MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex

GENERAL MANUAL – POLICY/PROCEDURE

Effective Date: January 22, 2013
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Issued By:- SLRI, Legal Services
Approved by:- Board of Directors

Title:- **RESEARCH MISCONDUCT POLICY**

Policy Number: I-f-25-46

Key Words: Research, Research Misconduct

Stakeholders:
Staff, Research Staff

Policy Statement:

Introduction/Objectives

The search for knowledge about ourselves and the world around us is a fundamental human endeavour. Research is a natural extension of this desire to understand and to improve the world in which we live, and its results have both enriched and improved our lives and human society as a whole.

In order to maximize the quality and benefits of research, a positive research environment is required. For researchers, this implies duties of honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of research results, and adherence to the use of professional standards. For the Mount Sinai Hospital and for the Samuel Lunenfeld Research Institute, it calls for a commitment to foster and maintain an environment that supports and promotes the responsible conduct of research.[1]

Researchers across all disciplines must be committed to incorporating and demonstrating the following values in every facet of their professional careers: honesty, fairness, trust, accountability, and openness.[2]

Allegations have the potential to cause great harm to Respondent(s), are extremely serious and can have severe repercussions to the career, livelihood and reputation of both the Complainant and Respondent as well as to the Hospital as a whole. As such, every case whether well founded or not must be treated with utmost confidentiality and seriousness.

The reputations of the Hospital and its researchers, and their collective responsibility for the ethical conduct of research, require that any Research Misconduct that occurs be promptly detected and effectively dealt with. The purpose of this policy is to ensure fair, accurate, objective inquiries and investigations of Allegations as promptly as the circumstances permit.

This policy is not intended to replace or supersede other Hospital mechanisms for resolving conflicts among individuals who are employed or appointed at the Hospital. Consistent with the Hospital's policies, every person working at or under the auspices of the Hospital is encouraged to resolve questions or concerns

[1] Canadian Panel on Responsible Conduct of Research, *The Tri-Agency Framework: Responsible Conduct of Research*, Ottawa, 2011, http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/, ["Tri-Agency Framework"], pg 1.
[2] The Expert Panel on Research Integrity, "Honesty, Accountability, and Trust: Fostering Research Integrity in Canada," *Council of Canadian Academies*, Ottawa, 2010, http://www.scienceadvice.ca/uploads/eng/assessments%20and%20publications%20and%20news%20releases/research%20integrity/RI_report.pdf, ["Honesty, Accountability, and Trust"], pg 38.

through direct discussion whenever appropriate and to raise issues with their immediate supervisor for resolution. It is expected that all research will be conducted with integrity in accordance with Mount Sinai Hospital's *Code of Ethical Conduct*.

1.1 External guidelines accepted by the hospital

The Director, Samuel Lunenfeld Research Institute, is responsible for creating a research environment that promotes integrity within the institution and for establishing a mechanism to deal with cases of suspected Research Misconduct.

The Hospital recognizes the following external guidelines, among others, that are applicable to the conduct of research at or under the auspices of the Hospital:

- University of Toronto Principles and Responsibilities Regarding Conduct of Research
- University of Toronto Policy on Ethical Conduct in Research
- Tri-Council Policy Statement on Integrity in Research and Scholarship
- Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans
- ICH Good Clinical Practice Guideline
- ICMJE Guidelines

Everyone involved in the conduct of research must comply with these external guidelines to the extent applicable to the research.

1.2 Responsibility to Report Research Misconduct

Every person has an obligation to report instances of observed, suspected and apparent Research Misconduct to the Responsible Officer in accordance with the procedures below (as further described in the flow chart in Schedule A).

Allegations may be received from any person (internal or external to the Hospital). Any hospital administrative staff member who receives an Allegation is obligated to report it immediately to the Responsible Officer. Allegations that involve activities of the Responsible Officer or a conflict of interest of the Responsible Officer are to be made to the President & CEO.

2. Definitions and Abbreviations

a) **"Allegation"** means a report or complaint of observed, suspected or apparent Research Misconduct.

b) **"Administrator"** has the meaning set out in section 4.7(c).

c) **"Complainant"** means the person who provides a written Allegation, whether the person is internal or

external to the Hospital.

d) **"Conflict of Interest"** may arise when activities or situation place an individual in a real, potential, or perceived conflict between the duties or responsibilities related to research, and personal, institutional, or other interests. These interests include, but are not limited to, business, commercial or financial interests pertaining to the individual, their family members, friends, or their former, current or prospective professional associates.[3]

e) **"Good Faith"** refers to the honest and reasonably held belief that Research Misconduct may have occurred. Reasonably held beliefs are not based on unsubstantiated rumours or innuendos.

f) **"Investigating Committee"** has the meaning set out in section 4.8(b).

g) **"Investigator"** has the meaning set out in section 4.8(c).

h) **"Researcher"** means any individual who is involved in research conducted at, or under the auspices of, the Hospital by designing research proposals (including grant applications and protocols for submission to REB or Animal Care Committee review), conducting research (including carrying out the research activities such as collecting data, entering data into databases and interacting with research subjects in any way), analyzing research results and preparing a report of the results for public dissemination (including writing up a manuscript, providing substantial input or editorial control over a manuscript or presentation, making a presentation or speaking publicly to represent the results of the research). Examples include, but are not limited to:

- Individuals with scientific appointments
- Members of the medical, dental, or professional staff of the Hospital
- Employees
- Research associates/ assistants
- Trainees (including students, residents, clinical fellows or post-doctoral fellows)
- Support staff
- Volunteers (or non-paid research staff)
- Visiting faculty and observers

i) **"Research Misconduct"** means any research practice that deviates seriously from the commonly accepted ethics/integrity standards of the relevant research community. A detailed non-exhaustive list of examples is set out in Schedule B.

j) **"Respondent"** means the person against whom an Allegation is made.

k) **"Responsible Officer"** means the Director, Samuel Lunenfeld Research Institute (SLRI) or Vice-President – Medical Affairs.

