

POLICY ON RESPONSIBLE CONDUCT OF RESEARCH AND RESEARCH MISCONDUCT

1.1 Purpose

The Ontario Institute for Cancer Research (OICR) is committed to operating with the highest ethical standards of practice in relation to how research is initiated, conducted, documented and disseminated. OICR expects that all Research Personnel embrace and promote integrity in research and scholarship. Individuals are personally responsible for the intellectual and ethical quality of their work and must ensure that their research meets OICR standards and the standards of any entities sponsoring any component of the research. The standards of conduct and related processes set out in this policy are designed to ensure, to the greatest extent possible, the integrity of OICR research in all its stages and to be consistent with the requirements of granting agencies, and the University of Toronto, as outlined in OICR's agreement with the University.

The policy aims to provide a framework for:

- Understanding the responsibilities of Research Personnel with respect to research integrity;
- Understanding the responsibility of OICR for promoting the Responsible Conduct of Research (RCR) and investigating and reporting allegations of Research Misconduct.

Through this policy, OICR seeks to ensure that OICR research activities are conducted in line with national, and international, policies pertaining to RCR, and aims to:

- Increase knowledge of, and sensitivity to, issues pertaining to the RCR:
- Improve the ability of Research Personnel to consider research participants during the design of research projects;
- Develop an appreciation for the range of accepted scientific and ethical practices for conducting research;
- Provide information about the regulations, policies, statutes, and guidelines that govern the conduct of research; and
- Develop positive attitudes toward life-long learning in matters involving the RCR.

This policy also outlines the mandatory RCR training required for all OICR Research Personnel.

2.0 Scope

This policy applies to all OICR Research Personnel, including but not limited to: Principal Investigators, Research/Scientific Managers and any person who conducts research at or under the auspices of OICR ("Research Personnel"), regardless of sources of funding. The policy also applies to all types of research activities, whether

funded or unfunded, including those which involve the use of animal, human, and/or biological materials.

3.0 Definitions

Complaint: for the purpose of this policy, "complaint" refers to an allegation of Research Misconduct.

Complainant: the person who makes a Complaint.

Home Institution: means a university, hospital, or research institute at which the individual is employed.

Investigating Committee: a group appointed by the Deputy Director, or designate, who will decide whether an allegation of Research Misconduct is founded. The Investigating Committee will be composed of members with the necessary expertise to review the allegation(s). At least one member of the Investigating Committee shall be external to OICR, and all members will be without conflict, whether real or apparent.

Principal Investigator: a lead scientist for a well-defined scientific research program or platform.

Research Ethics Board (REB) (as per the Tri-Council Policy Statement or TCPS): a body of researchers, community members, and others with specific expertise (e.g., in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

Research/Scientific Manager: an individual, reporting to the Principal Investigator, responsible for supporting scientific research initiatives through direct management of Research Personnel administratively and through project oversight.

Research Misconduct: refers to any deviation from the standards of ethics and integrity as outlined in this policy, including behaviour that threatens the integrity of any aspect of the research and related business processes. For examples of Research Misconduct, refer to Appendix A.

Research Personnel: any individual who performs research including bench/laboratory and/or bioinformatic work, and documents results/data from research activities (e.g., Principal Investigators, OICR Program/Project Managers, scientists, students, trainees, co-op students, OICR Associates, visiting scientists, contractors, research volunteers, research associates, etc.).

Respondent: the person against whom a Complaint has been made.

Responsible Conduct of Research: this term is used to encompass a range of topics associated with research ethics, ethical decision making, professionalism, and best practices.

Secretariat on Responsible Conduct of Research (SRCR): the SRCR is an administrative body that provides technical and policy advice, as well as substantive and administrative support for the Panel on Research Ethics (PRE), the Panel on Responsible Conduct of Research (PRCR) and Canada's three federal research agencies (the Tri-Council) – 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), or "the Agencies".

Tri-Agency Framework: Responsible Conduct of Research (RCR; "The Framework"): a document developed by the Agencies that outlines the responsibilities and corresponding policies for researchers, institutions, and the Agencies to promote a positive research environment. *The Framework* also details the minimum requirements for addressing allegations of Research Misconduct by both institutions and the Agencies.

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS): a joint policy of Canada's three federal research agencies – 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), or "the Agencies." This policy expresses the Agencies' continuing commitment to the people of Canada to promote the ethical conduct of research involving humans. It has been informed, in part, by leading international ethics norms, all of which may help, in some measure, to guide Canadian researchers, in Canada and abroad, in the conduct of research involving humans.

4.1 Policy

OICR is committed to providing a positive research and learning environment, and ensuring that all research activities conducted under the auspices of the Institute follow the highest standards of ethical conduct.

