RESPONSIBLE CONDUCT OF RESEARCH

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1. PRINCIPLE

The University of Ottawa Heart Institute (UOHI) and the Ottawa Heart Institute Research Corporation (collectively referred to as "the Institute" within this policy) promote and support the highest standards of research integrity. It expects of its members** excellence in all aspects of responsible conduct of research including applications, proposals, the research itself, reports and publications, and financial management.

The Institute abides by the *Tri-Agency Framework: Responsible Conduct of Research* (RCR) which provides the following definition:

Responsible Conduct of Research is the behavior expected of anyone who conducts or supports research activities throughout the life cycle of a research project (i.e., from the formulation of the research question, through the design, conduct, collection of data, and analysis of the research, to its reporting, publication and dissemination, as well as the management of research funds). It involves the awareness and application of established professional norms, as well as values and ethical principles that are essential in the performance of all activities related to research. These values include honesty, fairness, trust, accountability, and openness.

** includes faculty, students/trainees, administrative staff and anyone holding an Institute or University post or any office that gives institute status, such as that of a fellow or a research associate. Students, trainees and research faculty with a primary appointment at the University are also expected to comply with the University of Ottawa Policy 115 – Responsible Conduct of Research.

2. QUALITIES OF RESEARCH ETHICS AND INTEGRITY

The Institute considers that the highest standards in research ethics and integrity would entail (although not exclusively):

1. Using a high level of rigor in proposing and performing research; in recording, analyzing, and interpreting data; and in reporting and publishing data and findings;

2. Keeping complete and accurate records of data, methodologies and findings, including graphs and images, in accordance with the applicable funding agreement, institutional policies and/or laws, regulations, and professional or disciplinary standards in a manner that will allow verification or replication of the work by others;

3. Referencing and, where applicable, obtaining permission for the use of all published and unpublished work, including data, source material, methodologies, findings, graphs and images;

4. Including as authors, with their consent, all those and only those who have materially or conceptually contributed to, and share responsibility for, the contents of the publication or document, in a manner consistent with their respective contributions, and authorship policies of relevant publications (See Policy 6-230 Publication and Authorship);

5. Acknowledging, in addition to authors, all contributors and contributions to research, including writers, funders and sponsors;

6. Obtaining necessary approvals and authorizations prior to the initiation of the study protocol, and complying with approved protocols;

7. Appropriately identifying and managing any real, potential or perceived conflict of interest, in accordance with the institution's policy on conflict of interest (See Policy 1-260 Conflict of Interest);

8. The maintaining of confidentiality

    a. with respect to information supplied by another when requested and appropriate use of that information in a manner authorized by the supplier of the information, and in accordance with scholarly practice;

    b. with respect to study participant information that is protected according to PHIPA; patients' personal identifying information (PII) or personal health information (PHI) must be protected in accordance with the Personal Health Information Protection Act (PHIPA), Institutional policies, and the privacy plan approved by the applicable research ethics board;

    c. about colleagues and students, obtained through administrative duties or participation in teaching activities, or otherwise obtained on a confidential basis;

9. The appropriate use and allocation of money or other resources supplied for research purposes; and

10. Investigating allegations of breach of policy(ies) by following the established practices and procedures of the Institute; all inquiries and proceedings will be conducted expeditiously. (See Policy 6-20 Addressing Allegations of Breach of Policy in Research)

3. ROLES AND RESPONSIBILITIES

The Institute will promote Research Integrity through:

- an established series of policies and procedures aimed at ensuring:
    - The ability to comply with the regulations;
    - The proper management of funds and accountability to the funding agencies according to their guidelines;
    - The responsible conduct of research activities in accordance with the highest standards of professionalism, safety and ethics, in compliance with governing legislation, regulations and guidelines;
    - Appropriate publication and authorship practices;
    - Appropriate guidelines for defining and investigating allegations of breach of responsible conduct of research

- developing awareness of the need for the highest standards of integrity, accountability and responsibility in the research being conducted;

- establishing mechanisms to educate researchers regarding the Institute's expectations for scientific integrity including, but not limited to: mandatory RCR training for all research staff at time of onboarding and annually thereafter, encouraging awareness through communication and information sessions; establishing policies addressing specific related areas such as publication and authorship, conflict of interest, use and retention of data, internal auditing, etc.;

