POLICY CONSULTATION REPORT

DATE: April 7, 2025

FROM: Niall O'Halloran, Manager, Policy & Privacy

TO: Senior Leadership Team

SUBJECT: Ontario Tech's Policy for Research Involving Human Participants and Research Ethics Board (REB) Terms of Reference

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BACKGROUND/CONTEXT & RATIONALE:

The Policy for Research Involving Human Participants and REB Terms of Reference were revised to align with the latest Tri-Council Policy Statement 2 (TCPS2). The policy was previously approved in 2013, with minor editorial changes made on February 18, 2020. This policy supersedes and replaces the Research Ethics Policy (June 2013).

The REB Terms of Reference was approved in 2007. The revised documents now incorporate new requirements, procedures, compliance standards, and references to the TCPS2, ensuring clearer, more consistent, and transparent governance of the Research Ethics Board and research involving human participants conducted under the auspices of the university.

The policy and REB Terms of Reference were reviewed and approved by the members of the REB on October 16, 2024 and by Research Committee of Academic Council on November 19, 2024. The Research Board was consulted on November 19, 2024.

Two documents summarizing the amendments to the Policy and Terms of Reference have been submitted along with this report.

HOW TO COMMENT:

Community members can provide written comments using the policy feedback form.
Comments will be shared with the relevant Policy Owner for consideration.
The comment period will be open until 3:00 pm on January 17, 2025.

NEXT STEPS:

Feedback from consultation will be considered and incorporated as applicable.

SUPPORTING REFERENCE MATERIALS:

Policy for Research Involving Human Participants (Amended).

Research Ethics Board Terms of Reference (Amended).

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022)

Agreement on the Administration of Agency Grants and Awards by Research Institutions

Classification Number	LCG 1124
Framework Category	Legal, Compliance and Governance
Approving Authority	Board of Governors
Policy Owner	President
Approval Date	DRAFT FOR APPROVAL
Review Date	To be assigned
Supersedes	Research Ethics Policy, June 2013; Editorial Amendments, February 18, 2020

POLICY FOR RESEARCH INVOLVING HUMAN PARTICIPANTS

PURPOSE

1. This Policy and its related Procedure describe the standards, requirements, and responsibilities that apply to Research involving Human Participants at the University of Ontario Institute of Technology in accordance with the most recent Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2), as well as Canadian and international ethical standards and regulations.

DEFINITIONS

2. For the purposes of this Policy the following definitions apply:

"Auspices" means any support, guidance, sponsorship or approval from a person or organization in which the Research is being conducted under.

"Course-Based Research" defines Research activities intended solely for pedagogical purposes which are normally required of students (at all levels) with the objective of providing students with exposure to research methods in their field of study (e.g., interviewing techniques). These activities must not be part of a University Member's own research program or student theses.

"Ethics Approval" refers to the ethical acceptability of the Research Proposal granted by an REB in accordance with this Policy.

"Ethics Review Agreement" represents an agreement between the University and another research institution or organization that authorizes an alternative model(s) for ethics review of Research involving Human Participants. Such agreements may or may not be reciprocal in nature.

"Human Biological Materials" refers to any human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials, and stem cells collected from participants for Research purposes.

"Human Participants" describes individuals whose data, biological materials, or responses to interventions, stimuli or questions by a researcher are gathered or utilized for the purposes of a Research Proposal and/or answering the research question(s).

"Minimal Risk" is defined as Research in which the probability and magnitude of possible harm implied by participation in the Research is no greater than that encountered by participants in those aspects of their everyday life that relate to the Research.

"Multi-Jurisdiction Research" is Research involving humans that may require the involvement of multiple Canadian institutions and/or multiple Canadian REBs, but is not limited to, the following situations:

a) a Research Proposal conducted by a team of University Members affiliated with different institutions;
b) several Research Proposals independently conducted by a University Member affiliated with different institutions, with data combined at some point to form one overall Research Proposal;
c) a Research Proposal conducted by a University Member, where the Research Proposal involves collecting data or recruiting participants at different institutions;
d) a Research Proposal conducted by a University Member who has multiple institutional affiliations. For example, two universities, a university and a college, or a university and a hospital;
e) a Research Proposal conducted by a University Member that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g., statisticians, lab or x-ray technicians, social workers, or school teachers); or
f) a Research Proposal that a University Member conducts under the Auspices of a Canadian research institution in another province, territory, or country.

"Non-Compliance" means a failure to follow the most recent Tri-Council Policy Statement 2 (TCPS2), University policies, procedures, communications, and/or the approved REB Proposal. Non-compliance can include, but is not limited to, failure to obtain REB approval before starting a Research Proposal, inadequate supervision of the Research, failure to report adverse events or Proposal changes to the REB, failure to provide ongoing progress reports, or significant deviation(s) from the approved Proposal.

"Non-University Member" means any individual involved in a Research Proposal who is not directly affiliated with the University.

"Principal Investigator (PI)" is the head of the research team who has overall responsibility for the ethical conduct of the Research Proposal and for the actions of any member(s) of the research team. The PI is a University faculty member or staff. The PI is responsible for communicating any changes to the Research Proposal, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site University Members for multi-site Research Proposals, who must then inform their respective local REBs.

"Proposal" refers to the REB application, Research protocol, and/or supporting documents.

"Research" is defined as an undertaking intended to extend knowledge through disciplined inquiry and/or systematic investigation. Research involving Human Participants may include, but is not limited to, Proposals where data are derived through:

a. the collection of information through any interaction or intervention with a living individual;

b. the Secondary Use of Data previously collected from Human Participants;
c. identifiable private information about an individual; and/or
d. human remains, cadavers, human organs, tissues and biological fluids, embryos, or fetuses.

"REB" refers to the Research Ethics Board authorized by the University.

"Secondary Use of Data" is any identifiable and/or confidential data derived from Human Participants undergoing an alternate use for Research purposes when the information was originally collected for a purpose other than the current Research Proposal.

"Student Researcher" is a student enrolled at the University who conducts research involving human participants as part of their academic program requirements. This includes research undertaken for coursework, independent study, undergraduate or graduate theses, or other scholarly activities supervised by a faculty member. Student researchers are responsible for adhering to the TCPS2, applicable regulatory requirements and institutional policies.

"Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)" is the 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). This policy outlines ethical norms required and relevant to the conduct of Research involving humans.

"University" refers to the University of Ontario Institute of Technology.

"University Member" means any member of the University community who teaches, conducts research or works at or under the auspices of the University and includes any of the following:

a. A person who is an employee of the university (core or complementary faculty members, staff, adjunct faculty, research personnel).
b. Any person who is an appointee (including a volunteer on research related committees and boards) of the University.
c. Undergraduate or graduate students, post-doctoral fellows, visiting scholars and any other research personnel while they are engaged in research or scholarly activities under supervision of a Member.

SCOPE AND AUTHORITY

3. This Policy applies to all Research involving Human Participants including:

a. Research conducted by any University Member(s) and Non-University Member(s);
b. Research undertaken under the Auspices of, or in affiliation with the University, or in University-owned facilities, or utilizing University resources;
c. Research on human remains, cadavers, tissues, or biological fluids;
d. Course-Based Research activities that require students to collect information about Human Participants or analyze human remains, tissues, or fluids;
e. Research requiring access to University students, staff, and/or faculty members; and/or
f. off-site and Multi-Jurisdiction Research.

4. The President or successor thereof is the Policy Owner and is responsible for the implementation, administration, and interpretation of this Policy through the Vice-President Research and Innovation (VPRI).

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 most current editions of the Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions, the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2), and all applicable regulatory requirements. The University also values and respects academic freedom, which must be complimented by the requirement for Research involving Human Participants to meet high ethical standards and compliance with regulatory requirements. In doing so, the University shall maintain responsible conduct of Research in a manner that respects the rights, dignity, welfare of research participants, as well as protect research participants from possible harm which is expressed through the core principles of the TCPS2.

The University, through its establishment of a Research Ethics Board (REB), will oversee the ethical acceptability of all Research involving humans conducted under the Auspices of the University, regardless of where the Research is conducted for the purposes of achieving the highest ethical standards of research (TCPS2, Article 6.1). All Research involving Human Participants shall adhere to the requirements of this Policy and the associated Standard Operating Procedures, as well as applicable federal and provincial legislation, standards, and guidelines. University Members are responsible for being aware of and adhering to the standards of this Policy.

5. Research Involving Human Participants and/or Human Biological Materials

5.1. All Research involving Human Participants and Human Biological Materials being conducted under the Auspices of the University shall be subject to ethical review and approval by the University REB regardless of whether the Research is funded or unfunded, which includes off-site and Multi-Jurisdiction Research (TCPS2, Article 6.1).

