Christian Medical College

Vellore 632002

Tamil Nadu

Institutional Review Board

(Research and Ethics Committees)

October 2007

Standard Operating Procedures for the Office of Research Integrity

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Preamble

Integrity in research is essential so that scarce resources are not wasted, people are not given ineffective or unsafe treatments and public trust in research is not compromised. The Christian Medical College at Vellore, Tamil Nadu, India, reaffirms its commitment to the responsible conduct of research and has a number of initiatives to facilitate this. These initiatives include training researchers in research methodology, research and publishing ethics, Good Clinical Practice (GCP) Guidelines, grant writing and manuscript writing; ensuring proper scientific and ethical review of study proposals, protocols and informed consent documents; ensuring prospective registration of clinical trials; monitoring ongoing research through receipt and review of protocol amendments, adverse events reporting, progress and final reports, and audit of research, if deemed necessary. Standard operating procedures and policies for research, and the composition and policies for the Institutional Review Board are periodically revised in accordance with guidelines from the Indian Council of Medical research and regulatory authorities such as the Drug Control General of India. These procedures and relevant guidelines are made available to all institutional members on the institution's research website.

In addition, the **Office of Research Integrity** has been established to improve the oversight of research in the institution. The scope, policies and procedures of this office have been adapted from those recommended by the Office of Research Integrity, US Department of Health and Human Services (http://ori.dhhs.gov/policies/ori_policies.shtml), in the absence of relevant guidance from Indian facilitatory or regulatory agencies.

The Office of Research Integrity

The Office of Research Integrity was set up in the Office of Research by a senatus resolution (Senatus Minute no 2478(c) and dated 9th April 2007). The Additional Vice-Principal (Research) will be responsible for its functioning and is designated as the Research Integrity Officer (ROI). The ROI will report to the Principal (primarily) and to the Director (and the Medical Superintendant when deemed necessary) of CMC Vellore.

The senatus in its resolution also approved the setting up of a committee to assist the Additional Vice-Principal in his role as the Research Integrity Officer

(RIO). The committee members were chosen for a three year term and currently comprise Dr. Ramakrishna, Professor, Department of GI Sciences, Dr. George Mathew, Professor, Department of Surgery, Dr. Vinohar Balraj, Professor, Department of Community Health, and Dr. Priya Abraham, Professor, Department of Virology, CMC Vellore.

The recommendation of the Senatus was approved by the Principal and Director in writing to the Additional Vice-Principal (Research) on September 29, 2007. The senatus recommendation and the Draft Standard Operating Procedures were approved by the institution's Administrative Committee (110-a: 10-07 dated 25.10.2007**)** and will be presented to the Council for ratification in January 2008.

Scope:

This statement of policy and procedures is intended to describe and help carry out this institution's responsibilities in all matters pertaining to the integrity of Research conducted in CMC, irrespective of the source of funding. These policies also satisfy guidance and procedures for all research conducted in CMC that is funded by the US Public Health Service under the US Public Health Service (PHS) Policies on Research Misconduct, 42 CFR Part 93.

The scope of these policies applies only to allegations of research misconduct that occurred within ten years of the date the institution received the allegation.

Definitions:

The role of the Office of Research Integrity is to ensure the integrity of all research conducted in CMC. It is primarily concerned about Research Misconduct.

Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) **Fabrication** is the willful making up data or results and recording or reporting them.

(b) **Falsification** is the willful manipulation of research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research report.

(c) **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

(e) Disputes about authorship do not normally come under the scope of research misconduct. In some instances, failure to include a researcher, who contributed significantly to the research, as an author or to acknowledge his/her contribution could amount to plagiarism.

(f) Matters pertaining primarily to the scientific validity and ethical conduct of research will ordinarily fall under the purview of the Institutional Review Board (IRB), unless they pertain to research misconduct. The ORI will work in conjunction with the IRB in such instances.

(g) Allegations of research misconduct will entertained against a person who, at the time of the alleged research misconduct, was employed by, was an agent of, or was affiliated by contract or agreement with this institution.

Research Integrity Officer

The Research Integrity Officer (RIO) will ordinarily be the Additional Vice-Principal (Research), unless the Senatus or institution's administration decides to appoint another person to assume this role.

