



**Policy and Procedures for
ST. LUKE'S HEALTH SYSTEM
Boise - Meridian**

RI017 TV

POLICY TITLE:

Responding to Allegations of Research Misconduct

POLICY:

St. Luke's observes the highest standards of professional conduct in all of its research activities. St. Luke's will follow an established administrative process for reviewing, investigating, and reporting allegations of research misconduct. Incidents of possible research misconduct are to be reported promptly and will be addressed without retaliation to any party. All parties will be treated with fairness and respect, and confidentiality will be maintained to the maximum possible extent.

DEFINITIONS:

Allegation: Any written or oral statement or other indication of possible Research Misconduct made to an institutional official.

Complainant: The individual(s) who submits an Allegation of Research Misconduct.

Compliance Officer: The St. Luke's official responsible for assessing Allegations of Research Misconduct and determining when such Allegations warrant inquiries and for overseeing inquiries and investigations.

Conflict of Interest: The real or apparent interference of one person's interests with another person or entity where the potential bias may occur due to prior personal or professional relationships.

Executive Committee: The committee of the entity at which the Allegation of Research Misconduct occurred.

Fabrication: Making up data or results and recording or reporting them.

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 made in good faith if it is made with reckless disregard for or willful ignorance of facts that would disapprove the Allegation.

Inquiry: Preliminary information-gathering and preliminary fact-finding to determine whether an Allegation or apparent instance of Research Misconduct has substance and if an Investigation is warranted.

Investigation: The formal examination and evaluation of all relevant facts to determine that misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.

Office of Research Integrity (ORI): The office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the Research

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	<p>Misconduct and research integrity activities of the U.S. Public Health Service.</p> <p>Plagiarism: The appropriation of another person’s ideas, processes, results or words without giving them the appropriate credit.</p> <p>Preponderance of Evidence: Proof by information that, compared with that opposing that, it leads to the conclusion that the fact at issue is more probably true than not.</p> <p>Public Health Service (PHS): The unit of Public Health Services with the Department of Health and Human Services.</p> <p>Research Misconduct or Misconduct in Research: Research Misconduct as defined by the federal government means fabrication, falsification or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest errors, scholarly or political disagreements or differences of opinion in interpretations or judgments of data.</p> <p>A finding of Research Misconduct requires that the misconduct be committed intentionally, knowingly, or recklessly. A finding of Research Misconduct also requires that there be a significant departure from the accepted practices of the relevant research community and that the Allegation be proven by a preponderance of evidence.</p> <p>Research Record or Record: Any data, document, computer file, compact disc, 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 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.</p> <p>Respondent: The person against whom an Allegation of Research Misconduct is directed and who is the subject of a Research Misconduct proceeding.</p> <p>Retaliation: 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.</p>
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US Department of Health and Human Services Public Health Service Policies on Research Misconduct - Final Rule, Code of Federal Regulations, Vol. 42, Part 93 (Federal Register, Vol. 70, p. 28370 (May 17, 2005)

PROCEDURE(S):**I. INTRODUCTION****A. General Policy:**

1. Federal regulations require that institutions applying for or receiving federal research funding have an established administrative process for reviewing, investigating, and reporting Allegations of Research Misconduct. This Policy is intended to carry out St. Luke's Health System and its Affiliates ("St. Luke's") responsibilities under the Public Health Service ("PHS") Policies on Research Misconduct 42 CFR Part 93. This Policy sets forth the procedures that will be followed in reporting, inquiring into, and investigating allegations of Research Misconduct.