3. Applicability and Jurisdiction

[3] Tri-Agency Framework, pg 15.

3.1 Applicability

This policy applies to Allegations involving any person who, at the time of the alleged activities, was conducting research at or under the auspices of the Hospital. Researchers who are no longer employed by or appointed at the Hospital may still be subject to investigation and reporting under this policy. If, for any reason during the course of the inquiry or the investigation, the Respondent ceases to hold an appointment at the Hospital or leaves the jurisdiction, the Responsible Officer will decide, in his or her discretion, the manner of continuing the inquiry and/or investigation and to whom the allegation should be reported for investigation.

3.2 Jurisdiction

Jurisdiction between the University of Toronto and its affiliated teaching hospitals is determined by the Hospital and the University of Toronto in accordance with their Affiliation Agreement and the Framework to Address Allegations of Research Misconduct and Addendum, attached as Schedule C. Schedule C provides a process for determining institutional jurisdiction of research misconduct complaints involving students (including graduate students) enrolled at the University of Toronto as well as faculty members with cross-appointments. All allegations of misconduct made against employees or trainees who hold appointments (including status-only) or are registered students with the University of Toronto respectively will be shared with the appropriate University of Toronto authority.

3.3 Cooperation with Other Institutions or Agencies

The Hospital will cooperate with other institutions conducting inquiries or investigations as appropriate, including requesting or offering membership on an investigating committee and providing relevant information so that an institution conducting such inquiry or investigation can meet its responsibility for dealing with an Allegation.

The Hospital will comply with the written requirements and regulations of research sponsors and funding entities concerning matters of Research Misconduct.

The Hospital will cooperate with police investigations and investigations of regulatory bodies, for example, the College of Physicians and Surgeons of Ontario, as required or permitted by law.

If the Allegations involve research activities conducted under funding from a funding entity that has specified guidelines concerning the handling of Allegations, such guidelines will be respected. If the Allegation of research misconduct pertains to research, research training, applications for support of research or research training, or related activities for which funds have been provided or requested from a Public Health Services unit of the United States Department of Health and Human Services, (including operating divisions such as the National Institutes of Health), the Hospital will follow additional principles and procedures as set out by Public Health Services in accordance with applicable U.S. governmental requirements. The relevant information concerning funding support from Public Health Services may be found at http://ori.dhhs.gov/html/misconduct/regulation_subpart_a.asp.

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Procedure:

4.1 Prior Assessment

Prior to making an Allegation, Complainants should attempt, if possible, to seek an explanation from the potential Respondent to ensure that there is no misunderstanding.[4]

Prior to making an Allegation, individuals who are uncertain about whether to make an Allegation may discuss the matter with the Responsible Officer with or without naming the potential Respondent. The Responsible Officer shall not inform potential Respondents of such discussions and such discussions do not constitute an Allegation under this policy.

4.2 Content and Nature of Allegations

A formal Allegation may not necessarily have been preceded by an informal assessment as described in section 4.1. The Complainant is encouraged to identify himself or herself when making the Allegation as a sign that the allegation is not being made in bad faith. Allegations must be written, dated and signed by the Complainant. The Complainant shall set out all relevant information, state the reasonable grounds on which the Allegation is based, and include all supporting evidence, if available. Where the Complainant has made an Allegation to other institutions, concerning the same incident, they are encouraged to notify the Hospital of the other institutions. The Hospital will not respond to anonymous Allegations under this policy, however, anonymous allegations of a serious nature may be handled under other Hospital policies, such as the Code of Ethical Conduct or the Reporting and Investigation of Suspected Financial Wrongdoing.

The Complainant is required to make Allegations in Good Faith. Allegations must not be malicious, frivolous or based on rumour. The Complainant is also required to declare any actual, apparent, perceived or potential conflicts of interest at the time of making the Allegation.

Any person who knowingly makes an Allegation that is untrue, frivolous, vexatious or that the Complainant could reasonably and readily have determined was false through minimal diligence may be subject to disciplinary action. If the Responsible Officer determines that there are reasonable grounds to believe that the Complainant did not act in Good Faith, the Responsible Officer may refer that finding to the appropriate department chief or director and the Complainant's manager/supervisor.

4.3 Managing Allegations

If there are multiple Complainants or multiple Allegations about the same situation, the Complainants should make all attempts to identify a primary spokesperson to act on behalf of the Complainants. Each Complainant must submit a written signed statement and acknowledge the identity of the primary spokesperson. If no primary spokesperson is identified, the Responsible Officer may decide to (i) proceed with each Complainant treated separately or (ii) designate a primary spokesperson and/or determine that the Allegations be considered together in order to avoid multiple processes.

[4] University of Toronto, "Framework to Address Allegations of Research Misconduct," Research and Innovation, November 2006.

The Hospital will not pursue the same or substantially similar Allegation, unless new and compelling information becomes available that was not reasonably available at the time of the original Allegation. In such case, the matter will be treated as a new Allegation under this policy.

4.4 No Retaliatory Action

The Responsible Officer will make all reasonable efforts to ensure that no retaliatory action is taken against the Complainant, when he or she decides to identify him- or herself as the Complainant. Acts of retaliation or intimidation against any Complainant and/or Respondent are subject to appropriate disciplinary actions as incidents of Research Misconduct.