Deciding Officer

Deciding Official (DO) means the institutional official who makes final determinations on allegations of research misconduct and recommends to the Director of CMC any institutional administrative actions. The Deciding Official will not be the same individual as the Research Integrity Officer and should have no direct prior involvement in the institution's inquiry, investigation, or allegation assessment. A DO's appointment of an individual to assess allegations of research misconduct, or to serve on an inquiry or investigation committee, is not considered to be direct prior involvement.

The Deciding Officer will normally by the Principal of CMC, Vellore.

Inquiry and investigative committee

The RIO will be assisted by a standing committee consisting of four (or more if deemed necessary) members selected by the Senatus of CMC Vellore. These

core committee members will serve a three year term that can be extended; only half the committee may be replaced at the end of the term to ensure continuity. The core members should be well versed in research ethics and should be senior people, not less than the rank of Professor. The committee may be assisted by additional experts, as deemed necessary.

The General Policies and Principles follow (pages 4-16); Appendix I (Pages 17-23) detail the roles and responsibilities of the RIO; Appendix II (Page 24) provides the responsibilities of the core investigation committee members; Appendix III (Page 25) provides the responsibilities of experts and additional committee members

General Policies and Principles

A. Responsibility to Report Misconduct

All institutional members will report observed, suspected, or apparent research misconduct to the RIO. If an individual is unsure whether a suspected incident falls within the definition of research misconduct, he or she may meet with or contact the RIO at the Office of the Additional Vice-Principal (Research), Carman Block, CMC Campus, Bagayam, to discuss the suspected research misconduct informally, which may include discussing it anonymously and/or hypothetically.

If the circumstances described by the individual do not meet the definition of research misconduct, the RIO will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, an institutional member may have confidential discussions and consultations about concerns of possible misconduct with the RIO (Additional Vice-Principal (Research)), the Secretary of the IRB, the Principal, any of the Vice-Principals, the Director or the Medical Superintendant, and will be counselled about appropriate procedures for reporting allegations.

B. Cooperation with Research Misconduct Proceedings

Institutional members will cooperate with the RIO and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Institutional members, including respondents, have an

obligation to provide evidence relevant to research misconduct allegations to the RIO or other institutional officials.

C. Confidentiality

The RIO shall be required to: (1) limit disclosure of the identity of respondents and complainants to those who need to know in order to carry out a thorough, competent, objective and fair research misconduct proceeding; and (2) except as otherwise prescribed by law, limit the disclosure of any records or evidence from which research subjects might be identified to those who need to know in order to carry out a research misconduct proceeding.

The RIO should use written confidentiality agreements or other mechanisms to ensure that the recipient does not make any further disclosure of identifying information The RIO will indicate to the committee those witnesses for whom confidentiality must be maintained when the circumstances indicate that the witnesses may be harassed or otherwise need protection.

D. Protecting complainants, witnesses, and committee members

Institutional members may not retaliate in any way against complainants, witnesses, or committee members. Institutional members should immediately report any alleged or apparent retaliation against complainants, witnesses or committee members to the RIO or the Principal, Medical Superintendant or Director, who shall review the matter and, as necessary, make all reasonable and practical efforts to counter any potential or actual retaliation and protect and restore the position and reputation of the person against whom the retaliation is directed.

E. Protecting the Respondent

As requested and as appropriate, the RIO and other institutional officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

During the research misconduct proceeding, the RIO is responsible for ensuring that respondents receive copies of all the policies and procedures of the institution.

Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a witness or otherwise involved in the case) to seek advice. Respondents may not ordinarily bring lawyers or personal advisers to interviews or meetings on the case. In special circumstances this may be

permitted after prior approval from the Principal, but even in such instances, the lawyer or advisors role shall be restricted to advising, rather than representing, the respondent.

F. Interim Administrative Actions and Notifying Administrators of Special Circumstances

Throughout the research misconduct proceeding, the RIO will review the situation to determine if there is any threat of harm to public health, research funds and equipment, or the integrity of the institutionally approved research process. In the event of such a threat, the RIO will, in consultation with the Principal and other administrative officials, take appropriate interim action to protect against any such threat.

Interim action might include additional monitoring of the research process and the handling of funds and equipment, reassignment of personnel or of the responsibility for the handling of funds and equipment, additional review of research data and results or delaying publication.

The RIO shall, at any time during a research misconduct proceeding, notify the Principal immediately if he/she has reason to believe that any of the following conditions exist:

1) Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
2) Institutional resources or interests are threatened;
3) Research activities should be suspended;
4) There is a reasonable indication of possible violations of civil or criminal law;
5) Legal action is required to protect the interests of those involved in the research misconduct proceeding;
6) The research misconduct proceeding may be made public prematurely and legal action may be necessary to safeguard evidence and protect the rights of those involved; or
7) The research community or public should be informed.

