

# ONTARIO INSTITUTE FOR CANCER RESEARCH POLICY ON ETHICS AND INTEGRITY OF RESEARCH

## Purpose and Scope

The Ontario Institute for Cancer Research (OICR) is committed to operating with the highest ethical standards in relation to how research is initiated, undertaken, documented and disseminated. Individuals are personally responsible for the intellectual and ethical quality of their work and must ensure that their research meets the 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 the OICR's agreement with the university.

This policy applies to all full-time and part-time principal investigators, scientific staff, and post-doctoral fellows referred to collectively in this policy as "researchers" who are employees of OICR, as well as any person who conducts research at or under the auspices of OICR including students. 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. OICR supported researchers employed by any of OICR's partner institutions are expected to comply with the corresponding policies of their host institution.

Researchers will also be required to comply with the following policies and procedures:

- Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans [http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005\\_E.pdf](http://www.pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf)
- OICR Conflict of Interest Policy and Guidelines
- OICR Privacy and Confidentiality Policy and Procedures and other privacy-related policies and procedures
- The approval process of the applicable Research Ethics Board

## General Statement of Ethical Principles

Researchers are required to adhere to the following ethical principles generally accepted by the research community and endorsed by the Tri-Council Policy Statement<sup>1</sup>:

- Respect for human dignity aimed at protecting the multiple and interdependent interests of persons - from bodily to psychological to cultural integrity;
- Respect for free and informed consent of research subjects;
- Respect for vulnerable persons;
- Respect for privacy and confidentiality;

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<sup>1</sup> Tri-Council Policy Statement. Ethical Conduct for Research Involving Humans. Ottawa: Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, August 1998, as amended on October 2005.

- Respect for justice and inclusiveness;
- Balancing harms and benefits of research;
- Minimizing harm;
- Maximizing benefit;
- Inclusive research – for example, women shall not be excluded from research based solely on their gender or reproductive capacity; and
- Following good practices when conducting research on Aboriginal peoples, including exhibiting respect for the culture, traditions and knowledge of the Aboriginal group

### **Promoting Integrity and Ethics**

Researchers are required to ensure public trust by maintaining an uncorrupted environment in which ethical and moral conduct is pervasive. To that end, researchers must<sup>2</sup>:

- 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;
- 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 analysing 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; and
- 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.

Principal investigators/supervisors must<sup>3</sup>:

- Ensure that all research performed in their laboratories or other research settings is of the highest possible quality and meets ethical standards;
- Ensure trainees are informed of policies on conflict of interest and ethics and integrity;
- Be aware 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

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<sup>2</sup> Tri-Council Policy Statement: Integrity in Research and Scholarship. Ottawa: Medical Research Council of Canada. Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, August 2001.

<sup>3</sup> Taken from: Framework for Ethics in Research. University of Toronto Faculty of Applied Science and Engineering. Webpage, undated.

- Encourage peer review of research programs.

Additionally, researchers 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;
- Keep current on ethical issues related to research;
- Gain approval and meet the standards of the relevant Animal Care Council when involved in animal research; and
- Comply with all OICR policies, procedures and directions of the applicable Research Ethics Board, Use of Animals and Biohazards Committee(s) and funding agencies.

### **Treatment of Issues of Research Misconduct**

Researchers are personally responsible for their research and must not commit research misconduct. Allegations of research misconduct will be taken very seriously and OICR will respond in a timely, impartial, fair and transparent manner, maintaining appropriate confidentiality during the inquiry and investigation stages. If allegations of research misconduct are investigated and validated, the researcher(s) will be subject to appropriate disciplinary action. Researchers who are found innocent of misconduct will receive a letter with a copy to their file exonerating them.

### **Definition of Research Misconduct**

Research misconduct is defined as any deviation from the standards of ethics and integrity outlined in OICR's Policy on Ethics and Integrity of Research. It includes behaviour that threatens the integrity of any aspect of the research and related business processes. Research misconduct includes but is not limited to the following<sup>4</sup>:

- Fraud which is the fabrication of recording or reporting and other falsification of data, results, or source materials;
- Plagiarism which is the claiming of someone else's words or ideas as one's own;
- 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 the terms and conditions of grants and contracts; misuse of the OICR's resources, facilities and equipment; failure to identify correctly the source of research funds;
- Deliberate destruction of one's own research data or records to avoid the detection of wrong doing or the deliberate destruction of someone else's data or records without authorization;
- Retaliation against a person who acted in good faith and reported or provided information about alleged research misconduct;

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<sup>4</sup> University of Toronto Framework to Address Allegations of Research Misconduct, November 27<sup>th</sup>, 2006.