4.5 Processing of Allegations

The following general principles apply to handling Allegations:

a) All persons involved in an inquiry and/or investigation under this policy (including but not limited to Complainants, Respondents and those who assist in the inquiry and/or investigation) shall be treated with respect, fairness and with due sensitivity to their scientific, professional and personal reputations.

b) The process used to resolve Allegations must not damage the scientific process by inhibiting creativity and innovation. It is important to distinguish Research Misconduct from honest error, differences in methodology, interpretation, or judgment, and divergent paradigms in science.

c) The highest degree of confidentiality reasonably possible in the circumstances shall be maintained by all persons involved in the process (including but not limited to the Respondent, Complainant and anyone who conducts the inquiry or investigation). Each person conducting the inquiry or investigation will be responsible to restrict the dissemination of information to only those who should receive it.

d) Conflicts of interest shall be avoided wherever possible and must be openly declared where they cannot be avoided. The Responsible Officer must be vigilant not to permit personal conflicts between colleagues or other individuals to obscure the facts or divert attention from the substance of the Allegation. If it becomes apparent to any individual that a person conducting either an inquiry or an investigation hereunder has a conflict of interest, the case shall be referred to the Responsible Officer who may allocate the task to an alternate official.

e) Every person is required to cooperate with this policy, including providing relevant requested information and documents, and attending interviews. Failure to cooperate may result in disciplinary action.

f) All proceedings shall be conducted in a timely manner and be documented appropriately. The Responsible Officer has authority to modify timelines set out in this procedure as appropriate and with notice to the Respondent.

g) At any point in the procedure where the Responsible Officer wishes to seek advice from ad hoc advisors before rendering a decision, it is expected that the highest possible degree of confidentiality

shall be maintained by all those consulted. The Responsible Officer may consult with individual advisors or convene an ad hoc panel to conduct a documentary review of the facts of the case.

h) The Respondent must be provided with a meaningful opportunity to respond to the Allegations and to new information that is obtained throughout the process.

i) The person who conducts appeals under this procedure shall not be involved in either the inquiry or investigation.

j) These procedures do not preclude the Responsible Officer from taking appropriate steps to protect patients, the public, research participants, or other researchers, such as notifying medical leadership of patient care issues, notifying the police of criminal activities or restricting or suspending the Respondent's activities pending the outcome of the investigation.

k) It is recognized that there may be other processes of review or grievances at the same time as this procedure.

4.6 Procedure: Two-Step Approach

There are two steps in the procedures to address and handle Research Misconduct:

1. an inquiry step to determine if an investigation of the Allegation is warranted (section 4.7); and
2. an investigation step to determine if the alleged Research Misconduct has in fact been committed (section 4.8).

If, at any time in the Inquiry process, the Allegations can be resolved to the satisfaction of the Complainant, the Respondent and the Responsible Officer, this will be formally documented in a letter and signed by all three.

The Respondent may, at any time throughout the proceedings (Inquiry and Investigation), sign a written Admission of Research Misconduct. If the admission is accepted, there must be an agreed upon written resolution signed by the Responsible Officer and the Respondent, in consultation with the Respondent's Chief, President & CEO, Hospital Legal Counsel and others as determined by the Responsible Officer.

Regardless of an admission at any stage, the Responsible Officer may, at his or her discretion, continue with a full inquiry or investigation.

If the Responsible Officer determines that there are sufficient grounds to proceed with an investigation, the Responsible Officer may, at his or her discretion, dispense with the inquiry and proceed directly to the investigation stage.

4.7 Inquiry

a) Purpose of Inquiry

At the inquiry stage, factual information is gathered and expeditiously reviewed to determine if an

investigation of the Allegation is warranted. The inquiry is a preliminary process designed to determine if

- there are sufficient grounds to proceed with an investigation,
- the Allegation is outside the jurisdiction of this policy,
- the Allegation is frivolous, vexatious or in bad faith,
- the Allegation is clearly mistaken or unjustified,
- it is appropriate to offer the complainant and the Respondent an alternative dispute resolution process,
- there is a reasonable prospect that a further investigation will enhance the integrity of the scientific process.

It is not the purpose of the inquiry to determine if Research Misconduct has occurred.

b) Timing

Ordinarily inquiries shall begin within 20 working days of receiving the Allegation and the report of the findings shall be delivered no more than 60 working days from receipt by the Responsible Officer. There may be circumstances when it is not reasonably possible to comply with these timelines. In these cases, the Administrator (as defined below) shall work as quickly as is reasonably possible.

c) Process

After receiving the allegation, the Responsible Officer, in consultation with the Respondent's Chief where appropriate, shall chose the individual who will conduct the inquiry ("Administrator"). The Administrator shall disclose any actual, apparent, perceived or potential conflicts of interest to the Responsible Officer.

The Responsible Officer or Administrator will send each of the Complainant and the Respondent a letter outlining the process and will provide each with a copy of this Policy document. The Respondent will be given a copy of the Allegation and may be informed of the identity of the Complainant. The Respondent will be requested to provide a written response to the allegations. The Respondent has the right to and is encouraged to seek independent legal advice.

The Administrator will review relevant documents and records and may, at his or her discretion, consult with anyone (which may include interviews with the Complainant and/or Respondent) who has information that might be helpful. The Administrator will make a decision based on the information he or she is able to obtain, irrespective of whether individuals choose to cooperate with the inquiry.

If the evidence discloses a new related instance of possible Research Misconduct that was not part of the original complaint or which suggests additional Respondents, the Administrator will include such information in the Administrator's report to the Responsible Officer.

d) Outcome of Inquiry

The Administrator shall write a letter to the Responsible Officer that clearly outlines the Administrator's determination of whether an investigation is warranted or not and reasons. The Responsible Officer shall then write to each of the Complainant and the Respondent to inform them of the determination and to adequately summarize the reasons for the determination.

