



SAINT LOUIS UNIVERSITY

POLICY AND PROCEDURES FOR RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

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Responsible University Official: Vice President for Research

1.0 INTRODUCTION

As a Catholic, Jesuit institution, Saint Louis University seeks to foster a research environment that promotes the responsible conduct of research and adheres to the highest academic and ethical standards. The University is responsible for ensuring the integrity of its research programs in order to maintain public trust and that of research sponsors. It is the policy of Saint Louis University to review and, if necessary, investigate and resolve all instances of alleged research misconduct in a fair, thorough, and confidential manner in accordance with the procedures outlined in this document and applicable federal regulations.

2.0 PURPOSE

The purpose of this policy is to promote compliance with the highest scholarly standards among faculty, staff, and students of the University and to provide a fair and rapid method for resolving allegations of research misconduct. As a recipient of federal research and development funds, the University must have policies and procedures to address research misconduct. This policy and associated procedures serve to support University compliance with requirements set forth in federal regulations.

3.0 APPLICABILITY

This policy and the associated procedures apply to all members of the Saint Louis University research community engaged in the proposing, designing, conducting, or the reporting of research, regardless of the source of funding, if any, for those activities. This policy applies to any person paid by, under the authority of, or affiliated with the University, including faculty, students, staff, independent contractors, guest researchers, or collaborators at the time the misconduct is alleged to have occurred. This policy applies to research proposed, designed, conducted, or reported on or off Saint Louis University campus; and at the discretion of the University if such research is claimed, cited, or implied to have been done at Saint Louis University or where affiliation with the University is claimed, cited, or implied in connection with the research.

This policy applies only to research misconduct occurring within six (6) years of the date the University or the research sponsor receives an allegation of research misconduct, with the following exceptions:

- (a) Subsequent-use exception: The Respondent continues or renews any incident of alleged research misconduct that occurred before the six (6) year limitation through the citation, republication, or other use of the research record that is alleged to have been fabricated, falsified, or plagiarized for the potential benefit of the Respondent;
- (b) Health or safety of the public exception: The alleged research misconduct, if it occurred, possibly would have a substantial adverse effect on the health or safety of the public in the opinion of the University or the funding agency or external sponsor.

4.0 DEFINITIONS

The following definitions apply to this Policy:

Allegation: means a disclosure that is presented to the Research Integrity Officer (RIO) asserting that possible research misconduct has occurred. Allegations are considered to be in *good faith* when made with the honest belief that research misconduct may have occurred. An allegation is not in *good faith* if made in reckless disregard for or willful ignorance of facts that would disprove said allegation.

Complainant: means a person who, in good faith, has formally brought forward an allegation of research misconduct forward.

Evidence: means any document, tangible item, or testimony offered or obtained during a research misconduct proceeding (either inquiry or investigation) that tends to prove or disprove the existence of an alleged fact.

Fabrication: means making up data or results and recording or reporting them.

Falsification: means 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.

Inquiry: means the initial information-gathering, fact-finding process to determine whether sufficient evidence exists to move forward with a formal investigation into the alleged misconduct.

Intentionally: means an action that was undertaken with purpose.

Investigation: means the formal examination of all relevant research records and other information to determine whether misconduct has occurred.

Knowingly: means an action deliberately undertaken with knowledge and understanding of private information.

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

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.

Recklessly: means an action undertaken carelessly or without concern about its consequences.

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).

Research Integrity Officer (RIO): means the individual identified by the University as the person responsible for addressing research integrity and misconduct issues. The RIO at Saint Louis University is typically the Vice President for Research.

Research Misconduct: means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion. A finding of research misconduct requires that there be a significant departure from accepted practices of the relevant research community; that the misconduct be committed intentionally, knowingly, or recklessly; and that the allegation be proven by a preponderance of the evidence.

Research Record: means the record of data or results that embodies the facts resulting from research 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 by a Respondent in the course of the research misconduct proceeding.

Respondent: means any person or persons against whom an allegation of research misconduct has been filed.

Retaliation: means an adverse action taken against a Complainant, witness, or committee member by an institution or one of its members in response to a good faith allegation of research misconduct or good faith cooperation with a research misconduct proceeding.

5.0 RIGHTS AND RESPONSIBILITIES

5.1 Research Integrity Officer (RIO)

The Vice President for Research will normally serve as the Research Integrity Officer (RIO), who will have primary responsibility and authority for implementation of the procedures set forth in this document.