Research activities, whether funded or unfunded, are expected to align with institutional polices, and the policies, guidelines, and frameworks set forth by relevant agencies and/or sponsors — whether they be provincial, federal, or international. In particular, OICR requires that all research activities are compliant with the *Tri-Agency Framework:* Responsible Conduct of Research, administered by the Secretariat on Responsible Conduct of Research, and the Agreement on the Administration of Agency Grants and Awards by Research Institutions with the Canadian Institutes of Health Research (CIHR).

4.2 Compliance

All of OICR's Research Personnel must read, understand and incorporate the principles of RCR into their everyday research practices. OICR's Research Personnel must be compliant with this policy and other related policies outlined in this policy. Failure to comply will be dealt with in accordance with OICR's Progressive Discipline policy. Allegations of Research Misconduct must be reported immediately to the Deputy Director.

4.3 Mandatory RCR Training for all Research Personnel

In support of OICR's commitment to the highest ethical standards in research, the Institute has developed a training initiative to inform and educate research personnel on RCR. This training is required by CIHR, NIH and other granting agencies. All OICR Research Personnel, regardless of the length of their tenure at OICR, must complete the OICR RCR training at least every five (5) years, or as required by funders and/or OICR in response to changes in institutional/agency/sponsor policies.

4.3.1 Collaborative Institutional Training Initiative (CITI) RCR Training

All Research Personnel are required to take an RCR training course provided by OICR within 2 weeks of joining OICR, or when requested. OICR uses the online training modules provided by Collaborative Institutional Training Initiative (CITI)-Canada, made available through N2 (Network of Networks) of which OICR is a member.

RCR training is to be completed by all new OICR Research Personnel as a part of the onboarding process. Research/Scientific Managers must ensure that a training certificate is obtained prior to any Research Personnel initiating research activities at OICR.

Training must be renewed at least every five (5) years, or as requested by OICR due to changes in policy, etc.

Research Operations will track the completion of RCR training for Research Personnel and will handle cases of delinquency. Research/Scientific Managers should also keep a record of completed training for their Research Personnel. Failure of Research Personnel to complete the mandatory training may be escalated to the Research/Scientific Manager, Program Director, Deputy Director, and/or President as necessary. Continued delinquency will be handled in accordance with OICR's Progressive Discipline Policy.

4.3.1.1. Supplemental Training Modules

The CITI RCR training course includes two "supplementary" modules. While not required for all OICR Research Personnel, certain research activities may dictate the necessity of these courses.

4.3.1.1.1. Training for Research Personnel Working with Animals or Animal Samples/Tissues

The Animal Care and Use module is mandatory for all Research Personnel when they will be involved in research activities that require the use of animals or samples derived from animals. Research/Scientific Managers must ensure that any Research Personnel who will engage in research activities that involve the use of animals and/or animal tissues complete the *Animal Care and Use* module as part of their mandatory RCR training prior to engaging in any animal-related research activities.

4.3.1.1.2. Additional Training Requirements for Research Personnel Working with Human Research Participants, Human Samples, and/or Human Data

A mandatory research ethics training course (the *Biomedical Research and Ethics Tutorial*; see OICR Policy on Research Ethics Board Approval and Ethical Conduct for Research Involving Humans for additional details) is required to ensure compliance with policies on the use of human participants, human biological materials, and/or human data. The *Human Participants Research and Ethics module* offered through the RCR training can be used to supplement the *Biomedical Research and Ethics Tutorial*, but will not be considered an acceptable substitute.

4.4 Research Misconduct

OICR's Research Personnel are personally responsible for their research. All issues and suspected issues of Research Misconduct must be reported immediately to OICR's Deputy Director in accordance with Section 5.0 of this policy. OICR will respond to all Complaints in a timely, impartial, and transparent manner, maintaining appropriate confidentiality during the inquiry and formal investigation stages.

If a Complaint is formally investigated and validated, the Respondent will be subject to appropriate disciplinary action, in accordance with section 4.3.2.4 and/or OICR's Progressive Discipline policy.

In the case of students, OICR recognizes that the relevant university student codes will apply and that disposition of any instances of misconduct will be done in concert with the relevant university officers. Respondents who are found innocent of Research Misconduct will receive a letter, with a copy to their file, exonerating them.

4.4.1 Reporting Allegations of Research Misconduct

Individuals, including those not part of the OICR community, may make a Complaint. Before making a Complaint, Complainants are encouraged to seek an explanation from the Respondent to ensure the suspected issue of Research Misconduct is not simply a misunderstanding. Complainants are required to act in good faith and to declare any conflict of interest that they may have in accordance with OICR's Conflict of Interest Policy. Good faith reporting of Research Misconduct is the responsibility of all OICR employees and such action shall not jeopardize anyone's employment or standing with OICR (in accordance with OICR's Whistleblower Policy).