- acknowledging and recognizing the contribution of collaborators and students;

- protecting all research archives according to the Institute's record retention policy (See Policy 1-140 Corporate File Retention and Destruction);

- ensuring that the ratio of other research personnel, especially trainees, to Principal Investigators is small enough to allow effective communication and continuous supervision of all aspects of the research; and,

- ensuring awareness that the point of contact for any concerns regarding a breach of policy is to the Chief Scientific Officer (CSO) or delegate, or if unavailable or inappropriate then the Division Chief or Chief Executive Officer (CEO).

- investigating all allegations of breach of policy and reporting to the Secretariat on Responsible Conduct of Research when applicable.

Researchers and students are responsible for:

- providing true and accurate information in documents, applications submitted for funding and dissemination;

- applying for funding only if not currently ineligible to apply for and/or hold funds from the Tri-agency or any other funding organization world-wide for reasons of breach of responsible conduct of research policies;

- supervising and training by the PI for the designing of research and the processes of acquiring, recording, examining, interpreting, reporting, publishing and storing data; simply editing publications is inadequate supervision;

- training by the PI on principles of RCR and the fostering of a positive and constructive research-working environment;

- ensuring the appropriate recognition of contributions from collaborators, students and/or others (e.g. authorship or acknowledgement) (See Policy 6-230 Publication and Authorship);

- obtaining permission from authors for use of materials where applicable (ie confidential, unpublished or patented, etc.) (See Policy 6-230 Publication and Authorship);

- revealing any potential, perceived or real conflict of interest (financial or other) that might influence work or related work (See Policy 1-260 Conflict of Interest);

- holding regular collegial discussions among all research personnel to contribute to the scholarly efforts of group members and to provide informal review;

- conducting ethical human research in compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human*s and, if applicable, the *International Council for Harmonization Good Clinical Practice (ICH-GCP) E6 Guidelines* and others as applicable;

- conducting research in compliance with applicable Tri-Agency requirements and legislation for the conduct of research including but not limited to:

    - Canadian Council on Animal Care Policies and Guidelines;
    - Agency policies related to the Impact Assessment Act;
    - Licenses for research in the field;
    - Laboratory Biosafety Guidelines;
    - Controlled Goods Program;

- managing grant funds in compliance with institutional policies and the *Tri-Agency Framework: Responsible Conduct in Research* and the *Tri-Agency Guide on Financial Administration*, inclusive of submission of accurate progress reports according to applicable funding requirements; and,

- appropriate record retention:
    - Original primary data/evidence must be retained by the program in which they are generated. With the knowledge and authorization of the Principal Investigator, a member of the research team may make copies of the primary data for his or her own use, (PII/PHI may not be shared, research records must be de-identified) but the immediate supervisor and all collaborators must have free access at any time to all original data/evidence and products of the research. Authorization to make copies may not be withheld without valid reasons. To withhold authorization, it must be communicated in writing to the CSO and/or CEO of the Heart Institute.

  - All primary data shall be promptly recorded in clear, accurate, original and permanent form which shall not leave the unit at any time. These records must be kept according to Policy 1-140 1-140 Corporate File Retention and Destruction, unless determined otherwise by the Research Ethics Board of Record or regulations. All permanent records must remain in the Institute upon departure of the investigator from the Institute.
  - When a Principal Investigator leaves OHIRC, arrangements for the safekeeping of records and/or products must be made with their Division Chief and/or the Chief Scientific Officer of the Institute.

- proactively rectifying a breach of agency policy (e.g., correcting the research record, providing an apology letter to those impacted, repaying funds, retracting publication, etc);

- if participating in agency review processes, comply with the Tri-agency's *Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations* and confirm they are not currently under investigation for an alleged breach of the RCR Framework or other responsible conduct of research policies.

4. POLICIES RELATED TO THE RESPONSIBLE CONDUCT OF RESEARCH

The following is intended to provide an overview of the policies under which the Institute and its researchers and staff conduct research. It is important that the Institute explicitly states its commitment to the principles of honesty, trust and collegiality and to the idea that fair play must prevail at all times. The objective of Institute guidelines will be to create an atmosphere that encourages ethical conduct, without interfering with freedom of inquiry, and without causing unnecessary administrative burdens.