- Material failure to comply with relevant federal or provincial statutes or regulations applicable to the conduct and reporting of research;
- Failure to comply with a direction of OICR's Research Ethics Board (or alternative institutional REB) upon which an approval to proceed with the research was granted or failure to notify the relevant Research Ethics Board 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 or failing to declare any conflicts of interest when reporting alleged research misconduct;
- Misleading publication such as:
  - 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.
- Wilful 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.

## **Reporting Responsibility**

Individuals, including those not part of the OICR community, may make allegations of research misconduct. Before making a complaint, complainants are encouraged to seek an explanation from the individual involved (respondent) to ensure that the perceived misconduct is not simply a misunderstanding. Any person making such an allegation is required to act in good faith and to declare any conflicts of interest that they might have. The good faith reporting of research misconduct is a responsibility of all OICR employees and such action shall not jeopardize anyone's employment or standing with the OICR.

The alleged act of research misconduct must be reported to the Deputy Director in writing. The allegation shall identify the complainant, include all available relevant information and supporting evidence and be signed and dated.

If there are multiple complainants concerning the same allegation, each complainant shall submit an individually written and signed statement. If a primary spokesperson exists, they shall identify themselves as such and all other complainants shall acknowledge this agreement. If a primary spokesperson is not identified, the Deputy Director may treat each complainant separately, may designate a primary spokesperson and/or determine that the allegations will be considered together.

In the case of allegations of misconduct made by an external funding agency, OICR will report its findings to that agency regardless of the outcome of OICR's investigation. In the case of allegations of misconduct originating from any other source, OICR will report its findings to an external funding agency where the allegation involves work funded directly or indirectly by that agency and where OICR's investigation finds that misconduct has indeed occurred.

## **Investigation Procedures**

### **General**

Complaints of research misconduct will be taken seriously and their inquiry and resolution will receive prompt attention. All persons involved in the investigation proceedings including the subject(s) of alleged research misconduct (respondent) and those who assist in the inquiry will be treated with respect, fairness and due sensitivity. All allegations, inquiries and investigations will be held to the highest degree of confidentiality subject to any disclosure that might be required by law.

The procedures are as follows:

## **Inquiry**

An inquiry is undertaken upon receipt of an allegation of research misconduct to determine whether the allegation falls under this policy, whether there are sufficient grounds to proceed with an investigation and whether the allegation is frivolous, vexatious, clearly mistaken or unjustified. It is not the purpose of the inquiry to determine if misconduct has occurred. The inquiry is to be conducted as a confidential process given that the allegations are not verified and reasonable efforts will be taken to protect the privacy of the complainant(s) and the respondent(s).

- (i)** The allegation is communicated to the Deputy Director as above.
- (ii)** The Deputy Director will determine if the substance of the complaint constitutes research misconduct as set out in this policy. If it is deemed that the complaint does not fall under this policy, the Deputy Director will advise the complainant as to the appropriate course of action for handling the complaint.
- (iii)** If it is deemed that the substance of the complaint does constitute research misconduct, the Deputy Director will provide a copy or summary of the complaint to the respondent within five business days from receipt of the complaint, notify other relevant parties (e.g. the Dean of the University where the student is enrolled in cases involving graduate students) and respond to the complainant outlining the process to be followed.
- (iv)** The Deputy Director will follow-up with the complainant for additional written information as necessary and share this with the respondent. The Deputy Director will contact the respondent to discuss the complaint and may consult confidentially within OICR and externally as necessary to determine whether an investigation is warranted.
- (v)** If the Deputy Director decides not to proceed with an investigation, then the Deputy Director will write to the complainant and the respondent with the decision and provide a written summary explaining the rationale for the determination.
- (vi)** The Deputy Director may, upon consent from both the complainant and the respondent, conduct (either personally or through an appointed representative) non-binding, without prejudice, confidential mediation. If such mediation produces a resolution, the outcome shall be communicated to the President and Scientific Director and to the Chair of the Board of Directors.
- (vii)** If the Deputy Director determines that the criteria for research misconduct as set out in this policy have been satisfied, the complaint is merited and that a formal investigation is warranted, the Deputy Director will initiate the formal investigation, formally communicate this decision to the complainant and the respondent, and inform the President and Scientific Director and the Chair of the Board of Directors, in writing, that a report of an alleged act of research misconduct has been received and is under investigation.