B. Scope and Application

1. This policy for Responding to Allegations of Research Misconduct and associated procedures ("Policy") must be used to investigate and resolve all allegations of Research Misconduct regardless of funding source. Certain Research Misconduct allegations may include related concerns that do not fit squarely within the definition of Research Misconduct. Such concerns may be dealt with at the same time as the Research Misconduct allegations through the processes described in this Policy. Alternatively, such related issues (not allegations of Research Misconduct) may be resolved through other St. Luke's policies/procedures better suited for the nature of the concern. The Compliance Officer and the Director of Research Administration will determine what processes/procedures to use. If St. Luke's uses a different process/procedure to address concerns that do not fall within the definition of Research Misconduct, such process/procedure shall ensure the fair treatment of the subject of the inquiry or investigation.
2. This Policy applies to all individuals engaged in research activities including, but not limited to employees, investigators, research staff, and any other individuals involved in research activities associated with St. Luke's.
3. Allegations of Research Misconduct occurring more than six years prior to the submission of the Allegations shall not be reviewed under this Policy unless:
 - a. Applicable federal regulations require review of such Allegations
 - b. The alleged Research Misconduct was not reasonably discoverable at an earlier time
 - c. The Research Misconduct poses a current threat to the health and safety of employees, patients or research subjects.

II. GENERAL POLICIES AND PROCEDURES**A. Responsibility to Report Misconduct**

1. Persons subject to this Policy who become aware of a possible incident of Research Misconduct shall immediately report the information in the manner described in Section III. A. At any time, persons subject to this Policy may have confidential discussions and consultations about concerns of possible misconduct with the Compliance Officer, Director of Research Administration or the IRB Manager and will be counseled about appropriate procedures for reporting Allegations.

B. Protecting the Complainant

1. Persons subject to this Policy who receive or learn of an Allegation of Research Misconduct shall treat the Complainant who has made a Good Faith Allegation with fairness and respect and shall take reasonable steps to protect the position and reputation of the Complainant and other individuals who cooperate with the Inquiry or the Investigation against Retaliation. Any alleged or apparent Retaliation should be reported to the Compliance Officer. In addition federal regulations require that institutional policies “protect to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.” Accordingly, if a Complainant requires anonymity, St. Luke’s will make an effort to honor the request during the preliminary assessment or Inquiry to the extent permitted by law. If the matter is referred to an Investigation Committee and the Complainant’s testimony is required, however, anonymity may no longer be guaranteed.

C. Protecting the Respondent

1. Persons subject to this Policy who receive or learn of an Allegation of Research Misconduct shall treat the Respondent with fairness and respect and shall take reasonable steps to ensure that these procedures are followed. When a Respondent has been exonerated, St. Luke’s shall make substantial, sustained efforts to restore his or her reputation. Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the Respondent in the Inquiry or Investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the Inquiry or Investigation.

D. Confidentiality

1. Allegations of Research Misconduct, and proceedings conducted under this Policy, may be damaging to the professional reputations of persons involved. Accordingly, persons subject to this Policy who make, receive, or learn of an Allegation of Research Misconduct shall protect, to the maximum extent possible, the confidentiality of information regarding the Complainant, the Respondent, and other affected individuals. To the extent allowed by law, we shall maintain the identity of Respondents and Complainants securely and confidentially and shall not disclose any identifying information, except to: (1) those who need to know in order to carry out a thorough, competent, objective and fair Research Misconduct proceeding; and (2) ORI as it conducts its review of the Research Misconduct proceeding and any subsequent proceedings.
2. To the extent allowed by law, any information obtained during the Research Misconduct proceeding that might identify the subjects of research shall be maintained securely and confidentially and shall not be disclosed, except to those who need to know in order to carry out the Research Misconduct proceeding.

