

MISCONDUCT IN RESEARCH

POLICY:

St. John Hospital and Medical Center ("SJH&MC") is committed to the furthering of biomedical research. The objective of this policy is to foster a research environment that discourages misconduct in all research, promote standards for the ethical, uncompromised and unbiased conduct of research, and to set forth procedures for forthrightly addressing possible misconduct associated with research. Although the occurrence of error is recognized as a part of the research process, research misconduct is never condoned. This document addresses and sets forth SJH&MC's policy to require high ethical standards in research; to inquire into and, if necessary, investigate and resolve promptly and fairly all instances of alleged misconduct; and to comply in a timely manner with applicable requirements for reporting on cases of possible misconduct when sponsored project funds are involved.

Since a charge of misconduct, even if unjustified, may damage an individual's career, any such issue must be handled in a prudent and confidential manner. An inquiry or investigation must be handled promptly and expeditiously with full attention given to the rights of all individuals involved. Protection of the rights and reputations of the Complainant, the Respondent and collaborators, SJH&MC and if applicable, the sponsoring agency, and the publisher will be a priority of the Inquiry Committee and/or Investigation Committee formed to address the allegation(s). This policy should be read in conjunction with, and is in addition to, the requirements of the SJH&MC Medical Staff bylaws, other institutional policies and applicable contractual obligations (for example, obligations imposed by NIH grants or contracts with government agencies).

SCOPE:

This policy applies to all persons involved in the design, proposal, conduct, documentation, review, supervision, reporting and/or regulation of research. Such persons include, but are not limited to physicians, research staff, fellows, residents, students, nurses, pharmacists, SJH&MC and other St. John Health associates, principle investigators, sub and co-investigators, and study coordinators.

SJH&MC internal standards are set forth to determine and address Research Misconduct and are intended to comply with the standards and regulations addressing research misconduct in Public Health Service ("PHS") supported and Federal Food & Drug Administration ("FDA") covered research. PHS agencies include, but are not limited to, the National Institutes of Health (NIH) and Centers for Disease Control and Prevention. This policy should be read in conjunction with other applicable SJH&MC and/or St. John Health policies and procedures. The Federal regulations and the Office of Research Integrity ("ORI") set forth information in detail for all phases of the processes necessary for determining if specific misconduct may have occurred and the steps to follow in an investigation. While SJH&MC policies addressing Research Misconduct comply with

Federal regulations, SJH&MC internal standards to determine misconduct may be more broad than the Federal regulations. For example, an action not meeting the requirements of misconduct set forth for PHS research may require action pursuant to applicable SJH&MC and/or other St. John Health policy.

SECTION 1 DEFINITIONS

A. Definitions

The following terms shall have the meanings ascribed below.

Allegation(s): A disclosure of possible Research Misconduct through any means of communication.

Complainant(s): The person or persons who make the Allegation(s) of Research Misconduct. Whistleblower is an alternate term. This person is protected from retaliation by Federal regulation and institution policy. The Allegation must be made with the honest belief that research misconduct may have occurred. This person may be called as a witness in any resulting proceedings.

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

Falsification: The manipulation of research results, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Inquiry: The preliminary process by which Allegations of Research Misconduct are evaluated to determine if sufficient information has been provided by the complainant(s) to warrant an investigation.

Inquiry Committee: A committee convened to conduct an inquiry of Allegation(s) deemed to meet the definition of Research Misconduct and with supporting evidence. The Inquiry Committee will consist of the Chair of the IRB (or his/her designee if unable to participate), the Chair of the Respondent's department, the Chief Medical Officer, SJH&MC's Clinical Safety Risk Manager, the Director of Research, the IRB Manager and other members as deemed necessary due to the nature of the Allegation and as necessary to complete the inquiry process. The Inquiry Committee will be chaired by the Director of Research and the Committee will follow the procedures set forth in the policy.

Investigation: The process and formal development of a factual record and the examination of that record leading to a decision not to make a finding of Research Misconduct or to a recommendation for a finding of Research Misconduct which may include a recommendation for other appropriate actions including administrative sanctions.

