Title:  SARMC Institutional Review Board:  Scientific Misconduct

Policy Statement:  It is the policy of the Saint Alphonsus Health System (“Saint Alphonsus”) to maintain high ethical standards in research involving human subjects and to investigate and resolve promptly and fairly all instances of alleged or apparent misconduct.  This policy sets forth the procedure for reporting and investigating alleged or suspected misconduct involving biomedical and behavioral research and/or use of investigative devices conducted at Saint Alphonsus.  This policy will be made available to anyone doing such research at Saint Alphonsus and to funding agencies, upon request, through Saint Alphonsus Research Integrity.

Purpose:


2. The purpose of this policy is to set forth the procedure for identifying, investigating and reporting alleged or apparent misconduct in research involving human subjects at Saint Alphonsus.

Definitions:

1. “Allegation” means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

2. “Conflict of interest” means the real or apparent interference of one person’s interests with the interests of another person or organization, where potential bias may occur in the investigation process due to prior or existing personal or professional relationships.

3. “Inquiry” means gathering initial information to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

4. “Investigation” means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person and the seriousness of the misconduct.
5. “Misconduct” or “Misconduct in Science” means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific and medical community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretation or judgment of data.

6. “ORI” means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

7. “PHS” means the U.S. Public Health Service, an operating component of the DHHS.

8. “PHS regulation” means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled “Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science.”

Procedure:

I. Reporting

A. All employees or individuals associated with Saint Alphonsus should report observed, suspected or apparent scientific misconduct to Saint Alphonsus Research Integrity (367-8897) and/or the Director of Research (367-2233). If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may contact Research Integrity and/or the Director of Research to discuss the incident informally. At any time, individuals may have confidential discussions or consultations about these concerns with the entities listed above. Saint Alphonsus will protect the privacy of those who report potential misconduct in good faith to the maximum extent possible.

B. Upon receiving an allegation of possible scientific misconduct, Research Integrity and/or the Director of Research will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry. If there is sufficient evidence and the individual reporting the potential misconduct has not already done so, a written, signed and dated statement must be submitted. The identity of the reporting individual will remain confidential, although if an investigation is launched following an inquiry, it may be necessary to reveal the identity of the reporting individual.

II. Inquiry Procedure

A. Inquiry Committee

The inquiry shall be conducted by the Chair of the Institutional Review Board (IRB), or if he or she is the subject of the alleged or apparent
misconduct, then by the President of the Medical Staff, who shall appoint an ad hoc committee consisting of two physicians with research backgrounds to ensure the necessary and appropriate expertise to carry out a thorough evaluation of the relevant evidence in any inquiry. Individuals appointed to this committee and/or involved in making judgments about the merit of the allegations must have no apparent or suspected professional or personal conflict of interest in the case.

B. Inquiry Process

Within five (5) working days of receipt of the allegation, Saint Alphonsus Research Integrity and/or the Director of Research will notify the respondent in writing that a complaint has been made and identify the process that will be used to resolve the complaint. When an inquiry is initiated, the respondent may be asked to testify and to provide materials or documentation as necessary to conduct the inquiry. Confidentiality will be maintained and access to documents or other information related to the complaint will be restricted to the members of the ad hoc committee.

C. Inquiry Report

The inquiry must be completed within sixty (60) calendar days of its initiation unless circumstances require a longer period. A written report shall be prepared by the ad hoc committee that states what evidence was reviewed, summarizes relevant interviews and includes the conclusions of the inquiry. If the inquiry takes longer than sixty (60) days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

The individual(s) against whom the allegation of misconduct is made shall be given a copy of the report of inquiry and be given fourteen (14) days to respond to the allegations in writing. These comments will be made part of the inquiry record. The reporting individual will also receive a copy of the results of the inquiry.

D. Confidentiality

The confidentiality and privacy of the person or persons who in good faith report apparent misconduct shall be maintained to the maximum extent possible during the inquiry.

Similarly, all information gathered during the inquiry shall be considered professional/peer review information and maintained confidentially to the maximum extent possible to protect the individual(s) against whom the allegation is made. As stated in sec. II-C, an opportunity to comment on allegations and findings of the inquiry will also be afforded. Upon
completion of the inquiry, the Chair of the IRB (or if he or she is the subject of the inquiry, then the President of the Medical Staff), shall determine if an investigation is required based upon evidence provided by the inquiry. If an investigation is warranted, the report shall also be given to the President of the Medical Staff and the CEO.