- (viii)** If the Deputy Director has reasonable grounds to believe that the complainant did not act in good faith, the Deputy Director will write to the complainant and respondent to summarize these grounds and inform that the matter is being referred to the appropriate official for assessment and follow-up action.

## **Investigation**

The investigation is a formal process to examine the allegations and to weigh the evidence to determine if research misconduct has occurred and, if so, to identify the involved parties.

- (x)** The Deputy Director will appoint an investigating committee of two or more senior scientists to investigate the allegation. The members of the committee will have no conflicts of interest or known biases and will have the administrative and scientific experience to evaluate the allegations. The Deputy Director will designate one member of the committee to serve as Chair; the Chair will serve as the main communicator about the process to the OICR.
- (xi)** If the alleged misconduct involves a graduate student, the Deputy Director will work with the relevant Dean of the university where the student is enrolled to develop an investigative process.
- (xii)** The Deputy Director will inform both the complainant and the respondent of the committee members to ensure that the members do not have known conflicts or biases that will jeopardize the investigation.
- (xiii)** The Deputy Director may authorize delegation of components of the investigation to an investigator who will report to the committee. The committee may consult with external professionals such as legal experts, forensic investigators or other advisors, as appropriate, to assist in or conduct the assessment.
- (xiv)** The Deputy Director, the committee or other investigators shall ensure that all reasonable efforts are made to protect the reputations of the complainant and the respondent during the investigation.
- (xv)** Where applicable, the Deputy Director shall notify any external funding source(s) of the suspected or alleged research misconduct.
- (xvi)** Where necessary, the Deputy Director shall promptly take all reasonable and practical steps to obtain custody of the research records and evidence needed to conduct the misconduct investigation, as well as inventory, evidence and sequester the records in an appropriate manner.
- (xvii)** The complainant will have the opportunity to provide additional written information to the committee and the respondent will have the opportunity to respond in writing to all allegations. The complainant will also have the opportunity to respond to the respondent's response. These materials will form part of the investigation file and the respondent's response will be included in the final report.

- (xviii)** The 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 investigation file.
- (xix)** The respondent(s) will have opportunities for input during the investigation and will have the opportunity to respond to the complaint or concern in writing, and that response will be included in the final report of the investigation.
- (xx)** To protect confidentiality, the Chair of the committee shall be responsible for restricting the dissemination of information to only those who should receive it.
- (xxi)** If the complaint or report cannot be investigated without bias by the Deputy Director or if there is a conflict or a direct reporting relationship between the person conducting the investigation and the person(s) alleged to have engaged in a suspected or alleged research misconduct, then the alleged person(s) shall inform the President and Scientific Director of any complaint or report of actual or alleged wrongdoing, who shall then investigate the matter in a like manner or delegate the investigation to another individual.
- (xxii)** Investigations into allegations of suspected research misconduct shall be treated as neutral fact finding processes.
- (xxii)** The investigating committee will prepare a report that summarizes its findings and its decision concerning whether or not the allegation involved research misconduct. If the allegation involves scientific error rather than misconduct, the investigating committee must describe the error. All members of the committee must sign the report; minority reports are not allowed. The committee will deliver the report to the Deputy Director or other individual who initiated the investigation.