V. Conducting the Assessment and Inquiry

A. Assessment of Allegations

Upon receiving a ***written, signed and dated*** allegation of research misconduct, the RIO will immediately assess the allegation to determine whether it is sufficiently credible and specific so that potential evidence of research misconduct may be identified, and whether the allegation falls

within the definition of research misconduct. An inquiry must be conducted if these criteria are met.

The assessment period will be brief, preferably concluded within a week. In conducting the assessment, the RIO need not interview the complainant, respondent, or other witnesses, or gather data beyond any that may have been submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

The RIO shall, on or before the date on which the respondent is notified of the allegation, inform the Principal and with his permission (and if needed that of the Medical Superintendant) obtain custody of, inventory, and sequester all research records and evidence (or copies of the aforementioned that will serve as evidence) needed to conduct the research misconduct proceeding.

B. Initiation and Purpose of the Inquiry

If the RIO determines that the criteria for an inquiry are met, he or she will immediately initiate the inquiry process. The purpose of the inquiry is to conduct an initial review of the available evidence to determine whether to conduct an investigation. An inquiry does not require a full review of all the evidence related to the allegation.

C. Notice to Respondent; Sequestration of Research Records

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent in writing, if the respondent is known. If the inquiry subsequently identifies additional respondents, they must be notified in writing.

On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding (or copies of these), inventory the records and evidence and sequester them in a secure manner,

The RIO may consult with Principal, Director or Medical Superintendent for advice and assistance in this regard.

D. Notifying the Inquiry Committee and determining conflicts of interest

The RIO, in consultation with the Principal, will notify the standing core committee in writing of the allegation and the report of the assessment of the

RIO as soon after the initiation of the inquiry as is practical, and no later than 3 weeks.

The respondent and the complainant will be given an opportunity to object to the inclusion of a core member based on a personal, professional or financial conflict of interest and the core members may also declare such conflicts. These objections and declarations must be made in writing to the RIO within 10 days of receipt of the notification. The RIO and the Principal will make the final decision of whether a conflict exists and may make their own decision about potential conflicts, even if such are not voiced by the respondent or complainant or declared by the core committee member. A core committee member considered to have a potential conflict will not be involved in subsequent proceedings and will be informed only of the exclusionary decision and of no further details of the allegation.

In case the RIO is considered by the Principal, the respondent or the complainant to have a potential conflict of interest, then the Principal may, with the approval of the Director, appoint one of the Vice Principals, or another senior member of the faculty, to take the role of the RIO for the concerned investigation.

E. Charge to the Committee and First Meeting

The RIO will prepare a charge for the inquiry committee that:

1. Sets forth the time for completion of the inquiry;
2. Describes the allegations and any related issues identified during the allegation assessment;
3. States that the purpose of the inquiry is to conduct an initial review of the evidence, including the testimony of the respondent, complainant and key witnesses, to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible;
4. States that an investigation is warranted if the committee determines: (a) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct; and, (b) the allegation may have substance, based on the committee's review during the inquiry.
5. Informs the inquiry committee that they are responsible for preparing or directing the preparation of a written report of the inquiry that meets the requirements of this policy.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing

plans for the inquiry, and answer any questions raised by the committee. The RIO will be present or available throughout the inquiry to advise the committee as needed.

F. Inquiry Process

The inquiry committee may chose to interview the complainant, the respondent and key witnesses or may restrict themselves to examining the written response of the respondent to the written allegation of research misconduct by the complainant, and examining the relevant research records and materials submitted by the RIO as evidence. Then the inquiry committee will evaluate the evidence, including the testimony obtained, if any, during the inquiry.

After consultation with the RIO, the committee members will decide whether an investigation is warranted. The scope of the inquiry is not required to and does not normally include deciding whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses.

However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage if all relevant issues are resolved. In that case, the RIO shall promptly consult with the Principal and Director to determine the next steps that should be taken.

G. Time for Completion

The inquiry, including preparation of the final inquiry report and the decision of the Principal on whether an investigation is warranted, must be completed within 60 calendar days of initiation of the inquiry, unless the RIO determines that circumstances clearly warrant a longer period. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60-day period.

VI. The Inquiry Report

A. Elements of the Inquiry Report

A written inquiry report must include the following information:

(1) The name and position of the respondent;
(2) The name and position of the complainant (unless the RIO and Principal feel this may be masked to protect the complainant);
(3) A description of the allegations of research misconduct;

(4) The names and titles of the committee members and experts who conducted the inquiry;
(5) A summary of the inquiry process used;
(6) A list of the research records reviewed;
(7) Summaries of any interviews;
(8) The research protocol number that was assigned by the IRB for projects that were cleared by the IRB; for externally funded studies, the details of the sponsor and sponsors ID for the project
(9) The basis for recommending or not recommending that the allegations warrant an investigation;
(10) Any comments on the draft report by the respondent or complainant; and
(11) Whether any other actions should be taken if an investigation is not recommended.

Institutional counsel may review the report for legal sufficiency. Modifications should be made as appropriate in consultation with the RIO and the inquiry committee.

B. Notification to the Respondent and Opportunity to Comment

The RIO shall notify the respondent and complainant whether the inquiry found an investigation to be warranted, and provide relevant portions of the inquiry report for comment include a copy of the draft inquiry report for comment within 14 days. A confidentiality agreement should be a condition for access to the report.

Any comments that are submitted by the respondent or complainant will be attached to the final inquiry report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form.

The committee will deliver the final report to the RIO.

C. Institutional Decision and Notification

1. Decision by Deciding Official (Principal)

The RIO will transmit the final inquiry report and any comments to the DO, who will determine in writing whether an investigation is warranted. The inquiry is completed when the DO makes this determination.

2. Notification to investigational committee

Within 30 calendar days of the DO's decision that an investigation is warranted, the RIO will provide the standing core committee with the DO's written decision and a copy of the inquiry report. The RIO will also notify those institutional officials who need to know of the DO's decision. The RIO must provide the committee with the charges to be considered in the investigation.

3. Documentation of Decision Not to Investigate

If the DO decides that an investigation is not warranted, the RIO shall secure and maintain for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment by ORI of the reasons why an investigation was not conducted.
These documents must be provided to authorized personnel upon request.

VII. Conducting the Investigation

A. Initiation and Purpose

The investigation must begin within 30 calendar days after the determination by the DO that an investigation is warranted. The purpose of the investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to recommended findings on whether research misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged research misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice.

B. Notifying ORI and Respondent; Sequestration of Research Records

On or before the date on which the investigation begins, the RIO must:
(1) notify the Principal and Director of the decision to begin the investigation; and
(2) notify the respondent in writing of the allegations to be investigated.

The RIO must also give the respondent written notice of any new allegations of research misconduct within a reasonable amount of time of deciding to pursue allegations not addressed during the inquiry or in the initial notice of the investigation.

The RIO will, prior to notifying respondent of the allegations, take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed (or valid copies of

such evidence) to conduct the research misconduct proceeding that were not previously sequestered during the inquiry. The need for additional sequestration of records for the investigation may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Convening of the Investigation Committee

The RIO, in consultation with other institutional officials as appropriate, will convene a meeting of the standing investigation committee as soon after the beginning of the investigation as is practical and within 30 calendar days.

When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution. The respondent will be notified of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. This period for submitting objections will be no more than 14 calendar days. The RIO and Principal will make the final determination of whether a conflict exists.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The RIO will define the subject matter of the investigation in a written charge to the committee that:

a) Describes the allegations and related issues identified during the inquiry;
b) Identifies the respondent;
c) Informs the committee that it must conduct the investigation as prescribed in paragraph E. of this section;
d) Defines research misconduct;
e) Informs the committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent of it and who was responsible;
f) Informs the committee that in order to determine that the respondent committed research misconduct it must find that a preponderance of the evidence establishes that: (1) research misconduct, as defined in this policy, occurred (respondent has the burden of proving by a preponderance of the evidence any affirmative defences raised, including honest error or a difference of opinion); (2) the research

misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly; and

g) Informs the committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of this policy.

2. First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The RIO will be present or available throughout the investigation to advise the committee as needed.

E. Investigation Process

The investigation committee and the RIO must:

• 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 each allegation;

• Take reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;

• 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 a summary of the interview to the interviewee for correction, and include the summary in the record of the investigation; and

• Pursue diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continue the investigation to completion.

F. Time for Completion

The investigation is to be completed within 120 days of beginning it, including conducting the investigation, preparing the report of findings, providing the draft report for comment and sending the final report to the Principal. However, if the RIO determines that the investigation will not be completed within this 120-day period, he/she will submit to the Principal a written request for an extension, setting forth the reasons for the delay. The RIO will ensure that periodic progress reports are filed with ORI, if ORI grants the request for an extension and directs the filing of such reports.

VIII. The Investigation Report

A. Elements of the Investigation Report

The investigation committee and the RIO are responsible for preparing a written draft report of the investigation that:

1) Describes the nature of the allegation of research misconduct, including identification of the respondent;
2) Describes and documents the IRB clearance and support, including, for example, the numbers of any grants that are involved, grant applications, contracts, and publications listing this or external grant support;
3) Describes the specific allegations of research misconduct considered in the investigation;
4) Identifies and summarizes the research records and evidence reviewed and identifies any evidence taken into custody but not reviewed; and
5) Includes a statement of findings for each allegation of research misconduct identified during the investigation.

Each statement of findings must:

1) Identify whether the research misconduct was falsification, fabrication, or plagiarism, and whether it was committed intentionally, knowingly, or recklessly;
2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by respondent to establish by a preponderance of the evidence that he or she did not engage in research misconduct because of honest error or a difference of opinion;
3) identify whether any publications need correction or retraction;
4) identify the person(s) responsible for the misconduct; and
5) list any current support or known applications or proposals for support that the respondent has pending with funding agencies.

B. Comments on the Draft Report and Access to Evidence

1. Respondent

The RIO will give the respondent a copy of the draft investigation report for comment and, concurrently, a copy of, or supervised access to the evidence on which the report is based. The respondent will be allowed 30 days from the date he/she received the draft report to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

2. Complainant

The RIO will provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within 30 days of the date on which he/she received the draft report and the comments will only then be included and considered in the final report.

3. Confidentiality

In distributing the draft report, or portions thereof, to the respondent, the RIO will inform the recipient of the confidentiality under which the draft report is made available and seek written confirmation to ensure such confidentiality by requiring that the recipient sign a confidentiality agreement.

C. Decision by Deciding Official (Principal)

The RIO will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and complainant's comments are included and considered, and transmit the final investigation report to the DO, who will determine in writing: (1) whether the institution accepts the investigation report, its findings, and the recommended institutional actions; and

(2) the appropriate institutional actions in response to the accepted findings of research misconduct.

If this determination varies from the findings of the investigation committee, the DO will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the DO may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the RIO will normally notify both the respondent and the complainant in writing. After informing ORI, the DO will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Appeals

The respondent may appeal the decision of the DO that could result in a reversal or modification of the institution's findings of research misconduct. If such an appeal is made on sufficient grounds, it must be sanctioned by the Principal and Director on the basis of subversion of due process of investigation or fresh evidence not reviewed by the committee and completed within 120 days of its filing, unless the RIO, Principal of Director

finds good cause for an extension, based upon the institution's written request for an extension that explains the need for the extension. If the Principal grants an extension, he/she may direct the filing of periodic progress reports.

E. Notice to Principal of Institutional Findings and Actions

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 120-day period for completion of any appeal, submit the following to the Principal:

(1) a copy of the final investigation report with all attachments and any appeal.
(2) a statement of whether the committee found misconduct and, if so, who committed the misconduct

F. Notice to RIO by Principal

The Principal will submit to the RIO within 30 calendar days:

1) a statement of whether the institution accepts the findings of the investigation report or the outcome of the appeal; and
2) a description of any pending or completed administrative actions against the respondent.

G. Maintaining Records for Review by ORI

The RIO must maintain "records of research misconduct proceedings". Unless custody has been transferred to the Principal or he/ she has advised in writing that the records no longer need to be retained, records of research misconduct proceedings must be maintained in a secure manner for 7 years after completion of the proceeding.

The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by regulatory agencies to carry out its review of an allegation of research misconduct or of the institution's handling of such an allegation.

IX. Completion of Cases; Reporting Premature Closures to ORI

Generally, all inquiries and investigations will be carried through to completion and all significant issues will be pursued diligently. The RIO must notify the Principal in advance if there are plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for

any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to the principal

X. Institutional Administrative Actions

If the Principal as DO determines that research misconduct is substantiated by the findings, he or she will decide, in con junction with the Director or Medical Superintendant and other administrative authorities, on the appropriate actions to be taken.

The administrative actions may include:

1) Withdrawal or correction of all pending or published abstracts and papers emanating from the research where research misconduct was found;
2) Removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
3) Restitution of funds to the grantor agency as appropriate; and
4) Other action appropriate to the research misconduct.

XI. Other Considerations

A. Termination or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the institution's responsibilities.

If the respondent, without admitting to the misconduct, elects to resign his or her position after the institution receives an allegation of research misconduct, the assessment of the allegation will proceed, as well as the inquiry and investigation, as appropriate based on the outcome of the preceding steps. If the respondent refuses to participate in the process after resignation, the RIO and any inquiry or investigation committee will use their best efforts to reach a conclusion concerning the allegations, noting in the report the respondent's failure to cooperate and its effect on the evidence.

B. Restoration of the Respondent's Reputation

Following a final finding of no research misconduct, the RIO must, at the request of the respondent, undertake all reasonable and practical efforts to restore the respondent's reputation. Depending on the particular

circumstances and the views of the respondent, the RIO should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in any forum in which the allegation of research misconduct was previously publicized, and expunging all reference to the research misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation should first be approved by the Principal.

C. Protection of the Complainant, Witnesses and Committee Members

During the research misconduct proceeding and upon its completion, regardless of whether the institution or ORI determines that research misconduct occurred, the RIO must undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

The DO will determine, after consulting with the Director, and with the RIO, complainant, witnesses, or committee members, respectively, what steps, if any, are needed to restore their respective positions or reputations or to counter potential or actual retaliation against them.

D. Allegations Not Made in Good Faith

If relevant, the Principal and Director will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If they determine that there was an absence of good faith they will determine whether any administrative action should be taken against the person who failed to act in good faith.

Appendix I

Roles and responsibilities of the Research Integrity Officer (RIO)

The responsibility of the RIO is to receive and review all allegations of research misconduct, ensure fairness, transparency and justness in all enquiries (while maintaining confidentiality of all concerned), and to work towards promoting a climate of responsible research in the institution.

General

The Research Integrity Officer (RIO) has lead responsibility for ensuring that the institution:

1. Takes all reasonable and practical steps to foster a research environment that promotes the responsible conduct of research, research training, and activities related to that research or research training, discourages research misconduct, and deals promptly with allegations or evidence of possible research misconduct.

2. Has written policies and procedures for responding to allegations of research misconduct and reporting information about that response to ORI

3. Informs its institutional members about its research misconduct policies and procedures and its commitment to compliance with those policies and procedures.

4. Takes appropriate interim action during a research misconduct proceeding to protect public health, funds and equipment, and the integrity of the research process, which may include advising the Principal to stop ongoing research till the enquiry is completed.

Research Misconduct Proceeding

A. General

The RIO is responsible for:

1. Taking all reasonable and practical steps to ensure the cooperation of respondents and other institutional members with research misconduct proceedings, including, but not limited to, their providing information, research records and evidence.

2. Promptly taking all reasonable and practical steps to obtain custody of all research records and evidence (or copies of such records and evidence) needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner.

3. Providing confidentiality to those involved in the research misconduct proceeding.

4. Determining whether each person involved in handling an allegation of research misconduct (including committee members) has an unresolved personal, professional or financial conflict of interest and taking appropriate action, including refusal, to ensure that no person with such a conflict is involved in the research misconduct proceeding.

5. Keeping the Principal and Director appraised of the progress of the review of the allegation of research misconduct.

6. Chairing the committee meeting investigating the allegation of research misconduct and ensuring fairness and transparency of, and accuracy in the reporting of, the proceedings.

7. In cooperation with other institutional officials, taking all reasonable and practical steps to protect or restore the positions and reputations of good faith complainants, witnesses, and committee members and to counter potential or actual retaliation against them by respondents or other institutional members.

8. Making all reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputation of persons alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made.

9. Assisting the Principal, and other institutional officials, in implementing their decision to take administrative action against any complainant, witness, or committee member determined by the committee not to have acted in good faith.

10. Maintaining records of the research misconduct proceeding in a secure manner for 7 years after completion of the proceeding, or the completion.

11. Taking appropriate action if required, in conjunction with the Principal and the Director, to notify other involved parties, such as sponsors, law enforcement agencies, professional societies, and licensing boards, of those actions.

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B. **Allegation Receipt and Assessment**

The RIO is responsible for:

1. Consulting confidentially with persons uncertain about whether to submit an allegation of research misconduct.

2. Receiving allegations of research misconduct in writing.

3. Assessing each allegation of research misconduct to determine if an inquiry is warranted because the allegation falls within the definition of research misconduct, and is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

C. Inquiry

The RIO is responsible for:

Initiating the inquiry process if it is determined that an inquiry is warranted.

1. At the time of, or before beginning the inquiry, making a good faith effort to notify the respondent in writing, if the respondent's whereabouts are known.

2. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, informing the Principal and Director that such an enquiry is about to commence.

3. Taking all reasonable and practical steps to obtain custody of all research records and evidence (or copies of such evidence) needed to conduct the research misconduct proceeding, inventorying the records and evidence and sequestering them in a secure manner.

4. Informing the inquiry committee members as soon after the initiation of the inquiry as is practical.

5. Preparing a charge for the inquiry committee in accordance with the institution's policies and procedures.

6. Convening the first meeting of the inquiry committee and at that meeting briefing the committee on the allegations, the charge to the committee, and the appropriate procedures for conducting the inquiry, including the need for confidentiality and for developing a plan for the inquiry, and assisting the committee with organizational and other issues that may arise.

7. Providing the inquiry committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging witness interviews and recording or transcribing those interviews.

8. Being available or present throughout the inquiry to advise the committee as needed and consulting with the committee prior to its decision on whether to recommend that an investigation is warranted on the basis of the criteria in the institution's policies and procedures.

9. Determining whether circumstances clearly warrant a period longer than 60 days to complete the inquiry (including preparation of the final inquiry report and the decision of the Principal on whether an investigation is warranted), approving an extension if warranted, and documenting the reasons for exceeding the 60-day period in the record of the research misconduct proceeding.

10. Assisting the inquiry committee in preparing a draft inquiry report, sending the respondent and the complainant a copy of the draft report for comment within a time period that permits the inquiry to be completed within the allotted time, taking appropriate action to protect the confidentiality of the draft report, including masking the identity of patients or trial participants; receiving any comments from the respondent and the complainant; and ensuring that the comments are attached to the final inquiry report.

11. Receiving the final inquiry report from the inquiry committee and forwarding it, together with any comments the RIO may wish to make, to the Principal who will determine in writing whether an investigation is warranted.

12. Providing to the Principal, upon request, the research records and evidence reviewed, transcripts or recordings of any interviews, copies of all relevant documents, and the allegations to be considered in the investigation.

13. Within 30 days of a decision by the Principal that an investigation is warranted, providing the subcommittee with a copy of the written decision and notifying those institutional officials who need to know of the decision.

14. Notifying the respondent and the complainant whether the inquiry found an investigation to be warranted and informing them of the

date of the investigative committee meeting and of any further details required by the committee.

15. If the committee decides that an investigation is not warranted and the Principal and Director accept this decision, informing the complainant and respondent of this decision; securing and maintaining for 7 years after the termination of the inquiry sufficiently detailed documentation of the inquiry to permit a later assessment of the reasons why an investigation was not conducted.

D. **Investigation**

The RIO is responsible for:

1. Initiating the investigation within 30 calendar days after the determination by the committee and the Principal that an investigation is warranted.

2. On or before the date on which the investigation begins: (1) notifying the Principal and Director of the decision to begin the investigation; and (2) notifying the respondent in writing of the allegations to be investigated.

3. Prior to notifying the respondent of the allegations, taking all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence (or copies of such evidence) needed to conduct the research misconduct proceeding that were not previously sequestered during the inquiry.

4. In consultation with the committee and the Principal, inviting experts to join the enquiry committee for the specific allegation.

5. Convening the first meeting of the investigation committee and at that meeting briefing the committee on the charge, the inquiry report and the procedures and standards for the conduct of the investigation, including the need for confidentiality and developing a specific plan for the investigation

6. Providing the investigation committee with needed logistical support, e.g., expert advice, including forensic analysis of evidence, and clerical support, including arranging interviews with witnesses and recording or transcribing those interviews.

7. Being available or present throughout the investigation to advise the committee as needed.

8. On behalf of the institution, the RIO is responsible for each of the following steps and for ensuring that the investigation committee:

    a. uses diligent efforts to conduct an investigation that includes an examination of all research records and evidence relevant to reaching a decision on the merits of the allegations and that is otherwise thorough and sufficiently documented;
    b. takes reasonable steps to ensure an impartial and unbiased investigation to the maximum extent practical;
    c. interviews 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 records or transcribes each interview, provides the recording or transcript to the interviewee for correction, and includes the recording or transcript in the record of the research misconduct proceeding; and
    d. pursues diligently all significant issues and leads discovered that are determined relevant to the investigation, including any evidence of any additional instances of possible research misconduct, and continues the investigation to completion.

9. Upon determining that the investigation cannot be completed within 120 days of its initiation (including providing the draft report for comment and sending the final report with any comments), submitting a request to the Principal for an extension of the 120-day period that includes a statement of the reasons for the extension. If the extension is granted, the RIO will file periodic progress reports with Principal.

10. Assisting the investigation committee in preparing a draft investigation report that meets the requirements of the institution's policies and procedures, sending the respondent and complainant a copy of the draft report for his/her comment within 30 days of receipt, taking appropriate action to protect the confidentiality of the draft report, receiving any comments from the respondent (and complainant at the institution's option) and ensuring that the comments are included and considered in the final investigation report.

11. Transmitting the draft investigation report to institutional counsel, if needed, for a review of its legal sufficiency.

12. Assisting the investigation committee in finalizing the draft investigation report and receiving the final report from the committee.

13. Transmitting the final investigation report to the Principal and Director and:

    a. if the Principal or Director determines that further fact-finding or analysis is needed, receiving the report back from the Principal or Director for that purpose;
    b. If there is an appeal by the respondent that could result in a modification or reversal of the Principal's finding of research misconduct, ensuring that the appeal is completed within 120 days of its filing, and, upon completion of the appeal, transmitting to the Principal and Director, a copy of the investigation report with all attachments, a copy of the appeal proceedings,
    c. Request and file a statement of whether the institution accepts the findings of the appeal proceeding,
    d. Request and file a statement of whether the institution found research misconduct, and if so, who committed it and
    e. Request and file a written report of any pending or completed administrative actions against the respondent.

14. When a final decision on the case is reached, the RIO will normally notify both the respondent and the complainant in writing and will determine, in conjunction with the Principal and Director and other institutional officials as is deemed necessary, whether law enforcement agencies, professional societies, professional licensing boards, editors of involved journals, sponsors of the research and collaborators of the respondent, or other relevant parties should be notified of the outcome of the case.

15 In the case of research already approved by the IRB, the RIO will notify the member secretary of the final decision of the investigation.

16. Maintaining for a period of 7 years and providing to all regulatory agencies upon request, and after approval from the institutions administration (normally the Principal) all relevant research records and records of the institution's research misconduct proceeding, including the results of all interviews and the transcripts or recordings of those interviews.

Appendix II

Roles and responsibilities of core committee members

The core members of the committee appointed by the Senatus to assist the RIO in inquiries and investigations of alleged misconduct are responsible for:

1. Declaring any potential conflicts of interest with the complainant or respondent or the subject of investigation that might compromise the results of the inquiry or investigation; should such conflict exist, they are to declare it and if this is deemed to be pertinent in compromising the

results of the said investigation by the RIO or Principal, they are to withdraw from the investigation in question.

2. Maintaining confidentiality of all proceedings and matters pertaining to the investigation, unless required by the Principal, or Director, or regulatory or legal authorities to disclose such matters.

3. Cooperating with the RIO and the committee members in attending meetings, providing advice on matters related to the enquiry and submitting reports speedily to assist the process.

4. Advising the RIO on matters of procedure or the conduct of the enquiry and investigation that would uphold the integrity of the process and of the institution

5. Accepting to perform without remuneration, these duties and responsibilities for the greater good of the institution, unless there are any expenses related to the inquiry or investigation process that are approved by the RIO and are eligible for re-imbursement as per existing institutional rules.

APPENDIX III

Roles and responsibilities of inducted committee members and experts

Members of the faculty of the institution may be requested to help with the inquiry and investigation of alleged misconduct and provide counsel or testimony or expertise to the investigative committee and RIO. Similarly,

external experts or retired staff who have information about or expertise in the concerned research may also be approached to serve as members of the inquiry and/or investigative committee. Such members are expected to accept the same responsibilities as those outlined above, except that, in the case of extra-mural experts they may be reimbursed reasonable expenses incurred in travelling for meetings and in the conduct of the investigation.