E. ORI Notification

If the inquiry involves a project funded directly or indirectly (i.e., funding through a subcontract or through another party receiving funding for the project) by the Public Health Service (PHS) and if an investigation is warranted, the Director of the Office of Research Integrity must be notified in writing by Saint Alphonsus Research Integrity on or before the date the investigation begins. The notification should include, at a minimum, the name of the person(s) against whom the allegations have been made, the general nature of the allegation, and the PHS application or grant number(s) involved.

The Office of Research Integrity (“ORI”) will be notified within 24 hours of obtaining any reasonable indication of possible criminal violations.

III. Investigation

If the ad hoc inquiry committee determines a formal investigation is warranted, an investigation will be undertaken within thirty (30) days of the completion of the inquiry.

A. Timeframe and Notification Requirements for all Investigations

Saint Alphonsus will prepare and maintain documentation to substantiate an investigation’s findings. When PHS funds are involved, this documentation will be made available to the Director of ORI.

Saint Alphonsus will keep the ORI apprised of any developments during the course of an investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

An investigation should be completed ordinarily within 120 days of its initiation. This includes conducting the investigation, preparing the report of findings, making that report available for comment by the subjects of the investigation, and submitting the report to the ORI when PHS funds are involved.

If Saint Alphonsus determines that it will not be able to complete the investigation in 120 days and if PHS funds are involved, it must submit
to the ORI a written request for an extension and an explanation for the delay that includes an interim report on the progress to date and an estimate for the date of completion of the report and other necessary steps. If the request is granted, Saint Alphonsus must file periodic progress reports as requested by the ORI. If satisfactory progress is not made in Saint Alphonsus’ investigation, the ORI may undertake an investigation of its own if PHS funds are involved.

B. Investigation Procedure for Medical Staff Member

The investigation of a medical staff member will be conducted pursuant to the procedures for investigation for such conduct under the Bylaws of the Medical Staff of Saint Alphonsus (the “Bylaws”) then in effect. At the conclusion of the investigation, if misconduct is substantiated, action will be taken pursuant to the Bylaws.

C. Investigation Procedure for Non-Medical Staff Member

The investigation of a non-medical staff member will be conducted by an ad hoc committee appointed by the Chair of the IRB and at least two non-medical staff members who would be considered peers, with appropriate expertise to carry out a thorough evaluation of the relevant evidence.

The investigation of a non-medical staff member should include examination of all documentation, including but not limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations. Complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigation documentation.

At the conclusion of the investigation, if misconduct is substantiated, a report will be forwarded to the Saint Alphonsus CEO for appropriate disciplinary action. If an allegation is found to be incorrect and that it was not made in good faith, disciplinary action consistent with Saint Alphonsus policy may result. If an allegation is found to be unsupported but to have been submitted in good faith, no further formal action will be undertaken.


If the investigation of the project required notification to the ORI, a final report will be sent to ORI by Saint Alphonsus Research Integrity including a description of any disciplinary action taken, the policies and
procedures under which the investigation was conducted, how and from whom information was obtained, the findings and the basis for the findings, and an accurate summary of the views of any individuals found to have engaged in misconduct.

IV Immediate Notification of ORI in Inquiry or Investigation.

The Director of the ORI must be notified within 24 hours by Saint Alphonsus Research Integrity, if Saint Alphonsus learns at any stage of the inquiry or investigation that any of the following conditions exist with respect to a project funded by the PHS:

A. There is an immediate health hazard involved.

B. There is an immediate need to protect federal funds or equipment.

C. 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 allegation as well as his/her co-investigator(s) and associate(s), if any.

D. It is probable that the alleged incident is going to be reported publicly.

E. There is reasonable indication of possible criminal violation; in this instance, ORI must be notified within 24 hours of obtaining the information.

V. General Provisions.

Saint Alphonsus will take interim administrative actions, as appropriate, in an attempt to protect Federal funds and ensure that the purpose of the Federal financial assistance is carried out.

Saint Alphonsus will undertake diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and also undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, made allegations.

VI. Termination of Inquiry and Investigation.

If a decision is made to terminate an inquiry or investigation for any reason without completing the inquiry or investigation, a report of the planned termination (including a description of the reasons for such termination) should be made to the Director of the ORI when Federal funds are involved.

VII. Retention of Documents.

All documentation of either the inquiry or the investigation shall be
maintained by Saint Alphonsus for not less than five (5) years.

**Related Policies:** Saint Alphonsus
Institutional Review Board: Conflict of Interest

**Related Forms:** None

**References:**


[http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm)