



Item	7.7
Policy Owner	President
For approval by	UOIT Board of Governors
Last approved	June 2013

UOIT RESEARCH ETHICS POLICY

1. Purpose

This policy sets out the standards, requirements and responsibilities that apply to research involving human participants at the University of Ontario Institute of Technology (UOIT).

2. Policy

The University is committed to advancing the highest ethical standards of research involving human participants. The University shall achieve this standard through its compliance with the Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and all applicable current regulatory requirements.

In doing so, the University shall at all times maintain respect for human dignity in its research activities, which is expressed through the three core principles of the Tri-Council Statement: respect for persons, concern for welfare, and justice. The University, through its establishment of a Research Ethics Board, will oversee the ethical acceptability of all research involving humans conducted under the auspices of the university for the purposes of achieving the highest ethical standards of research.

All research involving human participants shall adhere to the requirements of this policy and its associated Standard Operating Procedures, as well as applicable federal and provincial legislation, standards, guidelines and regulations.

2.1 UOIT Research Ethics Board

The Research Ethics Board shall oversee all research involving human participants, as defined in TCPS 2 Section 2.1 that is conducted under the auspices of the University to ensure compliance with university policies and procedures, and all applicable regulatory requirements. The Research Ethics Board shall be responsible for reviewing research for its ethical acceptability on behalf of the institution and pay careful attention to the proportions of risk and benefit. The Research Ethics Board has the authority to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human participants.

All UOIT research involving human participants will proceed only after ethical approval has been granted by the Research Ethics Board.

The Research Ethics Board shall report to the President. Its membership shall be comprised of at least six members, including: one core faculty member to Chair the Board, two members with expertise in relevant research disciplines, fields, methodologies covered by the Research Ethics Board, one member knowledgeable in ethics, one community member who is not affiliated with the institution and one

member who is knowledgeable in the relevant law when biomedical research is under review. (*Research Ethics Board SOP 100: Research Ethics Board Administration*).

2.2 Research Involving Human Participants

All research involving human participants conducted under the auspices of UOIT shall be subject to ethical review and approval by the UOIT Research Ethics Board regardless of whether the research is funded or unfunded. Researchers wishing to engage in research involving human participants shall receive written approval from the Research Ethics Board prior to the commencement of their activities. If the research is funded then no research funds shall be used to support research activities involving human participants until the Research Ethics Board has approved the research and issued a written approval.

Approved research activities involving human participants shall be subject to ongoing review and monitoring by the UOIT Research Ethics Board to ensure the ongoing ethical acceptability in accordance with the Tri-Council Statement, university policy and procedure and any applicable current regulatory requirements. (*Research Ethics Board SOP 200: Research Ethics Board Operations*).

2.3 Non-Compliance

The Research Ethics Board may stop any research action or activity involving human participants that fails to comply with the approved research protocol, current federal and provincial regulatory requirements, and/or UOIT research policies and procedures. In such cases, the matter will be dealt with in accordance to *Research Ethics Board SOP 200: Research Ethics Board Operations*. Issues of non-compliance that constitutes a breach of responsible conduct of research shall be addressed through the *Integrity in Research and Scholarship* policy.

2.4 Reconsideration and Appeal

Researchers have the right to request, and the UOIT Research Ethics Board shall provide, reconsideration of decisions affecting a research project. If reconsideration is not successful, decisions of the Research Ethics Board may be appealed according to the process for appeal (*Research Ethics Board SOP 200: Research Ethics Board Operations*). The decision made by the appeals board is final.

3. SCOPE AND AUTHORITY

The President is responsible for the implementation of UOIT's Research Ethics Policy through the Research Ethics Board. The university, through the Office of the Vice-President Research, Innovation and International, is committed to providing education and appropriate administrative and financial support to the Research Ethics Board to fulfill their duties. The Research Ethics Board shall function independently in the decision-making process to carry out its role effectively and to properly apply the core principles of the TCPS - the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

This policy applies to all teaching, research or other programs or activities involving research on human participants, including:

- a) Research conducted by any individual or group affiliated with the University;
- b) Research undertaken under the auspices of, or in affiliation with, UOIT, or in university-owned facilities, or utilizing university resources.
- c) Research on human remains, cadavers, tissues, biological fluids
- d) Course-based activities that require students to collect information about human participants or analyze human remains, tissues, or fluids.
- e) Research requiring access to UOIT students, staff, and/or faculty members

4. Research Ethics Board Standard Operating Procedures (SOP)

The following Standard Operating Procedures are applicable to the Research Ethics Board and their functioning:

- a. REB SOP 100: Research Ethics Board Administration
- b. REB SOP 200: Research Ethics Board Operations

5. Related Policies and Procedures

- 2.1.1 *Tri-Council* Agreement on the Administration of Agency Grants and Awards by Research Institutions, Version: 2007.
- 2.1.2 The Second Edition of *the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, 2010
- 2.1.3 UOIT's *Integrity in Research and Scholarship* Policy, approved May 2003.

6. Forms and Related Documents

- 2.1.4 REB Application for Ethical Review Form
- 2.1.5 Course-based Research Request Form
- 2.1.6 Secondary Use of Data Form
- 2.1.7 Adverse/Unanticipated Event Report Form
- 2.1.8 Change Request and Study Renewal Form
- 2.1.9 Research Project Completion Form

7. Regulatory Bodies

- Tri-Council Policy Statement: Guidelines on Research Involving Human Subjects, Second Edition;
- The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Consolidated Guideline;
- Part C, Division 5 of the Food and Drug Regulations of Health Canada;
- Food and Drug Administration (FDA) in the USA;
- US Code of Federal Regulations (CFR); and
- The Ontario Personal Health Information Protection Act 2004 (PHIPA) and its applicable regulations
- Tri-Agency (the Agreement on the Administration of Agency Grants and Awards by Research Institutions)
- Any other regulatory body that guides research using human participants