If the Administrator has determined that there are insufficient grounds to proceed with an investigation, the Responsible Officer may propose alternate forms of dispute resolution, such as mediation, if appropriate.

The Responsible Officer shall report the results of the inquiry to the President & CEO or Respondent's Chief, other relevant members of the Hospital's senior management and anyone else who the Responsible Officer considers has a need to know, including for example, the Research Ethics Board ("**REB**") and the Director Government Research Infrastructure Programs if United States federal funds were involved in the research. Where it is determined that an investigation is warranted, the Responsible Officer may inform other related Institutions, and indicate that their cooperation and assistance may be required. If there is a reasonable likelihood that the alleged incident is going to be reported publicly or a reasonable likelihood that criminal charges will be laid, the Responsible Officer may, in consultation with the Legal Counsel and senior management responsible for communications, inform other parties such as the relevant funding sources, scientific journals and other professional bodies that an investigation will take or is taking place.

4.8 Investigation

a) Purpose of the Investigation
The investigation is a formal process to examine the Allegations and to weigh the evidence to determine if Research Misconduct has occurred, and if so, who the involved parties are.

b) Timing

The Responsible Officer will appoint a committee to perform the investigation ("**Investigating Committee**") within 15 working days of receiving the Administrator's letter. The Investigating Committee is expected to convene within 30 working days of its appointment. The investigation is expected to be completed within 60 working days of the first meeting of the Investigating Committee. The final report of the Investigating Committee is expected to be delivered within 30 working days after the completion of the investigation. There may be circumstances when it is not reasonably possible to comply with these timelines. In these cases, the Responsible Officer and Investigating Committee shall work as quickly as is reasonably possible.

c) Investigating Committee

The Investigating Committee reports to the Responsible Officer. It shall have a minimum of three members and will perform the investigation in accordance with this policy. The chair of the Investigating Committee must be a senior member of the Hospital or another academic institution. The Responsible Officer will assign administrative support to the Investigating Committee if necessary. The Investigating Committee may delegate an individual to perform certain duties of the

committee ("**Investigator**").

The members of the Investigating Committee and the Investigator shall each disclose any conflicts of interest to the Responsible Officer. The Responsible Officer will provide each member of the Investigating Committee with a written terms of reference, this policy, a copy of all the information gathered at the inquiry stage, applicable funding agency policies and any other relevant information.

The Investigator and/or Investigating Committee will review relevant documents and records and may, at his or her or its discretion, (i) consult with anyone (internal or external, including interviews with the Complainant and/or Respondent) who has information that might be helpful, and (ii) examine relevant documents, data and records (including those not available during the inquiry).

d) Process

The chair of the Investigating Committee shall notify each of the Respondent and the Complainant of the appointment of the committee (including membership). If the evidence discloses a new related instance of possible Research Misconduct that was not part of the original Allegation or which suggests additional Respondents, the Investigating Committee may expand the investigation upon notice to the Respondent and any new Respondents, giving each an opportunity to respond in writing.

All involved parties will be expected to cooperate with the investigation in a timely manner. The Investigating Committee will set a deadline by which all responses must be made and all evidence must be submitted. Late responses are only accepted if permitted by the chair. Failure to respond and other uncooperative behaviour will be referred to the Responsible Officer and could result in institutional sanctions. If either the Respondent or the Complainant decides not to participate further, the Investigating Committee will proceed with the investigation in any event.

The Investigating Committee is required to meet with the Respondent at least once. The Respondent must be given adequate opportunity to present his or her case and to respond to evidence and arguments being advanced by the Complainant or by the Investigating Committee. The Respondent and Complainant may have legal counsel or a representative present when meeting with the Investigating Committee. At any point, and especially if the Respondent's legal counsel attends, the chair of the Investigating Committee may ask the Hospital Legal Counsel to be present as well.

The Investigating Committee will take reasonable steps to provide reasonable access to relevant documents in their possession to the Respondent, provided that the Respondent signs a confidentiality agreement before any such materials are provided.

The Investigating Committee chair shall ensure that summaries of interviews are prepared, provided to the interviewed party for comment or revision, and included as part of the investigation file.

If there are interim findings that the Investigating Committee believes ought to be reported in order to protect the public good and the interests of other researchers, the chair may make a written interim report to the Responsible Officer setting out the findings, the reason for the report, and a recommendation regarding appropriate administrative action.

4.9 Outcome of the Investigation

a) Interim Reports

Upon receipt of an interim report, the Responsible Officer will determine if, pending the results of the investigation, any restrictions or suspension of the Respondent's activities are warranted. This may include, but is not limited to, freezing grant accounts, requiring a second authorized signature from an institutional representative on all expenses charged to the researcher's grant accounts, or other measures, as appropriate[5]. The Responsible Officer shall determine if a report of interim findings should be disclosed to protect the public, research participants, or other researchers. To protect any funding entity, the Responsible Officer may authorize the withholding of research funds until the Allegation is resolved.

b) Report of the Investigating Committee

The decisions of the committee as to whether or not there is a finding of Research Misconduct shall be made by majority vote. All members vote including the chair.

The Investigating Committee shall report its findings in writing to the Responsible Officer, setting out the elements listed in Schedule D. All members of the Investigating Committee must sign a statement indicating that they agree to the release of the report based on the majority decision.

The Responsible Officer shall provide a copy of the report to the Respondent and the Complainant. If there is more than one Respondent or Complainant, reasonable efforts will be made to provide each with parts of the report that are pertinent to him or her.