It is important that the Institute operates within an ethical framework within which all research is conducted. The need for this has been identified by all major funding agencies, whether or not the project has grant funding.

It is the responsibility of the researcher to ascertain whether or not a project requires ethical approval and/or additional authorizations to conduct the research.

Selection and Conduct of Research

The primary responsibility for the selection and conduct of research rests with the individuals (Principal Investigator) performing the research. Research projects should be managed and conducted with due consideration for Institute and University policies on research integrity and ethics. It is the duty of the Investigator or in the case of team grants, the team leader, to ensure that his/her staff and team members are aware of the Institute's policies with respect of the conduct of research.

Supervision of Personnel

Careful supervision is in the best interest of the research personnel, students, trainees, the institution and the academic community. The complexity of research methods, the necessity for monitoring patient safety and caution interpreting data requires an active role by the Principal Investigator. The Principal Investigator is ultimately responsible for supervision of every element of a research project.

Human Participants or Human Data

Before research projects that involve humans or their data may be begin, they must be approved by a qualified research ethics board such as the Ottawa Health Science Network Research Ethics Board (OHSN-REB) or another board under the terms of a Board of Record Agreement such as those within Clinical Trials Ontario (CTO) and CanReview. Standards as outlined in the current edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) and the International Council for Harmonization Good Clinical Practice (ICH-GCP) Guidelines must be adhered to in all research involving human subjects. (See Policy 6-40 Research Involving Humans).

Animal Care

The Institute is committed to ensuring that the use of animals in research and in teaching conforms to the most rigorous ethical standards that are compatible with the goals of science. The University of Ottawa is responsible for the operation of the institute's animal facilities, and it is insistent upon maintaining very high standards for the facilities which support research and teaching involving laboratory animals. The standards for animal care and use conform with or exceed those outlined in the Canadian Council on Animal Care (CCAC) *Guide to the Care and Use of Experimental Animals.* (See Policy 6-50 Research Involving Animals).

Laboratory Safety

Principal Investigators are responsible for communicating guidelines, procedures and standards regarding the environment, in teaching and research activities that they supervise and for ensuring compliance. Also, they are responsible for, where necessary, developing specific procedures for activities under their authority, in support of faculty directives, and in conformity with external agency requirements.

Supervisors and principal investigators must ensure appropriate training has been completed by staff and show due diligence in the application of health and safety measures in general. To be more precise, they must keep informed of the health and safety regulations applicable to the employees and students under their authority. Also, they must initiate and incorporate necessary preventive measures in order to control health and safety hazards associated with activities under their authority. Finally, they must ensure that employees and students under their authority work in the manner and with the protective devices, measures and procedures required under the Occupational Health and Safety Act, as well as ensure the use of equipment, protective devices or clothing required.

For more detailed information, please refer to Occupational Health, Safety and Biosafety's Laboratory Safety and Procedures Manual as well as to associated Health and Safety Policies.

Biosafety

The use of biohazardous materials in the Institute is governed by the Pathogen and Toxin license issued by the Public Health Agency of Canada. The license specifies the activities that researchers are permitted to conduct in OHIRC laboratories and , outlines the conditions of work. To this end, the Institute has established a biosafety policy and program that defines guidelines and responsibility for the proper use of biohazardous materials in its research and educational activities that will protect workers, students, the community and the environment. The Office of Occupational Health, Safety and Biosafety (OHSB) in consultation with the OHIRC Biosafety Committee (the Committee) has oversight of the Program. Responsibilities of Principal Investigators is laid out in Policy 4-600 Biosafety in Research Laboratories.

Radiation

The use of radioactive materials is governed by a consolidated license issued to the Ottawa Hospital (TOH) by the Canadian Nuclear Safety Commission (CNSC). The Radiation Safety Program is overseen by the TOH Radiation and Laser Safety Department (RLSD). The RLSD is responsible for administering the Consolidated License through the issuance of Internal Radioisotope Permits to researchers. Researchers are required to obtain a permit PRIOR to the acquisition and use of radioactive materials. It is an offence under the NSC Act to obtain radioactive materials without authorization under a license.

Researchers are reminded that the Research Grant Permit must be issued before grant funds may be released. For more detailed information, contact Occupational Health, Safety and Biosafety.

Laboratory and Office Space

Allocation of laboratory and office space is the responsibility of the CEO and the Senior Management Committee upon the recommendation of the Chief Scientific Officer. Researchers must ensure that they have the facilities needed to conduct a project before applying for research funding for that project. Researchers must explicitly inform Administration of any additional requirements, and obtain the CEO's approval, before applying for projects needing additional laboratory and/or office space.

Ownership of Equipment

Unless there are contractual obligations or granting agency regulations are to the contrary, equipment, including computers, purchased with research funds administered by the Institute belongs to the Institute.

Overhead/Indirect Costs

Overhead, or indirect costs, must be included in the budgets for all contracts and contract proposals. Some granting agencies also allow a provision for overhead in their grants and overhead should be included in funding applications if eligible. (See Policy 6-140 Allocation of Overhead Charges on Research Projects).

Intellectual Property

The Institute is committed to fostering creativity, innovation, and bringing new discoveries to market through various means, including the protection of intellectual property rights. The Institute's Intellectual Property Policy sets forth the

framework for ownership, protection and management of intellectual property rights and applies to any member of the academic, medical or administrative staff, postdoctoral fellow, visitor, student or person holding an academic appointment at the Institute. (See Policy 1-70 Intellectual Property).

Publication and Authorship

Researchers publish academic papers as part of the output of their research. It is incumbent on the Institute to support its researchers in producing publications that are in line with international best practice and Canadian national funder mandates. All research that is conducted at the Institute should be reported, and reports should reflect clear and complete accounts of the research that took place. (See Policy 6-230 Publication and Authorship).

Addressing Allegations of Breach of Policy in Research

The Institute, in collaboration with the University of Ottawa where applicable, must report a confirmed breach of Agency policy to the *Secretariat on Responsible Conduct of Research (SRCR)*. Confirmed breaches of the Tri-Agency Policies involving agency applications or awards will be published on the SRCR website, typically with a de-identified summary of the breach; however, if the breach is considered serious by the SRCR, the Agencies have the right to publish the fully identifiable details of the breach and the individual(s)/institution(s) involved. The number of allegations and general nature of the Agency breaches must also be posted to the Institute's website annually.

Policy 6-20 Addressing Allegations of Breach of Policy in Research provides a framework for investigating allegations of breach of policy, related to the responsible conduct of research. Allegations shall be dealt with in a fair, unbiased and timely manner.

5. REFERENCES AND RESOURCES:

Tri-Agency Framework: Responsible Conduct in Research

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

International Council for Harmonization (ICH) Good Clinical Practice Guidelines, Topic E6

Personal Health Information Protection Act (PHIPA), Ontario

Canadian Institutes of Health Research (CIHR), Best Practices for Protecting Privacy in Health Research

Canadian Council on Animal Care (CCAC) Policies and Guidelines

Canadian Biosafety Standards

Canadian Nuclear Safety Commission Regulation

Canada's Food and Drugs Act

University of Ottawa Responsible Conduct of Research Policy 115 and Procedure 29-2 Addressing Allegations of a Breach of Responsible Conduct of Research

UOHI Policy and Procedure Manual 1-70:	Intellectual Property
UOHI Policy and Procedure Manual 1-140:	Corporate File Retention and Destruction
UOHI Policy and Procedure Manual 1-260:	Conflict of Interest
UOHI Policy and Procedure Manual 4-600:	Biosafety in Research Laboratories
UOHI Policy and Procedure Manual 6-20:	Addressing Allegations of Breach of Policy
UOHI Policy and Procedure Manual 6-40:	Research Involving Humans
UOHI Policy and Procedure Manual 6-50:	Research Involving Animals
UOHI Policy and Procedure Manual 6-90:	Responsibilities of Principal Investigators
UOHI Policy and Procedure Manual 6-140:	Allocations of Overhead Charges on Research Projects
UOHI Policy and Procedure Manual 6-230:	Publication and Authorship