E. Responding to Allegations

1. In responding to Allegations of Research Misconduct, the Compliance Officer and the Director of Research Administration shall make diligent efforts to ensure that the following functions are performed:
 - a. Any assessment, Inquiry, or Investigation is conducted in a timely, objective, thorough, and competent manner.
 - b. Reasonable precautions are taken to avoid bias and real or apparent Conflicts of Interest on the part of those involved in conducting the Inquiry or Investigation. Specifically, reasonable steps shall be taken to ensure that the Compliance Officer, members of Inquiry Committee and Investigation Committee, and experts have no bias and no personal, professional or financial Conflict of Interest with the Respondent, Complainant, or the case in question. In making this determination, consideration shall be given to whether the individual (or any members of his or her immediate family) has

any of the following involvements with the Respondent or Complainant: financial involvement; co-author on a publication; sub-investigator or co-investigator; party to a scientific controversy; supervisory or mentor relationship; other special relationship such as a close personal friendship, kinship, or a physician/patient relationship. Consideration shall also be given to whether there is any other circumstance that might appear to compromise the individual's objectivity in reviewing the Allegations. The Complainant and the Respondent shall have the right to comment on whether the Compliance Officer and members of Inquiry Committee and Investigation Committees meet the above criteria. If the Complainant or the Respondent makes a prompt, reasonable, objection to the Compliance Officer concerning a member of an Inquiry Committee or Investigation Committee, the challenged person shall be replaced with another person who meets the stated criteria.

2. Immediate notification is provided to ORI under any one of the following circumstances (in cases involving PHS-funded research) and/or other federal research sponsors supporting the research in question (to the extent required by those sponsors' regulations) if:
 - a. The health or safety of the public is at risk, including an immediate need to protect human or animal subjects.
 - b. HHS resources or interests are threatened.
 - c. Research activities should be suspended.
 - d. There is a reasonable indication of violations of civil or criminal law.
 - e. Federal action is required to protect the interests of those involved in the Research Misconduct proceeding.
 - f. The research community or public should be informed.
 - g. There is an immediate need to protect the interests of the Complainant or Respondent as well as his/her co-investigators and associates, if any.
 - h. Interim administrative actions are taken, as appropriate, to protect federal funds and the public health, and to ensure that the purposes of the federal financial assistance are carried out.
 - i. The Research Misconduct proceeding may be made public prematurely.

- F. Cooperation by Persons Subject to this Policy
 1. Persons subject to this Policy, as defined in Section I.B are expected to cooperate with the Compliance Officer and other officials in the review of Allegations and the conduct of Inquiries and Investigations. Persons subject to this Policy have an obligation to provide evidence to the Compliance Officer or other officials on Research Misconduct Allegations.

- G. Access to Attorneys and Advisers
 1. Respondents may consult with their own legal counsel or non-lawyer personal adviser (who is not a participant or witness in the case) to seek advice, but such counsel or adviser shall not participate in meetings with the Inquiry Committee or Investigation Committee without the prior approval of the Chair of the Committee.

- H. Evidentiary Standards

In accordance with federal regulations, the following standards and burdens of proof apply to findings of Research Misconduct under this policy.

 1. Burden of Proof
 - a. St. Luke's has the burden of proof for making a finding of Research Misconduct.

III. SUBMISSION OF ALLEGATIONS; PRELIMINARY ASSESSMENT

A. Submission of Allegations

1. Any individual who in Good Faith suspects that a person subject to this policy is committing or has committed Research Misconduct shall immediately report the information to one of the following:
 - a. IRB Manager
 - b. General Counsel
 - c. Compliance line
 - d. Compliance Officer
 - e. Office of Research Administration
2. Whoever receives the report shall immediately report the information to the Compliance Officer. The Compliance Officer shall initiate the process for assessment of the Allegations, as described below.
3. If the circumstances described by the individual do not meet the definition of Research Misconduct, the Compliance Officer will refer the individual to other personnel with responsibility for resolving the problem.