The RIO will appoint the Inquiry Committee and, if subsequently needed, a separate Investigation Committee, and ensure that necessary and appropriate expertise is secured to carry out a fair, thorough, and authoritative evaluation of the relevant evidence in an inquiry or investigation. The RIO will ensure that confidentiality is maintained to the extent possible.

The RIO will assist Inquiry and Investigation Committees and all University personnel in complying with these procedures and with applicable standards imposed by government or other external funding sources. The RIO is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The RIO will report to government or other external funding sources as required by regulation and keep them apprised of any developments during the inquiry or investigation that may affect current or potential funding for the individual(s) under investigation or that the government agency needs to know to ensure appropriate use of public funds and otherwise protect the public interest.

5.2 Complainant

The Complainant will have an opportunity to submit evidence to the Inquiry and Investigation committees. If reasonable and practical, the Complainant will be interviewed by and provide evidence before the Inquiry and Investigation Committees. If interviewed by the Investigation Committee, the Complainant will have the opportunity to receive recordings of his or her testimony before the Committee for review and comment. The Complainant also will be informed, at least in summary fashion, of the results of the inquiry and investigation. In all circumstances, the Complainant will be protected from retaliation. Also, if the RIO has determined that the Complainant may be able to provide pertinent information on any portions of the draft inquiry and investigation reports, these portions may 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.

5.3 Respondent

The Respondent will be informed in writing of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions.

The Respondent will also have the right to be interviewed by and present evidence to the Inquiry Committee and the Investigation Committee, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The Respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation.

5.4 Deciding Official

The Vice President for Research, in addition to serving as the RIO, usually serves as the Deciding Official. In the case of a conflict of interest, the Dean of the School corresponding to the Respondent's primary appointment shall serve as the 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 (unless the Deciding Official is the RIO) or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions consistent with this policy.

6.0 GENERAL POLICY AND PRINCIPLES

6.1 Responsibility to Report Misconduct

It is the explicit duty of any member of the faculty, staff or student body or other individuals associated with Saint Louis University to report observed, suspected, or apparent research misconduct to the Research Integrity Officer, Dean of the School, Institute Director, or a department chairperson, who is in turn responsible for reporting the allegations to the Deciding Official (usually the Vice President for Research, or in the case of a conflict of interest, the Dean of the School corresponding to the Respondent's primary appointment). In the event that a research misconduct allegation shall be made against a Dean or higher academic officer, duties and responsibilities assigned herein to the Dean shall transfer to that Dean's or higher academic officer's immediate academic superior. With the exception of the specified line of reporting and on a need-to-know basis by other University officials such as University legal counsel, all allegations shall be held in absolute confidentiality. The allegations should usually be made in the form of a written, signed statement that states the allegation and specifies the evidence on which the allegation is based.

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 or, instead, use the University's compliance hotline to register a concern. 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 to other offices or officials with responsibility for resolving the problem.

At any time, an individual may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer, a Dean, or a department chair, and will be counseled concerning appropriate procedures for reporting any allegation.

6.2 Cooperation with Inquiries and Investigations

Individuals covered by this policy must cooperate with the Research Integrity Officer and other University officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other University officials on misconduct allegations.

6.3 Confidentiality

The Research Integrity Officer shall (1) limit disclosure of the identity of Respondents and Complainants to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding. The Research Integrity Officer may use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information.

6.4 Protecting the Complainant, Witnesses, and Committee Members

The Research Integrity Officer will 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 Research Integrity Officer and the Deciding Official will ensure that no retaliatory actions will be taken against these persons 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 and/or Deciding Official.

The University will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the Complainant requests not to be further identified, the University will attempt to honor the request during the allegation

assessment or inquiry within applicable policies and regulations and state and local laws, if any. While the Complainant is required to appear for an interview with the Investigation Committee (whenever reasonable and practicable), the Complainant's identity will be withheld from the respondent when that is requested. The University is required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

6.5 Protecting the Respondent

Inquiries and investigations will be conducted in a way 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 the thorough conduct of the inquiry or investigation.

The Respondent shall have the right to have an advisor (including personal legal counsel) present when appearing before the Inquiry and Investigation Committees. The advisor cannot be a principal or witness in the case and shall not be permitted to examine witnesses, make any statement, or otherwise participate in the proceedings. The advisor may quietly offer advice to the Respondent during the meeting.

