The Ottawa Hospital RESEARCH INSTITUTE | L'Hôpital d'Ottawa INSTITUT DE RECHERCHE

ADMINISTRATIVE POLICY

APPROVED: Senior Management Committee

POLICY NUMBER: ADM XI 110a

APPROVAL DATE: April 1, 2016

IMPLEMENTATION DATE: April 1, 2016

RESPONSIBLE CONDUCT OF RESEARCH

POLICY STATEMENT

PREAMBLE

The knowledge created through Research conducted by The Ottawa Hospital ("Hospital") and its research arm the Ottawa Hospital Research Institute ("Institute") contributes to the intellectual, social, health and economic fabric of society. Our communities and society trust the integrity of our Researchers and have confidence in our institutional and individual compliance with the regulations, policies, practices and ethical norms that govern Research. The Hospital and its Institute recognizes their responsibility to provide an environment that supports and promotes the responsible conduct of research.

PURPOSE

1. The purpose of this Policy is to confirm the Hospital and Institute's continued commitment to the highest standards of integrity in all aspects of Research, including seeking funding, conducting Research and reporting the results.

APPLICATION AND SCOPE

2. Capitalized words and expressions used in this Policy have a corresponding meaning attributed to them as set out in the Definitions at Section 28 of this Policy and Section 42 of Procedure ADM XI 110b.

3. This Policy applies to all Members of the Hospital and Institute engaged in Research under the Hospital and Institute's auspices or jurisdiction, regardless of the location of the Research, and includes all physicians and health professionals with Hospital appointments

4. The Director, Research Ethics and Integrity at the University of Ottawa will be consulted regarding any matter that falls within the scope of responsibility of the University of Ottawa, e.g. involving university employees and trainees.

POLICY

5. The Hospital and Institute are committed to:

    a) maintaining the highest standards of integrity in its research activities;

    b) maintaining a research environment that promotes the responsible conduct of research and academic freedom;

    c) fulfilling its responsibilities in upholding applicable legislation for the conduct of Research and the policies, rules, regulations and its contractual agreements with Research Sponsors and with the Agencies.

6. The Hospital and Institute recognizes its responsibility for promoting awareness and importance of responsible conduct of research.

7. The Hospital and Institute has established minimum requirements for the responsible conduct of research and procedures for addressing Allegations as set out in Procedure ADM XI 110b established under this Policy.

8. It is a collective responsibility of all Members of the Hospital and Institute to promote a culture of high integrity standards in Research activities, to ensure responsible conduct of Research and to abide by Applicable Laws for the conduct of research and Research Sponsors' Policies and/or Requirements.

9. Allegations of suspected Breaches of Responsible Conduct of Research, made in good faith, are a necessary and valuable service and individuals are expected to report in good faith any information pertaining to possible Breaches of Responsible Conduct of research and to participate, as appropriate, in the process Inquiry and/or Investigation to address such Allegations or Breaches.

10. The Hospital and Institute provides and maintains a fair and timely process for reporting, investigating and addressing Allegations and determines consequences through collective agreement provisions or under Procedure ADM XI 110b established under this Policy.

11. The Hospital and Institute are committed to continuing its work with the University and its affiliated partners to harmonize the procedures for investigating and addressing Allegations.

12. The Hospital and Institute will take appropriate preventative and corrective action when a Breach of Responsible Conduct of Research occurs and will, where warranted, hold individuals responsible in accordance with applicable collective agreement provisions, terms of employment or other Hospital and/or Institute Policies and Procedures.

13. A person may file or withdraw an Allegation pursuant to this Policy and its Procedure ADM XI 110b without fear of reprisal or threat, except where paragraph 14 of this Policy applies.

14. Where the Hospital and Institute has finally determined the Allegation is not made in good faith or is made with malice, the Hospital and Institute will take appropriate preventative and corrective action, and will, where warranted, hold individuals responsible in accordance with applicable collective agreement provisions, terms of employment or other Hospital and Institute Policies and Procedures.

CONFIDENTIALITY

15. Allegations will be treated in a confidential manner and in accordance with the provisions of any applicable collective agreement and having regard to applicable privacy legislation.

16. All individuals involved in an Allegation and the process for addressing such an Allegation must keep the matter confidential in order to safeguard individuals against unsubstantiated Allegations, to protect the rights of those involved in the Allegation and to preserve the integrity of the Inquiry and Investigation.