B. Preliminary Assessment of Allegations to Determine if Inquiry is Warranted

1. Upon receiving an Allegation of Research Misconduct, the Compliance Officer and the Executive Committee of the entity at which the allegation occurred shall, within 15 working days and without notice to any of the parties involved, consult with one another or other appropriate personnel to determine whether an Inquiry is warranted.
2. An Inquiry is warranted if the Allegation:
 - a. Falls within the definition of Research Misconduct under this Policy; and
 - b. Is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified; or
 - c. It involves either the PHS supported research, applications for PHS research support, or Research Records specified in 42 CFR Section 93-102(b).
3. If it is determined that an Inquiry is warranted, the Compliance Officer shall promptly:
 - a. Appoint an Inquiry Committee of at least three members with one member to serve as Chair. (See Section IV.B.1 below)
 - b. Secure the relevant Research Records (see Section IV.A below);
 - c. Notify the Complainant, the Respondent (see Section IV.C below); and
 - d. Provide the Respondent with a copy of the Allegations and this Policy.
4. There is not always sufficient information to permit Inquiry of an Allegation. For example, an Allegation that a researcher's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an Inquiry. In the case of such a vague Allegation, an effort should be made to obtain more information before initiating an Inquiry. This information may be sought from any reasonable source, including the Complainant if known. However, if further information is to be requested from the Respondent or other persons involved in the alleged misconduct, the Compliance Officer should secure the relevant Research Records before making such a request.
5. Anonymous Allegations of Research Misconduct will be considered only if sufficient evidence, in the judgment of the Compliance Officer is provided to permit Inquiry of the Allegations.
6. If it is determined that an Inquiry is not warranted, the matter will not proceed to an Inquiry and the Compliance Officer shall so inform the Respondent and Complainant in writing.

IV. INQUIRY

If it is determined that an Inquiry is warranted, the following procedures shall apply:

- A. Sequestration of Research Records
1. Upon notification to the Respondent that an Inquiry is being initiated, the Compliance Officer shall promptly take all reasonable steps to obtain custody of all Research Records and evidence needed to conduct the Research Misconduct proceeding, inventory those materials, and sequester them in a secure manner, except in those cases where the Research Records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments.
 2. Where appropriate, give the Respondent copies of or reasonable, supervised access to the Research Records.
 3. Undertake all reasonable and practical efforts to take custody of additional Research Records and evidence discovered during the course of the Research Misconduct proceeding, including at the Inquiry and Investigation stages, or if new Allegations arise, subject to the exception for scientific instruments in (1) above.
- B. Designation of Inquiry Committee
1. Within 15 working days of the determination that an Inquiry is warranted, the Compliance Officer in consultation with other officials as appropriate, shall appoint the Inquiry Committee and designate one of its members to serve as Chair. The Inquiry Committee shall consist of at least three individuals who do not have real or apparent Conflicts of Interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Inquiry. Ordinarily, the members of the Inquiry Committee will be drawn from within the institution. However, the Compliance Officer may designate committee members from outside the institution if necessary to obtain the relevant expertise and/or avoid Conflicts of Interest.
 2. The Inquiry Committee shall determine whether additional experts other than those appointed to the Committee need to be consulted during the Inquiry to provide special expertise regarding the analysis of evidence. If consulted, such experts shall provide a strictly advisory function to the Committee and shall not vote. At the request of the Chair, they may interview witnesses and participate in Committee deliberations. The experts' chosen may be from inside or outside of the institution.
- C. Notification of Complainant and Respondent
1. The Compliance Officer shall notify the Complainant and Respondent in writing of the opening of the Inquiry. If the inquiry identifies additional Respondents, they shall be promptly notified. The notification to the Complainant and the Respondent should: identify the research project in question and the specific Allegations; provide a copy of this Policy; refer to the definition of Research Misconduct; identify any external funding involved; list the names of the members of the Inquiry Committee (if appointed) and experts (if any); explain the opportunity to challenge the appointment of a member of the Inquiry Committee or expert for bias or Conflict of Interest; describe St. Luke's policy on protecting the Complainant against Retaliation; and describe the need to maintain confidentiality during the Inquiry and any subsequent proceedings. The notification to the Respondent should, in addition: provide a copy of the Allegation(s) and invite the Respondent to respond; explain the Respondent's opportunity to be interviewed, to present evidence to the Committee and to comment on the draft Inquiry report after it is prepared; and address the Respondent's obligation to cooperate in the Inquiry and any subsequent proceedings.