7.0 CONDUCTING THE ASSESMENT AND INQUIRY

7.1 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. An inquiry is warranted if the allegation (1) falls within the definition of research misconduct; (2) involves applications or proposals for extramural or intramural biomedical or behavioral research, or involves research training or activities related to research or research training, such as the operation of tissue and data banks and the dissemination of research information, regardless of whether an application for extramural support resulted in a grant, contract, cooperative agreement of other form of extramural support; and (3) is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

7.2 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, then he or she will immediately initiate the inquiry process. In initiating the inquiry, the RIO should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to conduct an initial review of the evidence to determine whether to conduct an investigation. The purpose of the inquiry is not to reach a final conclusion about

whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

7.3 Sequestration of the Research Records

On or before the date the Respondent is notified of the allegation or the inquiry begins, whichever is earlier, the Research Integrity Officer must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. Where research records encompass research or scientific instruments shared by a number of users, custody may be limited to copies of the data on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. Where appropriate, the University shall give the Respondent copies of, or reasonable supervised access to, the sequestered research records.

7.4 Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other University officials as appropriate, will appoint an Inquiry Committee and committee chair in a reasonable time frame (when possible, within ten (10) calendar days of the initiation of the inquiry). The Inquiry Committee should consist of three tenured faculty members who have no real or apparent, unresolved personal, professional, or financial conflicts of interest with the Complainant(s), Respondent(s), witnesses, or anyone otherwise involved 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.

The Research Integrity Officer will notify the Respondent of the allegation and of the proposed committee membership. If the Respondent submits a written objection to any appointed member of the Inquiry Committee based on bias or conflict of interest within ten (10) calendar days, the Research Integrity Officer shall consider any objections in order to determine whether to replace the challenged member with a qualified substitute.

7.5 Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the Inquiry Committee that describes the allegations and any related issues identified during the allegation assessment. The charge will clarify that the purpose of the inquiry is not to determine whether research misconduct definitely occurred or who was responsible. Instead, the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the Respondent, Complainant, and key witnesses to determine whether there is sufficient evidence of possible research misconduct to warrant an investigation.

At the Committee's first meeting, the Research Integrity Officer will review the charge with the Committee; discuss the allegations, any related issues, and the appropriate

procedures for conducting the inquiry; assist the Committee with organizing plans for the inquiry; and answer any questions raised by the Committee. The Research Integrity Officer and University Counsel will be present or available throughout the inquiry in order to advise the Committee as needed.

7.6 Inquiry Process

All meetings of the Committee shall be closed. The Inquiry Committee may interview each Respondent, Complainant (unless he/she specifically requests to remain unidentified to the Inquiry Committee), and key witness, as well as examine relevant research records and materials. Interviews will be conducted in person, unless impracticable due to issues of distance, in which case they will be conducted via telephone or video conferencing. Then the Inquiry Committee will evaluate the evidence and testimony obtained during the inquiry. In most instances, the Committee will interview the Respondent unless that person refuses. It is the prerogative of the Respondent to request an immediate implementation of an investigation if, on learning of the allegations, the Respondent wishes to forego the inquiry process. The Committee shall afford the Respondent a reasonable opportunity to refute the allegation including provision of any and all pertinent records of the research or other activity in question. If the Respondent or the Complainant refuses to appear or provide information before the Committee, or for any reason fails to do so, the Committee shall proceed with its inquiry in a manner it deems to be proper and make its decision based on the information available. If the Complainant is known to the Committee, the Committee shall not divulge the Complainant's name to the Respondent. If at any time during the inquiry the possibility of criminal violations arises, the Committee shall immediately notify the Research Integrity Officer who is responsible for informing the appropriate entities.

After consultation with the Research Integrity Officer and University Counsel, Committee members will decide whether there is sufficient evidence of possible research misconduct to recommend further investigation. An investigation is warranted if:

- (1) There is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and
- (2) The preliminary information-gathering and preliminary fact-finding from the inquiry indicates that the allegation may have substance.

The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses. However, if the Respondent makes an admission of research misconduct, the matter will be forwarded directly to the Investigation Committee without further deliberation of the Inquiry Committee.

7.7 Duration of Inquiry

The inquiry, including the preparation of the final inquiry report and the decision of the Deciding Official, should be completed within sixty (60) calendar days from the date of the initial Inquiry Committee meeting. If the Research Integrity Officer determines that

circumstances warrant a longer period, documentation outlining the reason for the decision must be included in the inquiry record.

8.0 THE INQUIRY REPORT

8.1 Elements of the Inquiry Report

The Committee shall prepare a written inquiry report that states the name and title of the committee members, the allegations, the 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, and the Committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. If the opinion of the Committee is divided, written reports shall be provided to the Research Integrity Officer detailing the several opinions and the basis for them. University Counsel shall review the report for legal sufficiency.

8.2 Time Limit for Completing the Inquiry Report

The University must complete the inquiry within sixty (60) calendar days of its initiation unless circumstances warrant a longer period. If the inquiry takes longer than sixty days to complete, the inquiry record must include documentation of the reasons for exceeding the 60-day period. The Respondent shall be notified by the RIO of the extension.

8.3 Comments on the Draft Report by the Respondent

The Research Integrity Officer shall provide the Respondent with a copy of the draft inquiry report, with the Complainant's name redacted, for review and comment.

8.3.1 Confidentiality

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

8.3.2 Receipt of Comments

Within ten (10) calendar days of receipt of the draft report, the Respondent will provide comments, if any, to the Research Integrity Officer. Any comments that the Respondent may submit will become part of the final inquiry report and record. The Research Integrity Officer will review the Respondent's response and, if deemed material, will return the response to the Inquiry Committee for further review and consideration. A copy of the Inquiry Committee's final report with the Complainant's name redacted will be provided to the Respondent.

8.4 Inquiry Decision and Notification

8.4.1 Decision by Deciding Official

The Research Integrity Officer will transmit the final inquiry report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible research misconduct to justify conducting an investigation. If the opinion of the Inquiry Committee is unanimous in finding that an investigation is warranted, the Deciding Official must initiate an investigation within thirty (30) calendar days of the receipt of the report. If the Committee agrees unanimously that the accusation is without merit, the Deciding Official shall dismiss the matter without further action. If the Committee is not unanimously agreed, the Deciding Official shall use his/her discretion to remand the matter to the Committee for further consideration, terminate the proceedings, or convene an investigation. The inquiry is completed when the Deciding Official makes the determination, which will be within ten (10) calendar days of the receipt of the report from the Inquiry Committee. If the Research Integrity Officer determines that circumstances warrant a longer period, documentation outlining the reason for the decision must be included in the inquiry record.

8.4.2 Notification

The Research Integrity Officer shall notify the Respondent in writing of the Deciding Official's decision of whether the inquiry found that an investigation is warranted. The notice must include a copy of the inquiry report and include a copy of or refer to any applicable government rules and regulations, as well as the University's policies and procedures regarding allegations of research misconduct.

The Research Integrity Officer shall notify the Complainant who made the allegation whether the inquiry found that an investigation is warranted. The Research Integrity Officer may provide relevant portions of the report to the Complainant for comment.

The Research Integrity Officer may also notify other entities whose relationship to the research or other activity in question is known and who might reasonably be expected to require such notification. Based on the report of the Committee, the Research Integrity Officer shall be empowered to take interim administrative actions, as appropriate, to protect federal or nonfederal funds, and ensure that the purposes of the financial assistance are carried out.

9.0 CONDUCTING THE INVESTIGATION

9.1 Initiation and Purpose of the Investigation

The investigation must begin within thirty (30) calendar days after the determination that an investigation is warranted. The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will

also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects, the general public or University employees, 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.

9.2 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. Where the research records encompass research or scientific instruments shared by a number of users, custody may be limited to copies of the data on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. 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 University'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.

9.3 Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other University officials as appropriate, will appoint an Investigation Committee and the committee chair in a reasonable time period in order to initiate the investigation. The Investigation Committee should consist of five individuals who were not involved in the inquiry process. Members of the Investigation Committee should be tenured faculty who have no real or apparent, unresolved personal, professional, or financial conflicts of interest with the Complainant(s), Respondent(s), witnesses, or anyone otherwise involved in the case, are unbiased, and have as far as practicable 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, subject matter experts, or other qualified persons. The Investigation Committee may seek expert scientific or other advice from outside consultants. Under unusual circumstances (e.g., a lack of expertise at the University), faculty from other educational institutions may be recruited to serve on an Investigation Committee.

The Research Integrity Officer will notify the Respondent, and when appropriate, the Complainant in writing of the proposed committee membership. If either submits a written objection within ten (10) calendar days to any appointed member of the Investigation Committee or consulting expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

9.4 First Meeting and Charge to the Committee

9.4.1 The First Meeting

The Research Integrity Officer will convene the first meeting of the Investigation Committee to provide the formal written charge and review the inquiry report, and the prescribed procedures and standards for the conduct of the investigation including the necessity for confidentiality and for developing a specific investigation plan. The Investigation Committee will be provided with a copy of this policy and procedures and, where federal funding is involved, the applicable federal regulation(s).

9.4.2 Charge to the Committee

The Research Integrity Officer will provide the Committee with a formal written charge. The charge will describe the allegation and related issues identified during the inquiry, define research misconduct, and identify the name of the Respondent. The charge will inform the Committee it must conduct the investigation as prescribed in this policy and any applicable federal regulations. The charge will state that the Committee is to evaluate the evidence and testimony of the Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation to determine in good faith whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible. The charge will inform the Committee that, in order to determine that the Respondent engaged in research misconduct, it must find that a preponderance of the evidence establishes that:

- (1) Research misconduct as defined in this policy occurred (Respondent has the burden of proving by a preponderance of evidence any affirmative defenses raised, including honest error or difference of opinion);
- (2) The research misconduct is a significant departure from accepted practices of the relevant research community; and
- (3) The Respondent committed the research misconduct intentionally, knowingly, or recklessly.

The charge will inform the Committee that it must prepare a written final report of its findings and recommendations.

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 RIO, who will determine whether it is necessary to expand the scope of the investigation and notify the Respondent.

9.5 Investigation Process

All meetings of the Investigation Committee shall be closed. The investigation will normally involve examination of all documentation including, but not limited to, relevant research records, computer files, proposals, manuscripts, publications,

correspondence, memoranda, and notes of telephone calls. Except in the case of exceptional circumstances, the Committee is required to interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the investigation, including witnesses identified by the Respondent. Exceptional circumstances must be documented by the Investigation Committee and verified by the Research Integrity Officer. Exceptional circumstances may include, but are not limited to, matters that involve unusual circumstances surrounding Complainant requests for anonymity or the inability to participate in an interview for health or other reasons. Interviews will be conducted in person, unless impracticable due to issues of distance, in which case they will be conducted via telephone or video conferencing. All interviews shall be audio- and/or video- recorded. The interviewee must be provided (if requested) the recording of his or her interview for comment as to the accuracy of the contents, and the recording must be included as part of the investigatory file.

The Respondent shall have the right to have an advisor (including personal legal counsel) present when appearing before the Investigation Committee. The advisor shall not be permitted to examine witnesses, make any statement, or otherwise participate in the proceedings. The advisor may quietly offer advice to the Respondent during the meeting. If the Respondent refuses to appear before the Investigation Committee or for any reason fails to do so, the Committee shall proceed with its investigation in a manner it deems to be proper.

10.0 REPORT OF THE INVESTIGATION COMMITTEE

10.1 Elements of the Investigation Committee Report

Within eighty (80) calendar days of the initial Committee meeting, the Investigation Committee shall present its report in writing to the Deciding Official. The report must include:

- (a) Names of the Investigation Committee Members.
- (b) Allegations. Describe the nature of the allegations of research misconduct.
- (c) Name and Position of Respondent(s).
- (d) Extramural support. Describe and document the extramural support (if any), including, for example, any grant numbers, grant applications, contracts, and publications listing extramural support.
- (e) Institutional charge. Describe the specific allegations of research misconduct for consideration in the investigation.
- (f) Policies and Procedures. Reference the University policies and procedures under which the investigation was conducted (i.e., this policy).
- (g) Research records and evidence. Identify and summarize the research records and evidence reviewed, and identify any evidence taken into custody but not reviewed.

- (h) Statement of findings. For each separate allegation of research misconduct identified during the investigation, provide a finding as to whether research misconduct did or did not occur, and if so –
 - (1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and if it was intentional, knowing, or reckless;
 - (2) Summarize the facts and the analysis which support the conclusion and consider the merits of any reasonable explanation by the Respondent;
 - (3) Identify the specific funding sources (if any);
 - (4) Identify whether any publications need correction or retraction;
 - (5) Identify the person(s) responsible for the misconduct; and
 - (6) List any current support or known applications or proposals for support that the Respondent has pending with any federal agencies.
- (i) Comments: Before drafting the final report, the Investigation Committee must consider any comments received from the Respondent and/or Complainant on the draft investigation report, and revise the report if appropriate. The final report must include as an attachment any comments made by the Respondent and Complainant on the draft investigation report.

If the Investigation Committee concludes that one or more allegations of research misconduct have been substantiated, the report may recommend what sanctions, if any, should be imposed upon the Respondent and what corrective action, if any, should be taken.

10.2 Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 calendar days of its initiation, which is defined as the date of the first meeting of the Investigation Committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the Respondent (and Complainant, if applicable) for comment, and submitting the report to the Deciding Official for approval. If the Research Integrity Officer determines that circumstances warrant a longer period, documentation outlining the reason for the decision must be included in the investigation record. The Respondent shall be notified of the extension by the RIO.

10.3 Comments on the Draft Investigation Report

10.3.1 Respondent

The Research Integrity Officer will provide the Respondent with a copy of the draft investigation report and, concurrently, a copy of, or supervised access to, the evidence on which the report is based. The comments of the Respondent, if any, must be submitted within thirty (30) calendar days of the date on which the Respondent received the draft investigation report. The Respondent's comments will be considered and, when appropriate, addressed in the final investigation report.

10.3.2 Complainant

The Research Integrity Officer may provide the Complainant a copy of the draft investigation report or relevant portions of that report. The comments of the Complainant, if any, must be submitted within thirty (30) calendar days of the date on which the Complainant received the draft investigation report or relevant portions of it. The Complainant's comments will be considered and, when appropriate, addressed in the final investigation report. In all circumstances, such comments will be included as an attachment to the final investigation report.

10.3.3 University Counsel

The draft investigation report will be transmitted to the University Counsel for a review of its legal sufficiency.

10.3.4 Confidentiality

In distributing the draft report, or portions thereof, to the Respondent and Complainant, the Research Integrity Officer will inform the recipients of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality (e.g., via signed confidential disclosure agreement).

10.4 Transmittal of the Final Investigation Report

After comments have been received and the necessary changes have been made to the draft report, the Investigation Committee should transmit the final report, including as attachments any comments received from the Respondent or Complainant, to the Deciding Official, through the Research Integrity Officer.

10.5 University Review and Decision

The Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended University actions. If the majority of the Investigation Committee finds that research misconduct did occur, it is incumbent on the Deciding Official to initiate appropriate sanctions against the Respondent. If the majority of the Investigation Committee finds that the accusation is without merit, the Deciding Official shall dismiss the matter without further action. The Deciding Official may also return the report to the Investigation Committee with a written request for further fact-finding or analysis when: a) there is new evidence that may be sufficient to alter a finding or recommendation that was not considered by the Committee and such evidence or facts were not known to the Committee, Complainant, or Respondent at the time of the original proceedings; or b) the Committee's proceedings were not conducted in substantial conformity with the prescribed procedures; or c) the decision does not appear to be based on substantial evidence, that is, the facts as detailed in the report were not sufficient to establish or support a finding that research misconduct occurred. Upon receipt of the Deciding Official's written request, the Investigation Committee will conduct such proceedings and deliberations as

it deems necessary and forward a supplemental investigational report to the Deciding Official. The Deciding Official will accept the final findings of the Investigation Committee's supplemental report and take appropriate action as outlined in this policy.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the Respondent and the Complainant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the Respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The Deciding Official shall report the final decision and administrative action to the Provost and other appropriate University officials as warranted.

11.0 UNIVERSITY ADMINISTRATIVE ACTIONS

11.1 Completing the Research Misconduct Process

The University should carry inquiries and investigations through to completion and must pursue diligently all significant issues. Saint Louis University will take appropriate administrative actions against individuals when an allegation of research misconduct has been substantiated. If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken after reviewing the recommendation(s) of the Investigation Committee and after consultation with the Research Integrity Officer and University Counsel. All decisions involving disciplinary actions will be in accordance with applicable policies covering faculty, staff, or students. The actions may include, but are not limited to, the following:

- Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- Removal of the responsible person(s) 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 or enrollment; and/or
- Restitution of funds as appropriate.

The Investigation Committee's final factual findings and the Deciding Official's determination that research misconduct occurred will be treated as conclusive and binding in any grievance or other internal University proceedings, including those conducted by any faculty committee or body charged with determining whether termination proceedings should be continued against a faculty member.

12.0 OTHER CONSIDERATIONS

12.1 New Allegations of Research Misconduct

In the event that new allegations of possible research misconduct arise that were not addressed during the inquiry or in the initial notice of the investigation, the Research Integrity Officer must give the Respondent written notice of any such new allegations within a reasonable amount of time of deciding to pursue them through inquiry or investigation.

12.2 Termination of University Employment or Resignation Prior to Completing Inquiry or Investigation

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

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, the inquiry or investigation will proceed. If the Respondent refuses to participate in the process after resignation, the Inquiry and/or Investigation 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.

12.3 Restoration of the Respondent's Reputation

If the University finds no research misconduct, the Research Integrity Officer and Deciding Official will, at the request of and in consultation with the Respondent, undertake all reasonable and practical efforts to restore the Respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer will normally notify those individuals aware of or involved in the investigation of the final outcome, publicize the final outcome in forums in which the allegation of research misconduct was previously publicized, or expunge all reference to the research misconduct allegation from the Respondent's personnel or equivalent file. Any University actions to restore the Respondent's reputation must be in consultation with the Deciding Official.

12.4 Protection of the Complainant and Others

Regardless of whether or not the University determines that research misconduct occurred, the Research Integrity Officer and Deciding Official will undertake reasonable efforts to protect the confidentiality of 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 RIO and Deciding Official will determine, after consulting with the Complainant, what steps, if

any, are needed to prevent or counter any potential or actual retaliation and restore the position or reputation of the Complainant, witnesses, or Committee members.

12.5 Allegations Not Made in Good Faith

The Research Integrity Officer 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 Research Integrity Officer will recommend to the Deciding Official whether any administrative action should be taken against the Complainant. The Deciding Official shall consult the appropriate University administrators to determine the appropriateness of the action.

12.6 Interim Administrative Actions

University officials will take interim administrative actions, as appropriate, if any of the following conditions exist:

- There is an immediate health hazard involved;
- There is an immediate need to protect a sponsor's funds or equipment;
- 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; or
- There is a reasonable indication of possible criminal violation.

13.0 Obligations and Notifications to External Agencies and Sponsors

The University must comply with all applicable regulations of funding agencies and requirements agreed upon through sponsored program agreements or related contractual obligations. The University will cooperate with those agencies and other external sponsors with regard to research misconduct in the manner specified by such agreements.

13.1 Notifications to Federal Funding Agencies

The two primary sets of regulations regarding research misconduct proceedings are outlined in federal regulations 42 CFR Part 93 for research funded by the Public Health Services (DHHS) and 45 CFR Part 689 for research funded by the National Science Foundation (NSF). The University officials charged with implementation of this policy are advised to review the current regulations and requirements, and to consult with the Research Integrity Officer in any situation regarding their applicability to research misconduct proceedings.

13.1.1 Outcome of an Inquiry

Federal agencies will be notified of the outcome of an inquiry involving funds from their agency. Documentation for all inquiries including those not carried forward to investigation shall be maintained and made available by the Research Integrity Officer to the funding agency upon that agency's request.

13.1.2 Decision to Initiate an Investigation

Written notification must be provided to federal funding agencies once it is determined that an investigation will be conducted. The timeframe for such notification varies by agency and is typically specified by them. In the case of NSF funding, the agency's Office of the Inspector General (OIG) must be notified immediately if an initial inquiry supports an investigation.

In instances of Public Health Service (PHS) funding, within thirty (30) calendar days of finding that an investigation is warranted, the Research Integrity Officer must provide the Office of Research Integrity (ORI) of the U.S. Department of Health and Human Services (DHHS) with the written finding by the responsible University official and a copy of the inquiry report which includes the following information:

- (a) The name and position of the Respondent
- (b) A description of the allegations of research misconduct
- (c) The PHS support, including, for example, grant numbers, grant applications, contracts, and publications listing PHS support;
- (d) The basis for recommending that the alleged actions warrant an investigation;
- (e) Any comments on the report by the Respondent or the Complainant.

Upon request, the Research Integrity Officer must provide the following information to ORI:

- (a) The University's policies and procedures under which the inquiry was conducted.
- (b) The research records and evidence reviewed, transcripts or recordings of any interviews, and copies of all relevant documents; and
- (c) The charges for the investigation to consider.

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

13.1.3 Requests for Time Extension(s)

The regulations vary on the timeframe for the inquiry and investigation processes, but the University has chosen to follow the timeframes specified by the PHS in this policy allocating sixty (60) days to complete an inquiry and 120 days to complete all aspects of an investigation. As specified in sections 8.2 and 10.2 of this policy,

the University must document any reasons for exceeding the specified timeframes. The RIO shall also provide federal funding agencies with notice and requests for time extensions as maybe required by that agency's regulations. In the case of PHS funding, no such notification is required at the inquiry stage, however the RIO must request any extension of time for the investigation in writing to ORI. In the case of NSF funding, the RIO must notify the agency's OIG if the inquiry is to be delayed past ninety (90) days or the investigation is delayed past 180 days in order to continue deferral of independent inquiry by NSF.

If an extension is granted, the University may be required by the federal funding agency to provide them with periodic progress reports; or the agency may undertake its own investigation prior to the University completing its own.

13.1.5 Early Termination

Federal funding agencies must be notified of any decision by the University to terminate an inquiry or investigation prior to completing all the proscribed requirements, and the notice shall include the reasons for such action.

13.1.6 University findings and actions

Federal funding agencies must be notified of the final outcome of an investigation and the University's administrative actions. The Research Integrity Officer shall provide federal funding agencies requiring such notification the following:

- (a) Investigation Report. Include a copy of the report, all attachments, and any appeals.
- (b) Final University action. State whether the University found research misconduct, and if so, who committed the misconduct.
- (c) Findings. State whether the University accepts the investigation's findings.
- (d) University administrative actions. Describe any pending or completed administrative actions against the respondent.

13.1.7 Circumstances requiring immediate notifications

At any time during a research misconduct proceeding, the University must notify the relevant federal funding agency immediately if it has reason to believe that any of the following conditions exist:

- (a) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- (b) Federal resources or the agency's interests are threatened;
- (c) Research activities should be suspended;
- (d) There is reasonable indication of possible violations of civil or criminal law;
- (e) Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- (f) The University believes the research misconduct proceeding may be made public prematurely so that the agency may take appropriate steps to safeguard evidence and protect the rights of those involved;
- (g) The research community or public should be informed.

The Research Integrity Officer in consultation with University Counsel shall make the aforementioned special notifications to the appropriate agency.

13.2 Reporting to Other External Sponsors

In the case of research that is not federally sponsored, all procedures outlined in this policy will apply, except for those regarding the notification of federal agencies. The Research Integrity Officer shall determine whether information concerning the charges and their disposition will be disclosed publicly or to specific parties, including the research sponsor(s).

13.2 Actions by Funding Agencies

Funding agencies and other external sponsors may take action against an individual or the University after a finding of research misconduct has been reported. Under the federal regulations, agencies have the right to perform their own investigation in cases involving federally funded research at any time prior to, during, or following the University's investigation.

14.0 RECORD RETENTION

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file that includes:

- (a) Records that the University secures for the research misconduct proceedings, except to the extent the University subsequently determines and documents that those records are not relevant to the proceeding or that the records duplicate other records that are being retained.
- (b) The documentation of the determination of irrelevant or duplicate records.
- (c) The inquiry report and final documents (not drafts) produced in the course of preparing that report, including the documentation of any decision not to investigate.
- (d) The investigation report and all records in support of that report, including the recordings or transcriptions of each interview conducted; and
- (e) The complete record of any institutional appeal.

The RIO will maintain records of research misconduct proceedings in a secure manner for seven (7) years after completion of the proceeding or the completion of any federal funding agency's proceeding involving the research misconduct allegation.

15.0 REFERENCES

PHS Research Misconduct Regulations: 42 CFR Part 93 (2011)

NIH Research Misconduct Regulations: 45 CFR Part 689 (2012)

POLICIES RESCINDED

Interim Policy for Responding to Allegations of Research Misconduct, February 22, 2007.

Saint Louis University Research Integrity Policy, March 07, 2007.

APPROVAL SIGNATURES

This policy was approved by:

x/ Signed Policy on File

Date: 10 FEB 2016

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