Investigation Committee: A committee convened to conduct an Investigation of an Allegation reviewed by the Inquiry Committee deemed to warrant Investigation.

Notice: A written communication, served in person, sent by mail or its equivalent to the last known address, facsimile number or e-mail address of the addressee.

Plagiarism: The appropriation of another individual's ideas, processes, records, results or words without giving appropriate credit to that individual.

Respondent(s): The person or persons who are alleged to have engaged in Research Misconduct or who is the subject of a Research Misconduct proceeding.

Research Misconduct: Research Misconduct will include one or more of the following:

(a) Fabrication, falsification, plagiarism, or other practices which seriously departs from those accepted within the research community in proposing, performing, or reviewing research or in reporting research results. The reporting of research results includes, but is limited to, works of authorship, reports, posters, ghost writing, editing, and making or creating presentations.

(b) For research conducted under an FDA marketing application (e.g. New Drug Applications, Investigational New Drug Applications, Investigational Device Exemptions, etc...) includes the falsification of data in proposing, designing, performing, recording, supervising or reviewing research or in reporting research results. Falsification includes acts of omission and commission.

(c) Deliberate or repeated noncompliance with applicable Federal and /or State laws and regulations.

(d) Deliberate, repeated or grossly negligent acts or omissions that place the safety and welfare of human subject participants in jeopardy.

Honest error, or honest differences in interpretations or judgments of data are not included in the definition of Research Misconduct, however knowing, intentional and reckless acts, along with continued or habitual negligence are included in the definition.

SECTION 2 PROCESS OVERVIEW

A. Compliance with Law

In all phases of Research Misconduct review (Allegation, Inquiry, Investigation) applicable Federal and State law will be followed. Applicable laws may include, but are not limited to:

- a) Public Health Service Act, 42 USC 289b

- b) Whistleblower Protection Provision, 42 CFR 50.103 (d)(13)
- c) Public policy
- d) 42 CFR Part 93
- e) 42 CFR Part 50

B. Steps Outlined

Research Misconduct will be addressed via the steps and processes set forth in this policy. The steps and Allegation response are as follows:

- Receipt of an Allegation
- Preliminary assessment of the Allegation
- Conduct of the Inquiry
- Conduct of the Investigation
- Institutional decision
- Reports and Notifications
- Administrative Actions/Sanctions
- ? Appeals

**SECTION 3
ALLEGATION**

A. Submission

Allegations, with the Complainant identified if the Complainant chooses to make his or her identity to be known, should be submitted to one of the following:

- ? Director of Biomedical Investigations and Research (hereinafter referred to as the "Director")
- Chair of the IRB,
- Clinical Safety Risk Manager,
- SJH Values Line or Corporate Responsibility Department,
- IRB Manager, or
- Chief Medical Officer

Allegations of Research Misconduct should be submitted to one of the above-cited individuals within a reasonable amount of time from the date of the alleged misconduct (i.e. within an amount of time that will allow for evidence to be available for the conduct of a reasonable Inquiry and/or Investigation). The identity of the Complainant, if known, will be treated in a confidential manner and be disclosed to only those individuals with a need to know, consistent with a fair, thorough, competent and objective Research Misconduct proceeding. If the Allegation is submitted to one of the above-cited individuals, it should be forwarded to the Director within one (1) business day. Upon receipt of the Allegation, the Director will notify the Chief Medical Officer (hereinafter referred to as the "CMO") and St. John Health Corporate Legal Services.

B. Allegation Content

Submitted Allegations should contain the following information:

- (i) Name of the Respondent(s)
- (ii) Name of the Complainant(s) (if given by Complainant)
- (iii) Names of any witnesses
- (iv) Description of the alleged Research Misconduct
- (v) When and where the alleged misconduct occurred
- (vi) Supporting documentation, if any
- (vii) The title or the study or research identity or grant/grantor identity
- (viii) The funding source

An Allegation should, in addition to stating the nature of the suspected misconduct and the elements noted above, present the evidence that supports the Complainant's belief that an incident of Research Misconduct has occurred.

C. Review of Allegations

Once an Allegation is received, a meeting or phone conference must occur between at least the Director, the Chair of the IRB, the Clinical Safety Risk Manager, and the IRB Manager. The meeting must occur promptly with all expediency but no later than within ten (10) days of receipt of the Allegation, absent extenuating circumstances. During the meeting the parties must review and assess the Allegation to determine if the Allegation constitutes a *bona fide* Allegation of Research Misconduct (i.e., a determination of whether the alleged incident(s) fit the definition of Research Misconduct as defined in this policy and whether the evidence presented is sufficiently credible and specific so that potential evidence of Research Misconduct may be identified). If it is concluded that a *bona fide* Allegation of Research Misconduct has been made, the misconduct procedure promptly enters its inquiry phase. If it is concluded that no *bona fide* Allegation of Research Misconduct has been made, and that an Inquiry will not be undertaken, the Complainant, if known, will receive Notice in writing of this decision, and the basis for the decision within seven (7) days of such decision.

If it is determined that an Allegation falls within the definition of Research Misconduct, the Director must ensure that all original research records and materials relevant to the Allegation are immediately secured and sequestered as appropriate and will convene an Inquiry Committee.

D. PHS and Government Supported Research

If the Allegation falls within the definition of Research Misconduct, a determination must be made as to whether the research also falls within the purview of the PHS (i.e. within PHS jurisdiction) or is otherwise research supported by funding from a Federal or State government agency or source (hereinafter collectively referred to as "PHS"). In order for the Allegation to fall within PHS jurisdiction it must:

- 1) Involve a suspicion/suggestion of Research Misconduct involving:

- (i) Applications or proposals for PHS support for biomedical or behavioral extramural or intramural research, research training or activities related to that research or research training, such as the operation of tissue and data banks and the dissemination of research information;
 - (ii) PHS supported biomedical or behavioral extramural or intramural research;
 - (iii) PHS supported biomedical or behavioral extramural or intramural research training programs;
 - (iv) PHS supported extramural or intramural activities that are related to biomedical or behavioral research or research training, such as the operation of tissue and data banks or the dissemination of research information; and
 - (v) Plagiarism of research records produced in the course of PHS supported research, research training or activities related to that research or research training.
- 2) Meet the definition in PHS regulation (42 CFR 50 subpart A and 42 CFR Part 93) or meets other applicable laws or regulations, and
- 3) Contain sufficient information to proceed with an Inquiry.

If the research falls within PHS jurisdiction, the ORI and PHS may need to be notified of the Allegation if an Investigation is deemed warranted by the Inquiry Committee as set forth in Section 4(D) of this policy.

SECTION 4 INQUIRY

A. Purpose

The purpose of an Inquiry is to determine whether an Allegation or apparent instance of Research Misconduct warrants a full Investigation or requires that special actions be taken pending resolution of the Allegation or apparent misconduct. The Inquiry will be conducted by the convened Inquiry Committee. The Inquiry Committee will determine whether the Allegation of misconduct appears to be well founded, the seriousness of the alleged misconduct, scope of the alleged incident, and relevance of any other information that is available. The purpose of the Inquiry is not to reach a final conclusion as to whether misconduct occurred or who was responsible but to initially review the nature and extent of any evidence or information pertaining to the Allegation to determine whether to conduct an Investigation. An Inquiry should be completed within sixty (60) calendar days after an Allegation is received.

To the extent possible, Inquiries and resultant Investigations will be conducted in a confidential manner so as to protect the affected parties.

B. Inquiry Committee

The Inquiry Committee will consist of the Chair of the IRB, the Chair of the Respondent's department, Chief Medical Officer, Clinical Safety Risk Manager, Director of Research (hereinafter referred to as the "Director"), IRB Manager and other members as deemed necessary to complete the inquiry process. In responding to an Allegation and during the Inquiry, the Inquiry Committee members and experts selected should be free from bias and have no real or apparent conflicts of interest either with any of the parties involved or the subject matter.

At the time of or before beginning the Inquiry, the Respondent must receive Notice of the Inquiry. The Notice must include: (i) that an Inquiry is being undertaken; (ii) of the procedure that will be followed; (iii) of the membership of the Inquiry Committee; and (iv) of the nature of the misconduct Allegation(s). A copy of the Notice should be retained by the Research Office. The Complainant, if known, may be given Notice that an Inquiry will be conducted.

The Inquiry Committee will, on or before Notice is given to Respondent, take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the Inquiry and any subsequent Investigation, inventory the records and evidence, and sequester them in a secure manner, except where the research records or evidence encompass instruments shared by numerous users, custody may be limited to copies of the data or evidence of such instruments if the copies are substantially equivalent to the data or evidence on such instruments.

The Respondent should be given forty-eight hours to challenge, in writing, the Committee's membership based on bias or conflict of interest. The Director will determine whether to replace the challenged member(s) with a qualified substitute(s). If the Director's participation is challenged, the Inquiry Committee will decide whether a true conflict on interests exists and whether to replace the Director with a new member. Nevertheless, the Inquiry Committee may convene prior during the forty-eight hour conflict notice period if patient safety could be impacted. In this instance, the Inquiry Committee will then take account of the Respondent's concerns raised in writing, if any. The Complainant may also be given an opportunity to challenge the Inquiry Committee membership.

C. Process

The Inquiry Committee may interview the Complainant(s), the Respondent, and key witnesses and should examine all relevant research records and materials. Then the Inquiry Committee will evaluate the evidence and testimony obtained during the Inquiry. Respondents who are non-responsive or uncooperative with the Inquiry Committee, and who do not cure such actions within one (1) day upon notice from the Inquiry Committee, may be subject to immediate administrative actions and/or sanctions in accordance with applicable policy. The Inquiry Committee members will decide whether there is sufficient evidence of possible Research Misconduct to recommend further investigation.

The Inquiry Committee will prepare a written report that states the name and title of the Committee members and experts, if any; the Allegation(s); the research support

(including any federal funding); 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 or not; 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.

Upon completion of the Inquiry, the Respondent will be provided with a copy of the draft inquiry report for comment and rebuttal. The Complainant may also be notified in writing of the decision and may be provided relevant portions of the Inquiry report for comment. The Complainant and Respondent will have 14 calendar days from their receipt of the draft report to provide their comments, if any, to the Inquiry Committee. Any submitted comments will become part of the final Inquiry report and record. Based on the comments, the Inquiry Committee may revise the report as appropriate.

A final Inquiry report must be generated within 60 calendar days from receipt of the Allegation. The Inquiry Committee may recommend:

1. *That an Investigation not be conducted due to the Allegation(s) being without merit; or*
2. *That an Investigation be conducted as the Allegation(s) merit such action.*

If the Allegation(s) do not merit an Investigation of Research Misconduct, the Respondent will receive a copy of the report and both the Respondent and Complainant will be notified in writing of the decision.

If the Allegation(s) merit an Investigation, the Respondent must receive Notice of the finding (prior to the commencement of an Investigation) and the Notice will contain a copy of the Inquiry report. The Inquiry Committee will also determine if notification of other appropriate or other entity committees is necessary and recommend any such notification to the Director. Where warranted, based on the Inquiry report, the appropriate committee will be asked by the Director to take any necessary action according to institutional policy to protect the health and safety of research subjects or patients.

All pertinent facts considered by and actions recommended by the Inquiry Committee will be sufficiently documented and evidence will be secured and retained for at least seven (7) years after the termination of the Inquiry by the Research Office, or, seven (7) years from the completion of any subsequent inquiry into the Research Misconduct initiated by PHS, ORI or DHHS, including the final disposition of any hearings or appeals requested by Respondent, whichever is later. This information will only be accessible to the individuals authorized by the Director.

A copy of the Inquiry report will be forwarded to the CMO, to Risk Management, and to the St. John Health Corporate Legal Services.

D. Federally Funded Research

For research involving Federal funds (i.e. PHS supported research), the decision to initiate an Investigation must be reported in writing by the Director, to the ORI within thirty (30) days of finding that an Investigation is warranted. At a minimum, the notification should include the name and position of the person(s) against whom the Allegations have been made, the general nature of the Allegation as it relates to the PHS definition of Research Misconduct, the PHS applications or grant number(s) involved, the basis for recommending an Investigation, and any comments on the inquiry report submitted by Respondent and Complainant. The ORI must also be notified of the final outcome of the Investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to the ORI.

If the Inquiry or Investigation is terminated for any reason without completing all relevant requirements of the PHS regulation (i.e. without completing the Inquiry or Investigation), the Director must submit a report of the planned termination to the ORI, including a description of the reasons for the proposed termination.

When the case involves PHS funds, SJH&MC cannot accept an admission of Research Misconduct as a basis for closing a case or not undertaking an Investigation without prior approval from the ORI.

The Director must notify the ORI at any stage of the Inquiry or Investigation if:

- (i) The health or safety of the public is at risk, including the need to protect human subjects or animals or if there is an immediate health hazard involved
- (ii) There is an immediate need to protect Federal funds or equipment
- (iii) There is an immediate need to protect the interests of the person(s) making the Allegations or of the individual(s) who are the subject of the Allegations as well as his/her co-investigators and associates, if any
- (iv) It is probable that the alleged incident is going to be reported publicly;
- (v) The Allegation involves a public health sensitive issue, *e.g.*, a clinical trial
- (vi) There is a reasonable indication of possible criminal violation (SJH&MC must inform the ORI within 24 hours of obtaining that information); or
- (vii) Research activities should be suspended.

SJH&MC will take appropriate interim administrative actions to protect Federal funds and insure that the purpose of the Federal financial assistance is carried out.

SECTION 5 INVESTIGATION

During all phases of the Investigation, the Respondent should be treated in a confidential manner, have the opportunity to comment on Allegations and findings, be provided a prompt and thorough Investigation, and be given a copy of the Inquiry report for comment.

A. Purpose

The purpose of the Investigation is to explore in detail, and validate the Allegations, to examine the evidence in depth, and to determine specifically whether Research 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 or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the Investigation will be set forth in an Investigation report.

B. Procedure

The Respondent will be given Notice of the Investigation before the Investigation commences. The Notice must include any new Allegation(s) of Research Misconduct. A copy of the Notice will be retained by the Research Office. The Director will immediately sequester any additional pertinent research records that were not previously sequestered during the Inquiry. This sequestration should occur before or at the time the Respondent is notified that an Investigation has begun. If Respondent refuses to surrender records in his or her possession, administrative actions or sanctioning may be imposed in accordance with SJH&MC and/or other St. John Health policies and procedures. The destruction, absence of, or Respondent's failure to provide research records adequately documenting the questioned research is evidence of Research Misconduct where it is demonstrated, by a preponderance of the evidence, that the Respondent intentionally, knowingly, or recklessly had research records and destroyed them, had the opportunity to maintain the records but did not do so, or maintained the records and failed to produce them in a timely manner (i.e. within the time frame requested by the Investigation Committee or its designee) and that Respondent's conduct constitutes a departure from accepted practices of the relevant research community. The need for additional sequestration of records may occur for any number of reasons, including the decision to investigate additional Allegation(s) 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.

The Director, in consultation with members of the Inquiry Committee will convene and appoint an Investigation Committee and the Committee chair within 10 calendar days of the of the determination that an Investigation is warranted or as soon thereafter as practicable. The Investigation Committee should consist of individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the Allegation(s), interview the principals and key witnesses, and conduct the Investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons. Individuals appointed to the Investigation Committee may also have served on the Inquiry Committee. The Investigation Committee members may include, but not be limited to:

The Chair of the IRB (or his/her designee if unable to participate)
A representative from Risk Management
A representative of the Medical Staff
The IRB Manager, and
Others as necessary to review the information.

The Director will notify the Respondent of the proposed Investigation Committee membership within 10 calendar days of commencing the Investigation. If the Respondent submits a written objection to any appointed member of the Investigation Committee or expert within 48 hours after receiving notice of Investigation Committee membership, the Director will determine whether to replace the challenged member or expert with a qualified substitute, and the Respondent will be notified of the Director's decision in writing.

The Investigation must be prompt, thorough and equitable. The Investigation Committee will initiate the Investigation within thirty (30) calendar days of the completion of the Inquiry report to determine whether Research Misconduct has been committed. The Complainant and Respondent will be notified and all involved parties are obligated to cooperate. All aspects of the Investigation (including the Investigation itself, the preparation of the draft Investigation report, review and comment of the draft report by Respondent, and submission of the final report to the ORI) should be completed within one hundred twenty (120) calendar days.

If the Director has reason to believe that the Investigation Committee will not be able to complete the Investigation in 120 days, the Director must submit to the ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Director must file periodic progress reports as requested by the ORI. An interim report will be required.

Minutes of all meetings of the Investigation Committee will be taken and stored by the Research Office. The Research Office will maintain sufficient documentation of the Investigation, including documentation of evidence review and findings. All evidence will be reviewed, secured and accessed only by those individuals designated by the Director. A permanent record of Investigation and Inquiry Committee reports, exhibits, minutes of meetings, and other materials will be kept by the Director. These records will be protected from release if release would compromise the conduct of an Investigation, constitute unwarranted invasion of privacy, or reveal the content of communications or recommendations of action to be taken. In the case of sponsored projects, the Director is responsible for determining and complying with reporting requirements, representing SJH&MC in all negotiations with the sponsor, and implementing any administrative actions that may be directed by the sponsor pursuant to contract or other arrangement.

The Investigation will include examination of all documentation including, but not limited to, review of grant or contract files, research records, computer files, proposals, reports, scholarly publications, manuscripts, correspondence, telephone calls, and other documents; inspection of laboratory or clinical facilities and/or materials; interviewing of

parties with an involvement in, or knowledge about, the case; and submission of a formal report of Committee findings, including response of the subject of the Allegation.

C. Reports

The Respondent will be given a copy of the Allegation, the report of the Inquiry Committee, and the scope of the Investigation of the Investigation Committee. The Respondent also will be kept informed by the Investigation Committee of the progress of the Investigation and will be given the opportunity to respond to the Allegation orally and in writing and to provide information for consideration by the Committee.

The Investigation Committee will focus on matters limited to the Allegation, but may review previous research efforts of the affected personnel or records of previous complaints of Research Misconduct, if germane to the Investigation. If, during its Investigation, the Investigation Committee discovers additional information giving rise to additional suspected misconduct of any kind, the Investigation Committee, if warranted, may notify the appropriate individuals within SJH&MC and other applicable entities as well as any State, local or Federal authorities, as appropriate. Respondent will receive Notice in writing of any new Allegation(s).

The Investigation Committee must within fifteen (15) days of completing its Investigation, prepare a draft and final report. The report must:

- (i) Describe the nature of the Allegation(s);
- (ii) Describe and document any funding or support, including any PHS funding;
- (iii) Describe the specific Allegation of Research Misconduct for consideration in the Investigation;
- (iv) Describe the policies and procedures under which the Investigation was conducted;
- (v) Identify and summarize the research records and evidence reviewed, and identify any evidence that was sequestered but not reviewed;
- (vi) For each separate Allegation, provide a finding as to whether the Research Misconduct did or did not occur and if so:
 - (a) identify the type of Research Misconduct (e.g. plagiarism, fabrication, etc...) and state if it was intentionally, knowing, reckless or grossly negligent;
 - (b) summarize the facts and analysis which support the conclusion and consider the merits of any reasonable explanation given by Respondent,
 - (c) identify specific funding and support,
 - (d) identify whether any publications need correction or redaction, and
 - (e) identify the person(s) responsible for the Research Misconduct; and
- (vii) Include and consider any comments made by the Respondent and Complainant on the draft investigation report.

The report will also include the actual text or an accurate summary of the views of any individual(s) found to have engaged in Research Misconduct as well as a description of any recommended sanctions and/or administrative actions to be taken by SJH&MC and/or applicable St. John Health entity. The Research Office will maintain and provide

the ORI, upon request, all relevant research records and records of the Investigation proceedings, including the results of any interviews and the transcripts and/or recordings of such interviews.

The Director will provide the Respondent with a copy of the draft investigation report for comment and rebuttal, and provide Respondent, concurrently with the draft report, supervised access to the evidence upon which the draft report is based. The Respondent will be allowed a maximum of 30 days to review and comment on the draft report. The Respondent's comments will be attached to the final report. The findings of the final report should take into account the Respondent's comments in addition to all the other evidence. The Director may provide the Complainant, if he or she is identifiable, with those portions of the draft investigation report that address the Complainant's role and opinions in the Investigation. The Complainant will be instructed that any comments on the draft Investigation Report must be returned to the Director within thirty (30) calendar days of the date the Complainant received the draft or portions of the draft report. The report may be modified, as appropriate, based on the Complainant's comments. The Complainant's comments will be attached to the final report.

In distributing the draft report, or portions thereof, to the Respondent and Complainant the Director will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality.

D. Institutional Review and Decision

The final report of the Investigation Committee will be sent to the Director and CMO, along with any minority reports (i.e. reports from Investigation Committee members who are in disagreement with the findings of the final report) and responses by the Respondent and/or Complainant. The CMO, in consultation with the Director, will assess the validity of the Allegation(s), review the report and provide final disposition. Based on a preponderance of the evidence, the CMO will make the final determination whether to accept the Investigation report, its findings, and the recommended institutional actions. The CMO may return the report to the Investigation Committee with a request for further fact-finding or analysis. The CMO's determination, together with the Investigation Committee's report, constitutes the final Investigation report.

If the CMO finds that the Respondent has not engaged in Research Misconduct, the CMO will dismiss the Allegation and notify the Respondent and Complainant, in writing, of the decision within ten (10) days. If the CMO finds that the Respondent has engaged in Research Misconduct, he/she may initiate procedures leading to possible sanctions. The CMO will inform the Respondent, the Complainant, the Director, and Respondent's departmental chair of his/her decision.

**SECTION 6
REPORTS AND NOTIFICATIONS**

A. PHS and ORI Notification

If the alleged misconduct falls under the purview of the PHS, the final Investigation report must be submitted to the ORI. The ORI must be given all of the following: the Investigation report, the final action taken, the findings of the Investigation, and any actions taken as a result of the Investigation. The names of all participants involved in an Inquiry and Investigation must be included in the report forwarded to the ORI.

If the Allegation involves PHS supported research, and if the CMO's determination varies from that of the Investigation Committee, the CMO will explain in detail the basis for rendering a decision different from that of the Investigation Committee in SJH&MC's letter transmitting the report to the ORI. The CMO's explanation should be consistent with the PHS definition of Research Misconduct, SJH&MC's policies and procedures, and the evidence reviewed and analyzed by the Investigation Committee.

B. General Reporting

The CMO 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 Investigation. The CMO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies and/or entities.

As it relates to regulatory reporting requirements, the affected individuals should be afforded confidential treatment to the maximum extent possible (42 CFR 50.103 (d)(3)).

SECTION 7 ADMINISTRATIVE ACTIONS/SANCTIONS

A. Sanctions Against the Respondent

SJH&MC and applicable St. John Health entities will take appropriate administrative actions and/or impose sanctions against individuals when an Allegation of Research Misconduct has been substantiated. If the CMO determines that the alleged Research Misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Director, Investigation Committee and other individuals as appropriate and necessary. The actions taken, which will take into account the seriousness of the misconduct, may include:

- (i) Correction of the research record;
- (ii) Temporary or permanent prohibition of future involvement in research performed at SJH&MC or its affiliates;
- (iii) Closure of any current studies, while protecting the rights and welfare of enrolled subjects;
- (iv) Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
- (v) Removal of the Respondent 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;
- (vi) Restitution of funds as appropriate; and/or
- (vii) Other action as may be recommended by the Investigation Committee.

The suspension or termination of any clinical research will be reported to applicable and appropriate government agencies, if any, as may be required by law and/or applicable policy.

B. Actions Against the Complainant

If relevant, the CMO 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 CMO, in collaboration with Work Life Services for St. John Health entity associates, will determine whether any administrative action should be taken against the Complainant.

C. Preventative Actions

SJH&MC and St. John Health entity officials, in consultation with the CMO and the Director, will take interim administrative actions, as appropriate and applicable, to protect any grant funds, State, local, private, Federal or Hospital funds and ensure that the purposes of the Federal financial assistance are carried out. SJH&MC officials, in consultation with the CMO, the Director and the Chair of the IRB may require that any research currently being conducted by the Respondent be suspended or terminated, as warranted by the nature and/or severity of the Allegation, until final completion of the Inquiry and Investigation (if an Investigation is conducted).

SECTION 8 MISCELLANEOUS

A. Respondent Termination/Resignation

The termination of the Respondent's employment at SJH&MC or other applicable entity, by resignation or otherwise, before or after an Allegation of possible Research Misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the Respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an Inquiry, but after an Allegation has been reported, or during an Inquiry or Investigation, the Inquiry or Investigation will proceed. If the Respondent refuses to participate in the process after resignation, the Inquiry 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.

B. Restoration of Respondent

If the CMO, based on the Investigation Committee's report, determines that there has been no Research Misconduct and the ORI concurs (when PHS funding is involved), after consulting with the Respondent, the Director will undertake reasonable efforts to restore the Respondent's reputation. Depending on the particular circumstances, the Director should consider notifying those individuals aware of or involved in the Investigation of the final outcome, publicizing the final outcome in forums in which the allegation of Research Misconduct was previously publicized, or expunging all reference to the Research Misconduct allegation from the Respondent's personnel file or other file similar in nature. Any action(s) taken by the Director to restore the Respondent's reputation must first be approved by the CMO.

C. Protection of Complainant

Regardless of whether the CMO or the ORI determines that Research Misconduct occurred, the Director will undertake reasonable efforts to protect Complainants who made Allegations of Research Misconduct in good faith and others who cooperate in good faith with Inquiries and Investigations of such Allegations. Upon completion of an Investigation, the Director will determine, after consulting with the Complainant, what steps, if any, are needed to restore the position or reputation of the Complainant. The Director is responsible for implementing any such steps. The Director will also take appropriate steps during the Inquiry and Investigation to prevent any retaliation against the Complainant. All such actions taken by the Director must receive approval from the CMO.

D. Record Retention

After completion of a case and all ensuing related actions, the Director will prepare a complete file, including the Allegation, records of any Inquiry or Investigation and copies

of all documents and other materials furnished to the Director, CMO or committees. The Director will keep the file for seven (7) years after completion of the case to permit later assessment of the case. The ORI or other authorized DHHS personnel will be given access to the records upon request when PHS funding is involved.

E. Policy Review

This Misconduct in Research Policy will be reviewed annually by the SJH&MC Research Director, and other SJH&MC personnel as appropriate, to determine if the policy requires revision to comply with laws, regulations or SJH&MC policies and procedures. If so, a sub-committee may be appointed to make recommendations for revisions.

F. Each individual conducting research at SJH&MC or an entity utilizing SJH&MC IRB services and serving in the capacity of a principle investigator, Co-PI, or Sub-PI must agree to sign a statement acknowledging SJH&MC's Misconduct in Research Policy and releasing SJH&MC from any and all liability associated with any and all Inquiries, Investigations and/or actions taken pursuant to the policy.