- D. Purpose of Inquiry; Criteria Warranting Investigation:
 - 1. The purpose of the Inquiry is to make a preliminary evaluation of the available evidence and testimony of the Respondent and key witnesses to determine whether there is sufficient evidence of possible Research Misconduct to warrant an Investigation. The purpose of the Inquiry is not to reach a final conclusion about whether the misconduct occurred or who was responsible.
 - 2. An Investigation is warranted if there is:
 - a. A reasonable basis for concluding that the Allegations fall within the definition of Research Misconduct under this Policy; and
 - b. Preliminary information-gathering and preliminary fact-finding from the Inquiry indicates that the Allegations may have substance.

- E. Inquiry Process
 - 1. The Inquiry Committee shall interview the Complainant, the Respondent, and key witnesses and examine relevant Research Records and materials. Supervised access to the data and/or documents should be available to the Respondent and the Complainant, and to other witnesses as appropriate. The Inquiry Committee shall summarize interviews in writing. The Respondent, Complainant, and witnesses shall be given the opportunity to review and correct such summaries of their own statements.

- F. Time for Completion of Inquiry
 - 1. The Inquiry must be completed within 60 calendar days of the appointment of the Committee unless circumstances clearly warrant a longer period and the Compliance Officer approves an extension. If the Inquiry takes longer than 60 days to complete, the Inquiry Report must include documentation of the reasons for exceeding the 60-day period.

- G. Inquiry Report:
 - 1. The Inquiry Panel must prepare a written report that includes the following elements:
 - a. The name and position of the Respondent;
 - b. A description of the Allegations of Research Misconduct;
 - c. A description of any external support for the research giving rise to the Allegations, including, for example, grant and contract numbers and references to grant applications;
 - d. References to any publications involving the research in question;
 - e. Any comments on the report by the Respondent;
 - f. The basis for recommending or not recommending that an Investigation is warranted.
 - 2. The Respondent shall be provided with a draft of the Inquiry Committee report and shall have 10 days to provide written comments on it. In preparing its final report, the Committee shall consider and attach any comments made by the Respondent on the draft Inquiry Committee report.

- H. Compliance Officer’s Decision on Inquiry Panel’s Recommendation
 - 1. The Chair of the Inquiry Committee shall transmit the final Inquiry report to the Compliance Officer who shall decide whether the findings from the Inquiry warrant conducting an Investigation, under the standards set forth above.

- I. Notice of Results of Inquiry; Report to Federal Authorities
 - 1. The Compliance Officer shall notify the Respondent and appropriate St. Luke’s personnel in writing of the decision whether to proceed to an Investigation. The notice to the Respondent will include a copy of the Inquiry report, a copy of the HHS final rule addressing Research Misconduct, Section 93.308 and this Policy. To the extent required by federal regulation, the Compliance Officer shall provide notice

to federal authorities concerning the Inquiry and the decision whether an Investigation is warranted. For example, for PHS-funded research, regulations require that institutions provide ORI with the written finding of the Compliance Officer and a copy of the Inquiry Report. (Code of Federal Regulations, Vol. 42, Sec. 93.309). Upon request from ORI the Director of Research Administration shall promptly send them a copy of our institutional policies and procedures under which the Inquiry was conducted, Research Records and evidence reviewed, transcripts or recordings of interviews, copies of all relevant documents, and the charges for the Investigation to consider.