Complaints must be made in writing or by email to the Deputy Director. The Complaint must include the following information:

- The name of the Respondent:
- All available relevant information (including evidence) in support of the allegation:
- The date of allegation; and
- The name and signature of the Complainant.

Complainants are encouraged to identify themselves when making a written Complaint to facilitate gathering of further information pertaining to the allegation.

Anonymous complaints may be considered for formal investigation in cases where sufficient information is provided to permit the collection of independent corroborative evidence. The Deputy Director is responsible for determining if an anonymous allegation will be considered for further investigation. In cases where the Deputy Director decides to proceed with further investigation into an anonymous complaint, he/she will designate an appropriate individual to act as the Complainant throughout the investigation. In cases where the Deputy Director decides not to proceed with further investigation into an anonymous complaint, no action will be taken and all copies of the allegation will be destroyed.

If there are multiple Complainants concerning the same allegation, each Complainant shall submit an individual written allegation. If a primary spokesperson exists, he/she shall identify himself/herself as such and all other Complainants shall acknowledge this agreement. If a primary spokesperson is not identified, the Deputy Director, or delegate (refer to Section 4.3.2.8) may treat each Complaint separately,

or may designate a primary spokesperson and determine that the allegations be jointly considered.

If the Complaint directly involves the Deputy Director and/or President and Scientific Director, delegation of roles and responsibilities for investigating the Complaint may be required (refer to Section 4.3.2.8).

4.4.2 Investigating Allegations of Research Misconduct

4.3.2.1 Inquiry

All persons involved in the investigation proceedings including the Complainant, the Respondent, and those who assist in the inquiry, will be treated with respect, fairness and due sensitivity. All allegations, inquiries and formal investigations will be held to the highest degree of confidentiality subject to any disclosure that may be required by law, with reasonable efforts taken to protect the privacy of the Complainant(s) and the Respondents(s).

An inquiry will be initiated within seven (7) working days of receipt of a Complaint to determine whether there are sufficient grounds to proceed with a formal investigation or whether the allegation is frivolous or clearly mistaken. It is not the purpose of the inquiry to determine if misconduct has occurred.

In the case of Visiting or Associate Scientists, the Deputy Director shall notify the individual's Home Institution that an allegation has been filed and shall work with said Home Institution to complete the inquiry process.

The inquiry process is described below.

- 1. The Deputy Director, or delegate, will determine if the substance of the Complaint constitutes Research Misconduct as defined in this policy. If it is deemed that the Complaint does not fall under the definition contained within this policy, the Deputy Director, or delegate, will advise the Complainant as to the appropriate course of action for handling the Complaint;
- 2. The Deputy Director, or delegate, will contact the Complainant for additional written information as necessary, and share this with the Respondent. The Deputy Director, or delegate, may consult confidentially within OICR and externally as necessary, to determine whether a formal investigation is warranted. The Deputy Director, or delegate, may, upon consent from both the Complainant and the Respondent, conduct (either personally or through an appointed representative) non-binding, without prejudice, confidential mediation:
- 3. If it is deemed that the substance of the Complaint does constitute Research Misconduct as defined in this policy, the Deputy Director, or delegate, will, within five (5) working days following completion of the inquiry:
 - a. Provide a summary of the Complaint to the Respondent;
 - b. Notify other relevant parties (e.g., the Dean of the University where the Respondent is enrolled in cases when the allegation involves students; relevant funding agencies, etc.);
 - c. Issue a written response to the Complainant outlining the formal investigating process that shall ensue; and
 - d. Inform, in writing, the President and Scientific Director and the Chair of the Board of Directors that a report of an alleged act of

Research Misconduct has been received and is under formal investigation.

If the Deputy Director, or delegate, decides not to proceed with a formal investigation, he or she will, within five (5) working days following the inquiry, issue a written response to the Complainant and Respondent (and SRCR if applicable), indicating the decision not to proceed with a formal investigation and providing rationale for the decision.

If the Deputy Director, or delegate, has reasonable grounds to believe that the Complainant did not act in good faith, he or she will write to the Complainant and Respondent to summarize these grounds and inform that the matter is being referred to the appropriate authority for assessment and follow-up action.

As considered necessary by OICR, or at the request of the Agencies, OICR may act to protect Agency funds by any means deemed appropriate. This may include freezing of cost centres, requiring additional signatures on expense claims, etc.