The Responsible Officer shall notify the President & CEO of the outcome and any resulting disciplinary action.

c) Cases where no Research Misconduct has been found

When an investigation determines that no Research Misconduct occurred, the Responsible Officer shall ensure that a letter confirming the finding of no Research Misconduct is sent, within 15 working days of receipt of the Investigating Committee's report, to the Respondent, with a copy to the Complainant and to other persons with knowledge of the Allegation (including all those who were notified under the authority of this policy). The Responsible Officer is not responsible for sending an official notice to every individual identified by the Respondent.

If the investigation discloses evidence of serious scientific error that requires further action (e.g., retraction of published research findings), the Responsible Officer, President & CEO and Respondent's Chief (if appropriate), chair of the Investigating Committee and the Respondent will consult together and the Responsible Officer will decide what action to take.

d) Cases where Research Misconduct has been found.

[5] Tri-Agency Framework, pg 8.

The nature and severity of disciplinary action will be proportional to the misconduct. The Responsible Officer may seek the opinion of ad hoc advisors (e.g., Human Resources, Legal Counsel, Dean of the University of Toronto or other affiliated university, etc.) as appropriate before he or she renders a decision as to appropriate disciplinary action.

The Responsible Officer will notify the Respondent in writing of the nature of the disciplinary action (**"Notice of Disciplinary Action"**) within 15 working days of receipt of the Investigating Committee's report. There may be circumstances when it is not reasonably possible to comply with this timeline. In these cases, the Responsible Officer shall work as quickly as is reasonably possible. Disciplinary action may include, but is not limited to:

- verbal warning
- issuance of a letter of concern to the respondent
- recommendations for remedial training
- special monitoring of future work
- request that the respondent correct the result of the misconduct, if appropriate
- verbal warning with a letter to be held temporarily on file in the Responsible Officer's office
- letter of reprimand to the Respondent's permanent personnel file
- withdrawal of specific privileges
- removal of specific responsibilities
- advising the respondent that the Institution will not consider him/her to serve on Institution committees (e.g. peer review, advisory boards, etc.)
- suspension
- steps to terminate the Respondent's research activities, and/or
- steps to terminate the Respondent's employment or appointment

The Responsible Officer at his or her discretion may communicate the outcome of the investigation to parties within or external to the Hospital, including but not limited to:

- Members of the Hospital's senior executive
- Chair of the Research Ethics Board
- Internal Research Counsel
- Chair or Dean of a relevant University of Toronto or other affiliated university department
- institutional representative of new institution if the Respondent has left the Hospital
- sponsoring agencies and funding sources
- co-authors, co-investigators, collaborators
- editors of journals in which fraudulent research or erroneous findings were published
- editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the individual has been affiliated in the past
- professional licensing boards
- professional colleges, bodies, societies, and/or
- police services.

Consideration will be given to addressing other researchers and students who were involved with the research, but who were unaware of the misconduct, with respect to finding them a suitable alternative research placement.

4.10 Appeals

The Respondent has the right to one appeal. The Respondent may only appeal the disciplinary action but not the findings of the Investigative Committee. Such appeal is made to the President & CEO. Notice of appeal must be delivered to the President & CEO within 5 working days of the receipt of the Notice of Disciplinary Action. The Responsible Officer will not institute irreversible disciplinary actions (such as public notifications) until 5 business days have elapsed from the issuance of the Notice of Disciplinary Action. The President & CEO's decision regarding the appeal is final.

The Complainant shall not have a right to appeal the outcomes of the inquiry and/or investigation, the disciplinary action or other decisions under this policy unless new and compelling information becomes available that was not reasonably available at the time of the original Allegation.

4.11 Record Keeping

After the Investigating Committee delivers its report, all members of the Investigating Committee shall return all documentation to the Responsible Officer. The Responsible Officer shall maintain detailed documentation of the inquiry and of the investigation (including, at a minimum, the report of the Administrator and of the Investigating Committee and all actions taken) in a confidential and secure manner for a period of at least three (3) years. Additional documents required by funding agencies will also be maintained. The Responsible Officer shall be permitted to periodically prepare and publish summaries of decisions (with personal identifiers removed) for the purpose of educating researchers on acceptable practices for scholarly integrity and research ethics.

4.12 Indemnification

The Hospital shall indemnify individuals serving as members of the Investigating Committee, the Investigator, the Administrator, ad hoc advisors, or other individuals assigned to assist any of the above or the Responsible Officer in the conduct of matters under these guidelines according to its policies against any claims arising from such service and the opinions, conclusions, and recommendations reached by such individuals, provided that their duties were disposed of in good faith and that the acts were within the scope of their assigned duties.

5. References

5.1 Related Policies

- Reporting and Investigation of Suspected Financial Wrongdoing
- MSH Code of Ethical Conduct

5.2 Sources

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***Approved by*:-** **Board of Directors**

***Title*:-** **RESEARCH MISCONDUCT POLICY**

- University of Toronto's Principles and Responsibilities Regarding Conduct of Research, October 11, 2002
- University of Toronto Framework to Address Allegations of Research Misconduct, November 27, 2006
- University of Toronto, "Policy on Ethical Conduct in Research"
- The Hospital for Sick Children, Ethical Conduct of Research (May 1, 2009)
- St. Michael's Hospital, Research Misconduct Policy and Procedure
- University Health Network, Misconduct in Research (draft 2010)
- Tri-Council Policy Statement, Integrity in Research and Scholarship
- Canadian Panel on Responsible Conduct of Research, *The Tri-Agency Framework: Responsible Conduct of Research*, Ottawa, 2011, http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/
- The Expert Panel on Research Integrity, "Honesty, Accountability, and Trust: Fostering Research Integrity in Canada,"*Council of Canadian Academies*, Ottawa, 2010 Honesty, Accountability, and Trust: Fostering Research Integrity in Canada.pdf

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Schedule D –Considerations for the Report of the Investigative Committee

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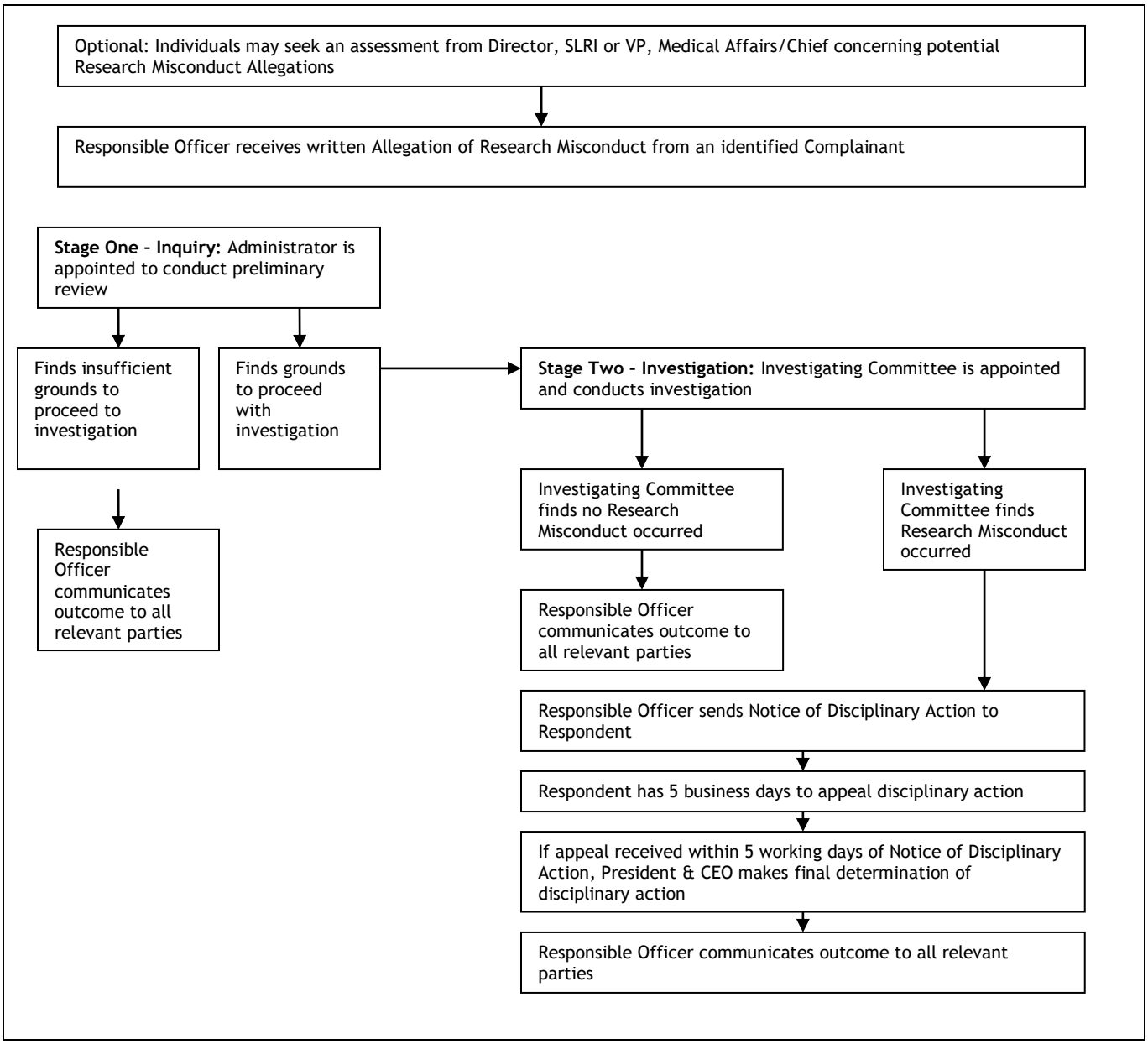

Schedule B – Examples of Research Misconduct

"Research Misconduct" means any research practice that deviates seriously from the commonly accepted ethics/integrity standards of the relevant research community. Examples of Research Misconduct include the following genuine breaches of the integrity of the scientific process:

a) Scientific misconduct

a. *Fabrication*: Making up data, source material, methodologies or findings, including graphs and images.

b. *Falsification*: Manipulating, changing, or omitting data, source material, methodologies or findings, including graphs and images, without acknowledgement and which results in inaccurate findings or conclusions.

c. *Destruction of research records*: The destruction of one's own or another's research data or records to specifically avoid the detection of wrongdoing or in contravention of the applicable funding agreement, institutional policy and/or laws, regulations and professional or disciplinary standards.

d. *Plagiarism*: Presenting and using another's published or unpublished work, including theories, concepts, data, source material, methodologies or findings, including graphs and images, as one's own, without appropriate referencing and, if required, without permission.

e. *Redundant publications*: The re-publication of one's own previously published work or part there of, or data, in the same or another language, without adequate acknowledgment of the source, or justification.

f. *Invalid authorship*: Inaccurate attribution of authorship, including attribution of authorship to persons other than those who have contributed sufficiently to take responsibility for the intellectual content, or agreeing to be listed as author to a publication for which one made little or no material contribution.

g. *Inadequate acknowledgement*: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.

h. *Mismanagement of Conflict of Interest:* Failure to appropriately manage any real, potential or perceived conflict of interest, in accordance with the Institution's policy on conflict of interest in research, preventing one or more of the objectives of the policy from being met.[6]

b) Material Breach of Confidentiality

- Material breach of a duty to protect personal information (including but not limited to personal health information) or of a duty of confidentiality owed to a human subject;
- Material breach of a duty of confidentiality owed to a colleague (e.g., failure to obtain the permission of the author before using new information, concepts or data originally obtained through access to

[6] This section taken from Tri-Agency Framework, pg 5.

confidential manuscripts or applications for funds for research or training that may have been seen as a result of processes such as peer review);
- Material breach of a duty of confidentiality that was promised or contracted to as a way to gain valuable information from a party internal or external to the hospital;
- Deliberate destruction of someone else's data or records without authorization; or
- Breach of a duty of confidentiality in an inquiry/investigation of research misconduct.

c) Financial Misconduct:

- Deliberate misuse of funds acquired for the support of research
- Making misleading budget requests for research;
- Provision of misleading information for contractual purposes;
- Deliberate breach of terms and conditions of grants and/or contracts;
- Misuse of resources, facilities or equipment of the hospital or any collaborators ; or
- Failure to correctly identify the source of research funds.

d) Offer or Acceptance of Finders Fees

- Offer or acceptance of finder's fees or completion fees (as defined in the Hospital's Research Conflicts of Interest policy); or
- Assessment of potential recruits for a research study with the knowledge that other researchers will obtain payment of finder's fees for that research study.

e) Material Failure to Adhere to Laws, Regulations, Policies and Guidelines (national, provincial, funding agency and hospital):

- Material failure to adhere to laws, regulations, policies and guidelines (national, provincial, funding agency and hospital) concerning, among other things:
    - Research involving human subjects and tissue,
    - research involving animals,
    - health and safety standards,
    - conduct and reporting of research, or
    - conflicts of interest;
- Material failure to (i) provide relevant materials to, (ii) comply with a direction of, or (iii) notify of protocol changes that may affect decision making and approvals of the hospital's Research Ethics Board, Animal Care Committee or Biosafety Committee as required by the applicable committee;
- Failure to reveal material conflicts of interest to the hospital, sponsors, funding agencies, colleagues or journal editors when submitting a grant, protocol or manuscript or when asked to undertake a review of research grant applications, manuscripts or when asked to test or distribute products; or
- Failure to declare conflicts of interest when making an allegation of Research Misconduct.

f) Condoning Research Misconduct

- Condoning or not reporting the performance by another researcher of any of the acts noted above;
- Encouragement or facilitation of another researcher to carry out Research Misconduct; or

- Otherwise creating an environment that promotes Research Misconduct by another.

g) Retaliation Relating to Research Misconduct

- Retaliation against a person who reported or provided information about alleged Research Misconduct in good faith.

h) Making an allegation in bad faith

- Knowingly making an allegation that is untrue, frivolous, vexatious or that the Complainant could reasonably and readily have determined was false through minimal diligence.

Schedule C - Research Misconduct Framework Addendum

Faculty of Medicine, Research Misconduct Framework Addendum *June 12, 2010*

Procedures for Determining Jurisdiction in Complaints Involving Certain Non-University Institutions

1.0 Preamble
In November 2006, the University of Toronto (the **"University"**) issued its *Framework to Address Allegations of Research Misconduct* (the **"Framework"**). The Framework is supplemental to the University *Policy on Ethical Conduct in Research* and prescribes detailed procedures for the handling of allegations of research

misconduct. The Framework complies with the requirements of the Tri-Council Agencies (CIHR, NSERC, or SSHRC) and other granting agencies.
This Addendum provides a process for determining institutional jurisdiction over Complaints of research misconduct made against persons to whom the Framework applies who have appointments at, and/or conduct their research in, Affiliated Institutions.

2.0 Definitions
Unless otherwise defined in this section, capitalized terms have the meanings set out in the Framework.

a) **"Affiliated Institution"** means a fully affiliated or community affiliated teaching hospital which is party to an affiliation agreement with the University signed by the authorized officers of the parties, and any other institution independent from the University which has agreed to be bound by the Framework under an agreement signed by the authorized officers of the parties. For greater certainty, no federated college of the University shall be considered to be an Affiliated Institution for the purposes of this Addendum.
b) **"Responsible Officer"** means (i) for the University, the University's Vice-Provost, Relations with Healthcare Institutions and (ii) for an Affiliated Institution, the Affiliated Institution's Vice-President, Research (or equivalent), or delegate as communicated in writing to the other party's Responsible Officer.
c) **"Status-Only Appointee"** means a person who has a primary appointment at an Affiliated Institution and excludes Teaching Staff, employees of the University and Students.
d) **"Student"** means a student enrolled in an academic program of the University.
e) **"Teaching Staff"** means employees of the University, University College, the constituent colleges and the arts and science faculties of the federated universities who hold the academic rank of professor, associate professor, assistant professor, full-time lecturer or part-time lecturer, unless such part-time lecturer is registered as a student, or who hold any other rank created by the University and designated by it as an academic rank under the *University of Toronto Act*. **Faculty of Medicine, Research Misconduct Framework Addendum** *June 12, 2010*

3.0 Applicability
This Addendum applies only to Complaints made against persons who conduct research under the auspices of either or both the University and an Affiliated Institution and who have an appointment at an Affiliated Institution and/or conduct their research at an Affiliated Institution.
The University and Affiliated Institutions agree to follow the procedures in this Addendum to determine jurisdiction and to determine if notice of the Complaint by one party to another is required hereunder. The University and Affiliated Institutions agree to comply with reasonable requests for information, documentation and attendance at meetings by the other. Timeframes as provided by the Framework are not changed by this Addendum.

4.0 Receipt of Complaint
If the University receives a Complaint against a Status-Only Appointee or an employee of an Affiliated Institution or where the research that is the subject matter of the Complaint was conducted, in whole or in part, at the Affiliated Institution, the University shall notify the Affiliated Institution's Responsible Officer.
If an Affiliated Institution receives a Complaint against a member of the Teaching Staff, a Student or a University employee or where the research that is the subject matter of the Complaint was conducted, in whole or in part, at the University, the Affiliated Institution shall notify the University's Responsible Officer.

If either the University or the Affiliated Institution receives a Complaint against an individual who is cross-appointed at the University and the Affiliated Institution but who is not listed above, the institution that received the Complaint shall notify the other party's Responsible Officer and they shall jointly determine jurisdiction in accordance with the procedures below.

If a Complaint is received against an individual who is cross-appointed at more than one Affiliated Institution, the Responsible Officers of the Affiliated Institutions may use the criteria below to determine jurisdiction.
Where, after jurisdiction has been assumed by either the University or an Affiliated Institution or jointly by more than one institution, it is subsequently determined that the Complaint involves additional institution(s), the Responsible Officer of the institution that has taken jurisdiction shall notify the Responsible Officer of the additional institution(s) and they shall jointly re-determine jurisdiction in accordance with the Framework and this Addendum.

5.0 Determining Jurisdiction

a) For Complaints against Status-Only Appointees or employees of an Affiliated Institution, jurisdiction is presumed to be solely at the Affiliated Institution unless the criteria below convince the Affiliated Institution's Responsible Officer otherwise. **Faculty of Medicine, Research Misconduct Framework Addendum** *June 12, 2010*

b) For Complaints against members of the Teaching Staff, Students or University employees, jurisdiction is presumed to be solely at the University unless the criteria below convince the University's Responsible Officer otherwise.

c) For Complaints against an individual not listed in 5a) or 5b) above who is cross-appointed at both of the University and the Affiliated Institution, jurisdiction should not be presumed by either the University or the Affiliated Institution and must be determined as outlined below.

Jurisdiction will be determined by establishing which institution has the stronger connection to the Complaint. In general, the following factors shall be considered in determining jurisdiction:

(i) Where was the research that is the subject matter of the Complaint conducted (e.g., University or Affiliated Institution premises)? If the Complaint involves several research studies or a body of research, the focus will be on where the research is primarily conducted.

(ii) Where did supervision for the research occur?

(iii) Which institution administered the research funding, if any?

(iv) Which institution is party to the research contract with any third party?

(v) Which institution's research ethics board, animal care committee or biosafety committee conducted the full board review of the research?

In some cases, it may be determined that both the University and the Affiliated Institution should have joint jurisdiction.

Responsibilities of the Institution that has Jurisdiction

The institution that has jurisdiction as determined hereunder shall be responsible for all communications to the Complainant and Respondent. Where there is joint jurisdiction, the Responsible Officers of the University

and the Affiliated Institution will jointly make decisions typically made by an institution with sole jurisdiction (e.g., who will act on their behalf to serve the role of Academic Administrator and who shall serve as Chair and members of any Investigation Committee that may be established) and any administrative action and reporting requirements shall be jointly determined by the institutions. Should the Responsible Officers be unable to reach a joint decision, the matter shall be referred to the applicable hospital CEO and the University Provost, in consultation with the University's Vice-President, Research, for resolution. Each party shall have the option of having at least one representative on the Investigation Committee. **Faculty of Medicine, Research Misconduct Framework Addendum** *June 12, 2010*

Notice Requirements
In cases where sole jurisdiction lies with either the University or an Affiliated Institution but circumstances warrant notice to the other institution, notice of the outcome of the Inquiry and/or Investigation shall also be made to the other institution.

Non-duplication and Sanctions
Neither the University nor the Affiliated Institution will pursue the same or substantially similar allegation, unless new and compelling information becomes available that was not reasonably available at the time of the original Complaint. In such case, the matter will be treated as a new Complaint under this Addendum and will be subject to the jurisdictional determinations outlined herein.

Notwithstanding that the University or an Affiliated Institution did not participate in or have jurisdiction to conduct an inquiry or investigation in connection with a Complaint, nothing in the Framework or this Addendum prevents either the University or the Affiliated Institution from imposing the same or comparable sanctions in connection with the Complaint based on the conclusions reached in the inquiry or investigation.

Schedule D - Considerations for the Report of the Investigative Committee

The report should contain the following elements:

- The full Allegation
- A list of the Committee members and their credentials
- The process and time lines followed for the inquiry and/or investigation
- A list of the people who contributed evidentiary material to the Investigation, including a list of those who were interviewed as witnesses
- A summary of relevant evidence
- A determination of whether Research Misconduct occurred
- If Research Misconduct occurred, its extent and seriousness
- Recommendations on remedial action to be taken and/or recommendations of changes to procedures or practices to avoid similar situations
- The researcher's response to the allegation, investigation and findings, and any measures the researcher has taken to rectify the breach

Recommendations of the Investigative Committee may include, without limitation:

- Withdrawing any or all pending relevant publications
- Notifying publications in which the involved research was reported
- Ensuring the unit involved is informed of appropriate practices for promoting the proper conduct of research
- Recommending any actions to be taken
- Informing any outside funding entity of the results and actions to be taken

Recommendations of the Investigative Committee should not include:

- Information that is not related specifically to the Institution's funding and policies as they pertain to the allegations
- Personal information about the researcher, or any other person, that is not material to the Institution's findings and its report to the Responsible Officer[7].

[10] Tri-Agency Framework, pg 9.

[7] Tri-Agency Framework, pg 9.