ACCOUNTABILITY

17. Throughout the process for addressing an Allegation, the Office of TOH Executive Vice President, Research and the CEO and Scientific Director of the Research Institute ("TOH EVP Research") shall be responsible for:

    a) ensuring that the process for addressing an Allegation set out in Procedure ADM XI 110b is dealt with in a timely manner and in accordance with Procedure ADM XI 110b.

    b) consulting with the Chief of Staff at TOH on all matters potentially pertaining to patient safety or quality or any matters related to TOH medical staff professionalism, including medical staff at the University of Ottawa Heart Institute ("UOHI")

    c) consulting with the President and CEO of the University of Ottawa Heart Institute, on any matters potentially pertaining to members of the University of Ottawa Heart Institute ("UOHI") and/or Ottawa Heart Institute Research Corporation ("OHIRC")

    c) providing reports on the status and outcome of Inquiries and Investigations into an alleged Breach of Responsible Conduct of Research to the appropriate bodies, including Research Sponsors, Agencies, the Secretariat on Responsible Conduct of Research or to the Hospital's Research Ethics Boards, as may be required, and having regard to confidentiality considerations and to applicable privacy legislation; and

    d) preparing public statistical annual reports on confirmed findings of Breaches of Responsible Conduct of Research and action taken, subject to applicable privacy legislation.

18. TOH EVP Research shall report to the Hospital and Institute Senior Management Committees on all activities related to the promotion and implementation of Policy ADM XI 110a Responsible Conduct of Research and Procedure ADM XI 110b.

IMPLEMENTATION AND REVIEW

19. TOH EVP Research is responsible for the implementation and review of this Policy and making recommendations for amendments to it for the final approval of the Senior Management Team of the Institute and Hospital.
20. TOH EVP Research through the Senior Management Teams of the Hospital and Institute, shall establish procedures relating to the implementation of this Policy including, without limitation, Procedure ADM XI 110b Procedure for Addressing Allegations of a Breach of Responsible Conduct of Research.

CONFLICT OF INTEREST

21. All parties involved in misconduct Allegations, Inquiries or Investigations shall reveal the presence of any and all potential, perceived or actual conflicts of interest. All parties involved in misconduct Inquiries or Investigations will have no potential, perceived or actual Conflicts of Interest.

22. If the person who would normally run an Inquiry or Investigation is in a Conflict of Interest, the Allegation should be addressed to the Director, HR, Research Administration and Integrity ("Director of Research Integrity"), who will consult the TOH EVP Research so that a replacement can be chosen.

23. If the Allegation is made against the Director of Research Integrity or if the Director of Research Integrity is in a Conflict of Interest, TOH EVP, Research will choose a replacement who will take on the duties of the Director of Research Integrity for the case.

24. If the Allegation is made against TOH EVP, Research or if TOH EVP Research is in a Conflict of interest, a replacement will be chosen by the President of the Hospital in consultation with the Chair of the Research Institute Board of Directors.

25. If the Allegation is made against the President and CEO of the Hospital or if the President and CEO of the Hospital is in a Conflict of Interest, the Director of Research Integrity, acting through the Chief of Staff of the Hospital, will consult the Chair of the Hospital Board of Governors to determine an appropriate course of action and process, consistent with the principles of this Policy.

DEFINITIONS

26. For the purposes of this Policy and Procedure ADM XI 110b established under this Policy, the following words and expressions shall have the corresponding meaning as set out below and in Section 42 of Procedure ADM XI 110b. For the most part these definitions are based on the *Tri-Agency Framework: Responsible Conduct of Research*.

Agency or Agencies: Refers to any one of the following or collectively as the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC).

Allegation: A declaration, statement, or assertion communicated in writing to the effect that there has been, or continues to be, a Breach of Responsible Conduct of Research, the validity of which has not been established.

Applicable Laws: An expression to encompass all of the laws, regulations, professional or disciplinary standards or guidelines, relating to Research or to investigating or addressing a Breach of Responsible Conduct of Research. Examples include the *Tri-Agency Framework: Responsible Conduct of Research*; 2nd edition of the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS 2); Canadian Council on Animal Care Policies and Guidelines; Agency policies related to the Canadian Environmental Assessment Act; Licenses for Research in the field; Laboratory Biosafety Guidelines; Controlled Goods Program; Canadian Nuclear Safety Commission (CNSC) Regulations; and Canada's Food and Drugs Act; access to information and protection of privacy laws.

Breach of Responsible Conduct of Research: An expression used to encompass the following non-exhaustive list, but which does not include honest error or honest differences of opinion in the carrying out of Research or scholarly activity:

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 applicable funding agreements, Hospital and Institute policies 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 thereof, or data, in the same or another language, without adequate justification or acknowledgment of the source.

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 or with Research Sponsors' Policies and/or Requirements.

i) **Misrepresentation in a funding application or related documents**:

(i) Providing incomplete, inaccurate or false information in a grant or award application or related document, such as a letter of support or a progress report, including misrepresenting one's credentials, qualifications and/or research contributions;

(ii) Applying for and/or holding an NSERC, SSHRC or CIHR award when deemed ineligible by NSERC, SSHRC, CIHR or any other research or research funding organization world-wide for reasons of Breach of Responsible Conduct of Research policies such as ethics, integrity or financial management policies.