- J. Restoration of Respondent's Reputation Where Investigation Is Not Warranted
 - 1. In cases where it is determined that Investigation is not warranted, the Respondent may meet with the Compliance Officer to determine whether it is necessary for the institution to take any steps to restore the Respondent's reputation. See Section II.C

V. INVESTIGATION

- A. Designation of Investigation Committee:
 - 1. If the Compliance Officer determines that an Investigation is warranted, he shall within 30 calendar days after such determination, appoint an Investigation Committee to explore the Allegations in detail, to examine the evidence in depth, and to determine specifically whether Research Misconduct has been committed, by whom, and to what extent. The Investigation Committee will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial Allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or it affects research that forms the basis for public policy, clinical practice or public health practice. The Investigation Committee should consist of at least three individuals who do not have real or apparent Conflicts of Interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the Allegation, interview the principals and key witnesses, and conduct the Investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. One of the members shall be appointed to serve as Chair. (Individuals appointed to the Inquiry Committee may also serve on the Investigation Committee).
 - 2. If there is an Allegation involving individuals from different categories of employees, students, etc. the Compliance Officer shall confer with the appropriate persons or other responsible officials and determine a single, coordinated process for conducting the Investigation.
 - 3. The Investigation Committee shall determine whether experts other than those appointed to the Committee need to be consulted during the Investigation to provide special expertise regarding the analysis of evidence. If consulted, such experts shall provide a strictly advisory function to the Committee and shall not vote. At the request of the Chair, experts may interview witnesses and participate in Committee deliberations. The experts' chosen may be from inside or outside of St. Luke's.
- B. Investigation Process:
 - 1. In conducting its Investigation, the Investigation Committee shall:
 - a. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all Research Records and evidence relevant to reaching a decision on the merits of the Allegations.

- b. Interview each Respondent, Complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the Respondent, and record or transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript in the record of Investigation.
- c. Give the Respondent written notice of any new Allegations within a reasonable time after determining to pursue Allegations not addressed in the Inquiry or in the initial notice of the Investigation.
- d. Notify the Respondent sufficiently in advance of the scheduling of his/her interview in the Investigation so that the Respondent may prepare for the interview and arrange for the attendance of legal counsel, if the Respondent wishes.
- e. Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible Research Misconduct, and continue the Investigation to completion; and
- f. Otherwise comply with the requirements for conducting Investigations in 42 CFR Section 93.310.

C. Time Limit for Completing the Investigation

- 1. The Investigation Committee shall use its best efforts to complete the Investigation within 120 days. If the Committee is unable to complete the Investigation within 120 days, the Chair shall ask the Compliance Officer for an extension of time. An extension may require approval of the responsible federal agency. For example, in cases involving PHS-funded research, it is necessary to obtain ORI approval to extend the Investigation beyond 120 days. (See Code of Federal Regulations, Vol. 42, Sec. 93.311)

D. Investigation Report

- 1. The Investigation Report shall contain the same type of information as the Inquiry Report regarding the nature of the Allegations, sources of external support, Research Records, evidence reviewed, evidence taken into custody, but not reviewed, relevant Records and evidence not taken into custody and the explanation why. In addition, the Investigation Report shall provide, for each separate Allegation of Research Misconduct identified during the Investigation, a finding as to whether Research Misconduct did or did not occur, and if so:
 - a. Identify the person(s) responsible for the misconduct;
 - b. Identify whether the Research Misconduct was falsification, fabrication, or plagiarism, and whether it was intentional, knowing, or reckless;
 - c. Summarize the facts and the analysis which supports the conclusion and consider the merits of any reasonable explanation by the Respondent;
 - d. Identify the specific external support involved, if any;
 - e. Identify whether any publications need corrections or retraction; and
 - f. List any current support or known applications or proposals for support that the Respondent has pending with any federal agencies, regardless of their relationship to the misconduct.
- 2. The Respondent shall be provided with a draft of the Investigation Committee report and concurrently a copy of, or supervised access to, the evidence on which the report is based. The Respondent shall have 30 days (which time shall be part of the total time for the Investigation) to provide written comments on the Investigation report. The Committee shall, in preparing its final report, consider and attach any comments made by the Respondent on the draft Investigation report.

3. The Chair of the Investigation Committee shall forward copies of the final Investigation Report to the Compliance Officer and the Respondent. Following submission of the Investigation Report to the Compliance Officer and the Respondent, no additional evidence may be introduced into the record as a matter of course.