The report should contain:

- A description of the complaint;
  - List of committee members and their credentials;
  - List of people who contributed to the investigation;
  - A summary of the relevant evidence;
  - A statement about whether or not research misconduct occurred, and if it occurred, a statement of its extent and seriousness;
  - Recommendations for remedial action.
- (xxiii)** Following the investigation, the investigating committee will return all supporting documents used in the investigation.
  - (xxiv)** The Deputy Director, or other individual if the Deputy Director does not oversee the investigation, will distribute the report to the complainant, respondent, President and Scientific Director, and Chair of the Board.
  - (xxv)** The respondent or complainant will have five working days to respond to the Deputy Director regarding the findings prior to the Deputy Director taking any administrative actions.
  - (xxvi)** Following each investigation where it is determined that research misconduct has occurred, Senior Management and/or the reporting supervisor and/or the OICR

scientist must take corrective and disciplinary action (see below). In some cases, disciplinary action may be enacted and enforced by the Chair of the Board of Directors.

**(xxvii)** If the investigation involves the President and Scientific Director, either the Deputy Director or the Chair of the Board shall provide a report to the Board of Directors who shall then determine if any corrective or disciplinary action must be taken.

**(xxviii)** Where it is deemed that a criminal offence has occurred, the Deputy Director or the President and Scientific Director are duty bound to inform the appropriate law enforcement authorities and legal counsel for OICR.

**(xxix)** All reports, complaints and investigations of research misconduct will be retained as a part of the records of the Corporate Secretariat for a period of no less than seven years. It is illegal and against the OICR's policy to destroy any corporate audit or other records that may be subject to or related to an investigation by the OICR or any federal, provincial, state or regulatory body.

### **Timing**

- All inquiries must begin within five business days of receipt of an allegation of research misconduct;
- Formal investigations must begin within five business days after the preliminary inquiry has been completed and must be completed as soon as possible, but not extending 60 business days; and
- Extensions beyond this must be approved by the President and Scientific Director and/or Board of Directors.

### **Disciplinary Action, is not limited to, but may include:**

- 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 individual's permanent personnel file;
- Withdrawal of specific privileges;
- Removal of specific responsibilities;
- Demotion;
- Loss of merit;
- Loss of research funding;
- Suspension without pay; and
- Termination.

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

- Co-authors, co-investigators, collaborators;
- External funding agencies which have directly or indirectly funded the work in question;
- Editors of journals in which fraudulent research or erroneous findings were published;
- Professional licensing boards;

- Editors of journals or other publications, other institutions, sponsoring agencies and funding sources with which the respondent has been affiliated in the past;
- Professional societies; and
- Police services.

### **Responsibility of the Complainant**

All suspected or alleged acts of research misconduct should be factual, rather than speculative and should contain as much specific detail as possible to allow for proper assessment. The complaint describing an alleged violation or concern should be candid and should clearly set forth all of the information that the employee or research staff knows regarding the allegation or concern. In addition, the complaint should contain sufficient corroborating information to support the commencement of an investigation.

The Deputy Director may, using reasonable discretion, determine not to commence an investigation if a complaint contains only unspecified or broad allegations of research misconduct.

Any allegations that prove not to be substantiated, to have been made maliciously or knowingly to be false or to be repeated unfounded complaints shall be viewed as a serious offence and shall be subject to disciplinary action.

### **Participation in an Investigation**

Individuals who are asked to provide information or otherwise participate in an 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 investigation subject, the nature of evidence requested or provided or information given to investigators, unless agreed to by the investigator.

### **Special Circumstances**

The Deputy Director shall inform the appropriate OICR personnel (not involved or implicated in the allegation or investigation) and notify external agencies or authorities including police directly and without signing authority for payments or purchases by an employee or research staff 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 alleged incident will be reported publically; or
- A reasonable indication of possible criminal violation.

## **Protection of Professional Reputations**

The gathering and assessing of information in cases of alleged research misconduct can be extremely difficult. It is essential to protect the professional reputations of those involved, as well as the interests of the public and of anyone who might be harmed by the alleged misconduct. 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 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 the positions and reputations of those involved in the research (including research subjects) and in the research misconduct proceeding from harm (including retaliation);
- Where appropriate, efforts will be made to restore the reputations of the respondent(s) when allegations are not confirmed.

## **Recurring Complaints**

In cases where a complaint has already undergone an inquiry or an investigation and the matter has been closed, the Deputy Director 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.