Within two (2) months of receiving an allegation of Research Misconduct, the Deputy Director shall advise any funding agency who may be involved in the research being investigated, that an allegation has been filed. When the allegation concerns research funded by the Agencies, the Deputy Director shall send a copy of the allegation and a letter to detail the inquiry process to the Secretariat on Responsible Conduct of Research (SRCR).

4.3.2.2 Formal Investigation

The formal investigation will examine the allegations and weigh the evidence to determine if Research Misconduct has occurred and, if so, identify the parties involved. The formal investigation into a Complaint shall be treated as a neutral fact finding process.

In the case of Visiting or Associate Scientists, the formal investigation shall be led by the Home Institution of the Visiting or Associate Scientist. OICR shall fully cooperate with this investigation.

Investigations led by OICR shall proceed as follows:

- 1. The Deputy Director, or delegate, will, within seven (7) working days following the decision of the inquiry to proceed with a formal investigation, appoint an Investigating Committee consisting of two or more members, with at least one member external to OICR, to perform an in-depth, formal investigation into the Complaint. Investigating Committee members will have no actual, apparent, reasonably perceived or potential conflict of interest or bias, and will jointly have the appropriate scientific and administrative background to evaluate the Complaint. The Investigating Committee will operate under the direction of and be responsible to the Deputy Director, or delegate;
- 2. If the Complaint involves a student, the Deputy Director will work with the relevant Dean of the university faculty where the Respondent is enrolled to develop an appropriate investigating process;
- The Deputy Director, or delegate, will inform both the Complainant and the Respondent of the specific Investigating Committee members to ensure that the members do not have known conflicts or biases that may jeopardize the formal investigation;

- 4. The Investigating Committee may consult with external professionals such as legal experts, forensic investigators or other advisors, as appropriate, to assist in or conduct the formal investigation
- Where applicable, the Deputy Director, or delegate, shall notify the SCRC and any external funding source(s) of the Complaint within two (2) months of receiving notice of the allegation;
- 6. Where necessary, the Deputy Director, or delegate, shall promptly take all reasonable and practical steps to obtain custody of the research records and evidence needed to conduct the formal investigation, as well as inventory, evidence and sequester the records in an appropriate manner;
- 7. The Complainant and Respondent will have the opportunity to provide additional written information to the Investigating Committee, and the Respondent will have the opportunity to respond in writing to all allegations. These materials will form part of the formal investigation file and may be included in the final summary report;
- 8. The Investigating Committee may, at its discretion, request an interview with any or all of the Complainant(s), the Respondent(s) or other relevant individuals. Written interview summaries will be prepared and provided to the interviewed party for comment or revision and included in the formal investigation file;
- 9. To protect confidentiality, the Investigating Committee shall be responsible for restricting the dissemination of information to only those who should receive it;
- 10. The Investigating Committee will prepare a report that summarizes its findings and its decision concerning whether or not the allegation involved Research Misconduct. The summary report shall be completed within 60 days following the start of the formal investigation. If this timeline cannot be met, the Investigating Committee will submit to the Deputy Director, or delegate, a procedural report citing the reasons for delay and the progress to date. If the Complaint involves scientific error rather than misconduct, the Investigating Committee must describe the error. All members of the Investigating Committee must sign the report; minority reports are not allowed. The Investigating Committee will deliver the summary report to the Deputy Director, or delegate;
- 11. The summary report must contain:
 - a. A description of the Complaint;
 - b. The Respondent's response to the allegation, investigation, and finding, and any measures taken by the Respondent to rectify the alleged misconduct;
 - c. A summary of the relevant evidence;
 - d. A statement about whether or not Research Misconduct occurred, and if it occurred, a statement of its extent and seriousness:
 - e. The process and timelines followed during the investigation;
 - Recommendations for remedial action;
 - g. A list of Investigating Committee members and their credentials; and
 - h. A list of people who contributed to the formal investigation;

- 12. The Deputy Director, or delegate, will review the summary report and may seek written clarification from the Investigating Committee if required. The Deputy Director, or delegate, shall sign and date the summary report, therein binding the content and decision regarding Research Misconduct;
- 13. Within ten (10) working days following the completion of the formal investigation, the Investigating Committee will return all supporting documents used in the formal investigation to the Deputy Director, or delegate;
- 14. The Deputy Director, or delegate, will distribute the summary report to the Complainant, Respondent, President and Scientific Director, and Chair of the Board;
- 15. The Respondent and Complainant will have five (5) working days to respond to the Deputy Director, or delegate, regarding the findings specified in the summary report, prior to the Deputy Director, or delegate, taking any administrative action;
- 16. Following the completion of an investigation, the Deputy Director shall forward a copy of the report to the SRCR, as necessary. The report is to be filed with the SRCR no more than seven (7) months following initial receipt of the allegation of Research Misconduct;
- 17. Following each formal investigation where it is determined that Research Misconduct has occurred, the Senior Management and/or the reporting manager must take corrective and disciplinary action (refer to Section 4.3.2.4). In some cases, disciplinary action may be enacted and enforced by the Board of Directors;
- 18. Where it is deemed that a criminal offence has occurred, the Deputy Director, or delegate, is duty bound to inform the appropriate law enforcement authorities and legal counsel for OICR; and
- 19. All written materials pertaining to a Complaint will be retained as a part of the records of the Corporate Secretariat for a period of no less than seven (7) years and only the Deputy Director or his/her authorized designate will have access to these records. It is illegal and against OICR's policy to destroy any corporate audit or other records that may be subject to or related to an investigation by OICR or any federal, provincial, state or regulatory body.

4.3.2.3 Participation in a Formal Investigation

Individuals who are asked to provide information or otherwise participate in a formal investigation have a duty to fully cooperate and be truthful, honest and candid with investigators. Evidence shall not be withheld, destroyed or tampered with, nor shall witnesses be influenced, coached or intimidated. Participants shall refrain from discussing the investigation with anyone not connected to the investigation and shall not discuss with the Respondent the nature of evidence requested or provided, unless agreed to by the Deputy Director, or delegate.

The Deputy Director, or delegate, shall inform the appropriate OICR personnel (not involved or implicated in the allegation or investigation) and notify external agencies or authorities, including police, directly if one or more of the following circumstances exist:

- An immediate health hazard, including humans or animal research subjects;
- An immediate need to protect OICR funds or equipment;
- A likelihood that any Complaint will be reported publicly; or
- A reasonable indication of possible criminal violation.

4.3.2.4 Disciplinary Action

In line with OICR's Progressive Discipline policy, disciplinary action that may be imposed on a Respondent if found guilty of Research Misconduct is not limited to, but may include:

- Repayment of agency/sponsor funding;
- Special monitoring of future work;
- Verbal warning with a letter to be held temporarily on file with the Deputy Director:
- Letter of reprimand to the Respondent's personnel file;
- Withdrawal of specific privileges;
- Removal of specific responsibilities;
- Demotion;
- Loss of merit;
- Loss of research funding;
- Suspension without pay; and
- Termination.

4.3.2.5 Communication of Findings

As required by *The Framework*, when an allegation of Research Misconduct is made against OICR Research Personnel who conduct research funded by the Agencies, the Deputy Director, or delegate, shall, within two (2) months of receiving notice of such allegation, inform the SRCR. Following the conclusion of the investigation, the Deputy Director, or delegate, will, within seven (7) months of receipt of the allegation, send a copy of the Investigating Committee's summary report to the SRCR. The SRCR may accept the summary report, or seek additional clarification. In exceptional circumstances, the SRCR may elect to conduct its own review or compliance audit on the incident, and may require recourse in addition to that imposed by OICR.

In cases of confirmed Research Misconduct, the Deputy Director, or delegate, will, within 30 working days of receipt, forward the summary report resulting from the formal investigation to the funding agency, as applicable, where the misconduct involved work funded directly or indirectly by that agency.

At the discretion of the Deputy Director, or delegate, the outcome of the formal investigation may be communicated directly to other parties within host partnered institutions and/or to other parties external to OICR, including but not limited to:

- 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 Respondent has been affiliated in the past;
- Professional licensing boards; and
- Police services.

4.3.2.6 Protection of Professional Reputations

The collection and assessment of information in cases of alleged Research Misconduct can be extremely difficult. In the course of conducting inquiries or investigations, the following provisions are applicable:

- Expert assistance should be sought as necessary to conduct a thorough and authoritative evaluation of all evidence;
- Precautions should be taken to avoid unresolved personal, professional or financial conflicts of interest on the part of those involved in the inquiry or formal investigation;
- The anonymity of the Respondent(s) and, if they wish it, the confidentiality of the Complainant(s) shall be protected (where feasible), and care shall be taken to protect from harm, the positions and reputations of those involved in the inquiry and formal investigation; and
- Where appropriate, efforts will be made to restore the reputation of the Respondent(s).

4.3.2.7 Recurring Complaints

In cases where a Complaint has already undergone an inquiry or a formal investigation and the matter has been closed, the Deputy Director, or delegate, will not pursue the same allegation unless new and compelling information that could not have reasonably been available at the time of the original Complaint is brought forward. In cases of recurring Complaints based on the same allegations that are not made in good faith, disciplinary action may ensue in accordance with OICR's Progressive Discipline policy.

4.3.2.8 **Delegating Authority**

If the Complaint cannot be investigated without bias by the Deputy Director, the Complaint directly involves the Deputy Director, or if there is a conflict through a direct reporting relationship, the Respondent shall inform the President who shall confirm the bias and/or conflict of reporting relationship and delegate oversight of the investigating process to another appropriate individual.

If the Complaint directly involves the President, the Deputy Director shall inform the Chair of the Board of Directors who shall delegate oversight of the investigating process to another appropriate individual.

5.1 Responsibilities

5.2 Complainant Responsibility

All allegations of Research Misconduct should be factual and contain as much detail as possible to allow for proper assessment. The Complaint should be candid and should clearly set forth all of the information that the Complainant knows regarding the allegation. In addition, the Complaint should contain sufficient corroborating

information to support the commencement of a formal investigation (refer to Section 4.3.2.2 of this policy).

The Deputy Director, or delegate, may, using reasonable discretion, determine not to commence a formal investigation if a Complaint contains only unspecified or broad allegations of Research Misconduct.

Unsubstantiated Complaints, allegations known to have been made maliciously or knowingly to be false, or repeatedly unfounded Complaints shall be viewed as serious offences whereby the Complainant shall be subject to disciplinary action in accordance with OICR's Progressive Discipline policy.

5.2 Principal Investigators and Research/Scientific Managers

OICR's Principal Investigators and Research/Scientific Managers shall educate and mentor trainees; encourage all Research Personnel to participate in OICR's RCR training program; address RCR training as required in the funding solicitation, request for proposal, announcement, and other sponsor requirements; and ensure that all RCR training requirements set by OICR, funding agencies, or sponsors are met by providing all trainees with a copy of this policy and informing them that they must complete the RCR training (refer to Section 4.2).

OICR's Principal Investigators and Research/Scientific Managers must:

- Ensure that all research performed in their laboratories or other research settings is of the highest possible quality and meets ethical and privacy/confidentialitystandards;
- Ensure trainees are informed of policies on conflict of interest and ethics and integrity and are trained in the RCR;
- Be aware of all data or results generated by researchers of the team for which they are responsible including documentation, analysis, interpretation, transfer, retention and disposal;
- Be aware of all uses and intended uses of all data or results generated by researchers of the team for which they are responsible;
- Monitor work performed by students, trainees and members of the research team; and
- Encourage peer review of research programs.

5.3 Research Personnel

OICR's Research Personnel shall complete the RCR training activities within the required timeframe (refer to Section 4.2). If compliance to required training is not met, the individual may be subject to disciplinary action in accordance with OICR's Progressive Discipline Policy.

OICR's Research Personnel are required to engender public trust by maintaining an environment that is conducive to the ethical and moral conduct of research. To that end, OICR Research Personnel must:

- Recognize the substantive contributions of collaborators and students; use unpublished work of other researchers and scholars only with permission and with due acknowledgement; and use archival material in accordance with the rules of the archival source:
- Maintain up-to-date, accurate, and complete records of data, findings, etc. to allow for verification or replication of the research by others;

- Obtain the permission of the author before using new information, concepts or data originally obtained through access to confidential manuscripts or applications for funds for research or training that may have been seen as a result of processes such as peer review;
- Use scholarly and scientific rigour and integrity in obtaining, recording and analyzing data, and in reporting and publishing results;
- Ensure that authorship of published work includes all those who have materially contributed to, and share responsibility for, the contents of the publication, and only those people;
- In addition to all authors, acknowledge all other contributors to the research, including sponsors;
- Reveal to sponsors, universities, journals or funding agencies any material conflict of interest, financial or other, that might influence their decisions on whether the individual should be asked to review manuscripts or applications, test products or be permitted to undertake work sponsored from outside sources:
- Manage all instances of conflicts of interest in accordance with OICR's Conflict of Interest Policy;
- Report all issues and/or suspected issues pertaining to Research Misconduct in accordance with the policies and procedures outlined in this policy; and
- Comply with this policy on Responsible Conduct of Research and Research Misconduct.

OICR supported researchers employed by any of OICR's partner institutions are expected to comply with the corresponding policies of their host institution. In the case of students, OICR recognizes that the relevant university student codes will apply.

Additionally, OICR's Research Personnel must:

- Have the freedom to disseminate advances arising from OICR or related funded research to other researchers, practitioners, policy makers and the public without undue delay, and in accordance with signed contracts and/or agreements:
- Gain approval and meet the standards of Good Animal Practices of the Canadian Council on Animal Care (CCAC) if involved in animal research directly or through third party facilities; and
- Ensure research involving biohazards is conducted in a manner that meets all applicable safety standards and practices outlined in OICR's Biosafety and Biosecurity Policy.
- For projects involving the use of human participants, human biological materials, and/or human data, OICR abides by the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and all OICR Research Personnel are required to adhere to the guidelines for the conduct of research. Training on Research Ethics is required by all Research Personnel regardless of whether the research project involves the use of human participants, human biological materials, and/or human data, and is covered in OICR's Policy on Research Ethics Board Approval and Ethical Conduct for Research Involving Humans.
- Comply with all required/applicable regulatory and guidance policies and procedures including, but not limited to:

- 2nd edition of Tri-Council Policy Statement: for Ethical Conduct for Research Involving Humans
- Canadian Council on Animal Care (CCAC)
- Agency policies related to the <u>Canadian Environmental</u> Assessment Act
- Licenses for research in the field
- o Laboratory Biosafety Guidelines
- o Canada's Food and Drugs Act
- Health Canada guidelines, Food and Drug Regulations-Amendment (Schedule No.1024) Clinical Trial Framework
- Office for Human Research Protections US Department of HHS
- Personal Health Information Protection Act, 2004
- International Conference on Harmonization Good Clinical Practice (ICH GCP E6)
- The Declaration of Helsinki
- Policies and Procedures of applicable funding agencies (e.g., CIHR, NIH, NSERC).

5.3.1 Responsibilities of Research Personnel who Apply for or Hold Agency Funding

As per the Framework, the responsibilities outlined below are applicable to any OICR Research Personnel who apply for, or hold funding from the Agencies:

- Applicants and holders of Agency grants and awards shall provide true, complete and accurate information in their funding applications and related documents and represent themselves, their research and their accomplishments in a manner consistent with the norms of the relevant field.
- Applicants certify that they are not currently ineligible to apply for, and/or hold, funds from 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.
- Principal funding applicants must ensure that others listed on the application have agreed to be included.
- Researchers who receive funds from the Agencies must provide true, complete and accurate information on expenditures, and use the funding in accordance with the Agencies' policies, specifically, the *Tri-Agency Financial Administration Guide*.

By accepting research funds from an external funder, OICR Research Personnel are confirming that they will uphold the research integrity policies of the funder for the duration of the sponsored project.

5.4 OICR

5.4.1 Deputy Director

The Deputy Director shall promote an environment conducive to the RCR; ensure research activities are carried out in accordance with this policy; and determine the content, length, level, and format of instruction for OICR's RCR training program. In this role, the Deputy Director shall seek guidance from the OICR Executive, Program

Directors, Human Resources, Ontario Cancer Research Ethics Board, and Research Operations.

5.4.2 Research Operations

Research Operations shall coordinate the Responsible Conduct of Research training and maintain records of training completion and certificate expiration. They shall also ensure that training certificates are in place at the time of proposal submission/acceptance of award for external funding agencies.

6.1 Related Documents

- Appendix A: Examples of Research Misconduct
- OICR Policies:
 - Biosafety and Biosecurity Policy
 - Conflict of Interest Policy
 - Notebooks and Documentation of Scientific Data
 - Privacy and Confidentiality Policy and Procedures and other privacyrelated policies and procedures
 - o Progressive Discipline Policy
 - Research Ethics Board Approval and Ethical Conduct for Research Involving Humans
 - Whistleblower Policy

7.1 References

- The Tri-Agency Framework: Responsible Conduct of Research (2011), http://www.rcr.ethics.gc.ca/eng/policy-politique/framework-cadre/;
- Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans, 2014,
 - http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/;
- NIH Office of Intramural Research Guidelines for the Conduct of Research https://oir.nih.gov/sourcebook/ethical-conduct/research-ethics/nih-guidelines;
- Tri-Agency Financial Administration Guide
 http://www.nserc-crsng.gc.ca/Professors-Professeurs/FinancialAdminGuide-GuideAdminFinancier/index_eng.asp;
- The Agreement on the Administration of Agency Grants and Awards by Research Institutions
 - http://www.science.gc.ca/default.asp?lang=En&n=56b87be5-1.

8.1 Revision History

Document Number	Modified Date (YYYY-MM-DD)	Level of Change	Revision Comments	
RE-CON.104.001	Not applicable	No change	 New document 	
RE-CON.104.001	2012-04-13	Minor change	 Logo updated; removed OICR from title 	
RE-CON.104.002	2017-07-27	Major change	combined policies to ensure that the RCR policy was comprehensive (RCR, RCR Training, Ethics and	

			•	Integrity of Research, Research Misconduct); Added sections on Research Misconduct; Revised training requirements.
RE-CON.104	2020-03-09	Minor Change		Extension of the review and approval period of policy to 3 years

Document Title:	Policy on Responsible Conduct of Research and Research Misconduct						
Associated	OICR Research Ethics and Integrity Attestation (F-RE-CON.104-01); OICR Annual						
Form(s):	Administrative Accountability Attestation (F-RE-CON.104-02)						
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Appendix A: Examples of Research Misconduct

The following are examples of Research Misconduct, as provided in the *Tri-Agency Framework: Responsible Conduct of Research*. This list is not intended to be exhaustive. Allegations of Research Misconduct should be investigated according to the procedures outlined in this policy.

Breaches of Agency Policies by Researchers

Agency funded researchers - including those researchers who hold awards outside of Canada or at organizations in Canada that have not signed the Agreement on the Administration of Agency Grants and Awards by Research Institutions (the Agreement) - must comply with Agency policies. By signing an application for a grant or an award, and by accepting a grant or an award, a researcher agrees to comply with the Agencies' policies.

Breaches of Agency Policies

Breaches of Agency policies include, but are not limited to, the following:

I. Breaches of Tri-Agency Research Integrity Policy:

- Fabrication/Fraud: Making up data, source material, methodologies or findings, including graphs and images.
- 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.
- 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.
- 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.
- 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.
- 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.
- Inadequate acknowledgement: Failure to appropriately recognize contributions of others in a manner consistent with their respective contributions and authorship policies of relevant publications.
- 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 Framework from being met.

II. Misrepresentation in an Agency Application or Related Document:

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.

- Applying for and/or holding an Agency 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.
- Listing of co-applicants, collaborators or partners without their agreement.

III. Mismanagement of Grants or Award Funds

Using grant or award funds for purposes inconsistent with the policies of the Agencies; misappropriating grants and award funds; contravening Agency financial policies, namely the *Tri-Agency Financial Administration Guide*, Agency grants and awards guides; or providing incomplete, inaccurate or false information on documentation for expenditures from grant or award accounts.

IV. Additional sources of Research Misconduct¹

- Failure to honour the confidentiality that the researcher promised or was contracted to as a way to gain valuable information from a party internal or external to the institution:
- Financial misconduct, which is the deliberate misuse of funds acquired for support of research, including but not limited to failure to comply with terms and conditions of grants and contracts; misuse of OICR's resources, facilities, and equipment; failure to identify correctly the source of research funds;
- Retaliation against a person who acted in good faith and reported or provided information about alleged Research Misconduct;
- Material failure to comply with relevant federal or provincial statutes or regulations applicable to the conduct and reporting of research;
- Failure to obtain the required approvals, permits, certifications, etc., prior to conducting research activities for which they are required;
- Failure to comply with a direction of the Research Ethics Board (OCREB, or alternative institutional REB) upon which an approval to proceed with the research was granted or failure to notify the relevant REB of significant protocol changes that may affect its prior decision to approve the research proceedings;
- Failure to comply with a direction of an animal care committee or biosafety committee upon which an approval to proceed with the research was granted or failure to notify the committee of significant protocol changes that may affect its prior decision to approve the research proceedings;
- Failure to provide relevant materials to the applicable Research Ethics Board, animal care committee or biosafety committee either required by the institution or which the research or academic community considers to be materials relevant to decision-making:
- Failure to reveal material conflicts of interest to OICR, sponsors, colleagues or journal editors when submitting a grant, protocol or manuscript, when asked to undertake a review of research grant applications or manuscripts, or when testing or distributing products;
- Making false or misleading statements that are contrary to good faith reporting of alleged Research Misconduct;
- Misleading publication such as:

¹ In part from the University of Toronto Framework to Address Allegations of Research Misconduct, January 1, 2013

- Failing to appropriately include as authors other collaborators who prepared their contribution with the understanding and intention that it would be a 'joint' publication;
- Failing to provide collaborators with an opportunity to contribute as an author in a 'joint' publication when they contributed to the research with the understanding and intention that they would be offered this opportunity;
- Falsely claiming someone else's data as one's own;
- Preventing access to research data to a legitimate collaborator who contributed to the research with the explicit understanding and intention that the data was their own or would be appropriately shared;
- Giving or receiving honorary authorship or inventorship;
- Denying legitimate inventorship;
- Knowingly agreeing to publish as a co-author without reviewing the work including reviewing the final draft of the manuscript;
- Failing to obtain consent from a co-author before naming that person as such in the work; and
- Portraying one's own work as original or novel without acknowledgement of prior publication or publication of data for a second time without reference to the first.
- Willful misrepresentation and misinterpretation of findings resulting from conducting research activities;
- Condoning or not reporting the performance by another university member of any of the acts noted above; and
- Encouraging or facilitating another researcher to carry out scholarly misconduct (e.g. a supervisor telling his graduate student to falsify data) or otherwise creating an environment that promotes misconduct by another.