E. Appeal: Review by Compliance Office

1. Within 14 days of receipt of the Investigation Committee report, the Respondent may appeal in writing to the Compliance Officer solely on the following grounds:
 - a. That there has been a material failure to follow the procedures prescribed in this Policy and that the Respondent called the error to the attention of the Investigation Committee or had reasonable grounds for not doing so. The appeal must specify the nature of the procedural error and why the Respondent believes it is likely to have affected the outcome of the Investigation; or
 - b. That the Respondent has new and material evidence that was not reasonably available to the Respondent during the Investigation. The appeal must specify the nature of the new evidence, why it was not reasonably available during the Investigation, and why the Respondent believes it is likely to have affected the outcome of the Investigation.
2. If the Compliance Officer, on his or her own initiative or upon appeal by the Respondent, finds that (a) there was procedural error or the Respondent has new evidence that was not reasonably available during the Investigation, and (b) there is a substantial possibility that the error or new evidence may have affected the outcome of the Investigation, the Compliance Officer may refer the matter back to the Investigation Committee or to a new Investigation Committee appointed to reopen the case.
3. In addition to the review procedure under Section E.2, the Compliance Officer, in his or her discretion, may return the report to the Investigation Committee for further fact-finding or analysis or may appoint a new Investigation Committee to reevaluate the record and submit supplemental findings.
4. Any appeal must be completed within 120 days of the final Investigation determination.

F. Notification of Outside Parties

When the report has been accepted, the Compliance Officer shall provide ORI:

1. A copy of the Investigation report, all attachments, and any appeals
2. A statement of whether the institution found Research Misconduct and, if so, who committed it
3. A statement of whether the institution accepts the findings in the Investigation report
4. A description of any pending or completed administrative actions against the Respondent.
5. The Compliance Officer may, as appropriate, notify other external sponsors, law enforcement agencies, professional societies, professional licensing boards, journals, collaborators of the Respondent, or other parties with a legitimate need to know the outcome of the proceeding.

VI. ADMINISTRATIVE ACTION AS A RESULT OF INVESTIGATION

- A. If it is determined that Research Misconduct occurred, the Compliance Officer in consultation with other responsible St. Luke’s personnel, shall recommend the appropriate actions to be taken according to applicable St. Luke’s disciplinary procedures or medical staff bylaws. The recommended actions may include:
 1. Removal of the Respondent from the particular project.

- 2. Withdrawal or correction of all pending or published abstracts and papers emanating from the research where Research Misconduct was found.
 - 3. Restitution of funds as appropriate.
 - 4. Special monitoring of future work or appropriate steps of the St. Luke's Corrective Action Policy including termination from employment.
 - 5. Disciplinary action per St. Luke's Medical Staff Bylaws may be initiated.
- B. If it is determined that no Research Misconduct occurred, the Respondent shall meet with the Compliance Officer to discuss how the Respondent's record shall be cleared and what reasonable efforts will be taken to restore the Respondent's reputation. See Section II.C.

VII. OTHER CONSIDERATIONS

- A. Termination of Employment or Resignation Prior to Completion of Inquiry or Investigation
 - 1. If the Respondent, without admitting to misconduct, elects to resign his or her position after an Allegation of Research Misconduct has been received, proceedings under this Policy shall continue. If the Respondent refuses to participate in the process after resignation, the Inquiry Committee and/or Investigation Committee shall 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 review of the matter.

<u>RELATED DOCUMENTS:</u>	Appendix A: Research Misconduct Reporting Form Corrective Action and Fair Hearing Plan See C360 for Related Documents
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POLICY/PROCEDURES
AUTHORIZED BY:

Original signed by Joanne Clavelle, MS, RN, NE-BC, FACHE
Vice President, Patient Care Services/CNO

12/01/09
Date

SYSTEM POLICY
AUTHORIZED BY:

System Vice President, Nursing and Patient Care Services

Date