(iii) Listing of co-applicants, collaborators or partners without their agreement.

j) **Mismanagement of Grants or Award Funds**: Using grant or award funds for purposes inconsistent with the Institute or Research Sponsor policies; misappropriating grants and award funds; contravening Research Sponsor financial policies; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

k) **Breaches of policy and regulatory requirements**:

(i) Failing to meet Hospital and Institute Policies or Procedures, Applicable Laws, or Research Sponsors' policies, rules, regulations, or contractual agreements or to comply with relevant policies, laws or regulations including, without limitation;

a. the *Tri-Agency Framework: Responsible Conduct of Research*;
b. 2nd edition of *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS 2);
c. Canadian Council on Animal Care Policies and Guidelines;
d. Agency policies related to the Canadian Environmental Assessment Act;
e. Licenses for research in the field;
f. Laboratory Biosafety Guidelines;
g. Controlled Goods Program;
h. Canadian Nuclear Safety Commission (CNSC) Regulations;
i. Canada's Food and Drugs Act;
j. access to information and protection of privacy laws.

(ii) Failing to obtain appropriate approvals, permits or certifications before conducting research activities.

Conflict of Interest: A Conflict of Interest may arise when activities or situations 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, his/her family members, friends, or former, current or prospective professional associates.

Inquiry: The process of reviewing an Allegation to determine 1) whether the Allegation is responsible, 2) the particular policy or requirements of responsible conduct of research that may have been breached, and 3) whether an Investigation is warranted based on the information provided in the Allegation.

Investigation: A systematic process of examining an Allegation, collecting and examining the evidence related to the Allegation, and making a decision as to whether a Breach of Responsible Conduct of Research has occurred.

Member(s) of the Hospital and Institute: An expression to encompass all Hospital and Institute individuals that may be engaged in Research, including but not limited to:

a) employees, including all unionized and non-unionized staff as well as those whose salary is paid through sources other than the Hospital and Institute's operating funds, such as research grants and external contracts;
b) students, meaning individuals registered at the University, whether full time or part time and including special students, at the undergraduate or graduate level;
c) appointed scientists or investigators, post-doctoral or clinical fellows, Research Trainees, medical residents, visitors, including visiting students and volunteers; and
d) physicians with Hospital privileges, including physicians at UOHI.

Primary Appointment: The lead institution (University or affiliated research hospital) responsible for the appointment and personnel costs of the Principal Investigator or Researcher. For undergraduate and graduate students whose work is being conducted in fulfillment of their academic programs such as thesis-related work, the Primary Appointment shall be at the University of Ottawa.

Principal Investigator: The person who has ultimate responsibility for a research project. In the case of a project funded by an external or internal grant or contract, the Principal Investigator is the holder of the grant or contract. In the case of a project that is not funded, the Principal Investigator is the initiator of the Research project. The Principal Investigator is usually the supervisor of the Research Team and is usually an investigator or scientist at the Hospital or Institute.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Research Sponsor: The funding agency, foundation, organization or individual, or other entity, public or private, international, national, provincial or foreign, providing funding to the Hospital or Institute and Member of the Hospital or Institute.

Research Sponsors' Policies and/or Requirements: An expression to encompass all of the policies, rules, directives, guidelines, regulations, processes, funding agreements with the Hospital or Institute and contractual requirements established by Research Sponsors or Agencies, related to applying for and managing research funds, performing Research,

disseminating Research results and the investigation of an Allegation. Examples of such policies and requirements include the 2nd edition of *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans* (TCPS 2), *The Tri-Agency Framework: Responsible Conduct of Research* and the *Agreement on the Administration of Agency Grants and Awards by Research Institutions*.

Research Trainee: Any undergraduate or graduate student, post-doctoral fellow or clinical fellow engaged in a research project, including visiting students and fellows.

Researcher: Anyone who conducts research activities.

Secretariat on Responsible Conduct of Research (or "**SRCR**")**:** The body responsible for providing substantive and administrative support for the Agencies with respect to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 2nd edition (TCPS 2), and the *Tri-Agency Framework: Responsible Conduct of Research* (the Framework).

Institute Policies and Procedures: An expression to encompass the Institute's administrative policies and administrative procedures and academic regulations.

RELATED DOCUMENTS

Agency documents

- Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions (2013)
- Tri-Agency Framework: Responsible Conduct of Research (2011)
- Tri-Council Policy Statement: Ethical conduct for Research Involving Humans, second ed. (2014)

Ottawa Hospital Research Institute documents

- Conflict of Interest
- Technology Transfer/Intellectual Property Policy
- Research Grants and Salary Award Approval
- Research Contract Approval

The Ottawa Hospital documents

- TOH Fraud Prevention Policy No. 01274

University of Ottawa

- Policy 115 - Responsible Conduct of Research
- Procedure 29-2 – Addressing Allegations of a Breach of Responsible Conduct of Research

Other

- The United States Public Health Service (PHS) regulation, "Public Health Service Policies on Research Misconduct,":42 CFR 93
  http://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf