the State of Alabama, whichever is later.

Related Information

- O UNIVERSITY OF SOUTH ALABAMA WHISTLEBLOWER AND NON-RETALIATION POLICY
- O U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF RESEARCH INTEGRITY

Responsible Party(ies):

Vice President for Research and Economic Development University President Senior University Attorney Director, Research Compliance and Assurance

History

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