5.2. University Members wishing to engage in Research involving Human Participants and/or Human Biological Materials shall receive written approval from the REB prior to the commencement of their activities (TCPS2, Article 2.1). If the Research is funded, no research funds shall be used to support Research activities involving Human Participants and/or Human Biological Materials until the REB has approved the Research and issued a formal written approval (Agreement on the Administration of Agency Grants and Awards by Research Institutions, 2018).

5.3. Approved Research activities involving Human Participants and/or Human Biological Materials shall be subject to ongoing review and monitoring by the University REB to ensure the ongoing ethical acceptability in accordance with the TCPS2, University policies and procedure, and any applicable regulatory requirements (TCPS2, Article 2.8).

5.4. University Members and the REB must be aware of additional approvals from various officials, relevant agencies committees or groups under study to access research sites or participants. Before the Proposal commences, Ethics Approval and all other required approvals with respect to such Research Proposal must be obtained (TCPS2, Chapter 3).

6. President

6.1. The President shall establish the University REB, define an appropriate reporting relationship, and provide the REB with necessary and sufficient ongoing financial and administrative resources, through the VPRI, for the effective and efficient operation of the REB to fulfill its mandate (TCPS2, Article 6.2).

6.2. The President has delegated decision-making authority to the REB to review, approve, reject, propose modifications, terminate any proposed ongoing Research involving Human Participants and/or Human Biological materials in accordance with the TCPS2 (TCPS2, Article 6.3).

6.3. The President, other University Members and/or Non-University Members shall respect the independence, accountability, decision-making and authority delegated to the REB and may not override an REB decision to a Research Proposal that was made on ethical grounds and in accordance with the TCPS2 (TCPS2, Article 6.2).

7. Vice-President Research and Innovation (VPRI)

7.1. Under the authority of the President, the VPRI bears the responsibility for developing and implementing this Policy. The VPRI must provide the REB with the appropriate financial and administrative resources (e.g. research ethics administration staff, a research ethics office), financial support, policy development and interpretation and provision of research ethics training and education opportunities to the REB and University Members to fulfill its mandate and meet the ethical requirements of the TCPS2 (TCPS2, Article 6.2).

7.2. In consultation with the REB, the VPRI has the authority to enter into any Ethics Review Agreements with other institutions to conduct the ethics review and approval of the Research.

8. University Research Ethics Board (REB)

8.1. The REB shall function independently in the decision-making process to carry out its role effectively and to properly apply the core principles of the TCPS2, applicable procedures and regulations (TCPS2, Article 6.2).

8.2. The Chair, Vice-Chair and members of the REB are accountable to the President for the integrity of its research ethics review process (TCPS2, Article 6.2).

8.3. The REB may delegate research ethics reviews to a designated sub-committee of the REB. The sub-committee must be members of the REB and shall have relevant experience, expertise, training, and resources to review the ethical acceptability of all aspects of the Proposal in accordance to the TCPS2 (TCPS2, Article 6.4).

8.4. A representative of the REB or delegate of the REB shall issue annual public reports summarizing the REB's activities and initiatives relevant to the ethics review of Research involving humans (TCPS2, Article 6.1).

9. University Deans, Directors and Department Chairs

9.1. University Deans, Directors, and Department Chairs are required to understand and adhere to this Policy, relevant ethical guidelines, and applicable regulations. They are responsible for ensuring that research involving human participants is conducted ethically within their respective areas and for staying informed about ongoing research. Additionally, they must foster an environment that supports

ethical research practices by promoting broad awareness of this Policy and the importance of ethics review.

10. University Members

10.1. All University Member(s) must be familiar with and comply with this Policy, applicable ethical guidelines, and associated regulations. Additionally, they must foster an environment that supports ethical research practices by promoting broad awareness of this Policy and the importance of ethics review.

11. University Members as the Principal Investigator

11.1. The University Member who is named as the PI must ensure that Ethics Approval is obtained prior to the start of Research activities.

11.2. The University Member who is named as the Principal Investigator (PI) has the primary responsibility to oversee their Research Proposal and ensure it is carried out in an ethical manner and in accordance with applicable ethical guidelines and associated regulations. In addition, they are responsible for the protection of the rights and welfare of Human Participants and human materials.

11.3. The University Member PI has the responsibility to ensure that the members of the research team comply with the Proposal as outlined in the REB application and supporting materials.

11.4. The University Member PI shall ensure that the members of the research team are aware of the contents of this Policy and of other applicable ethical guidelines and regulations that are relevant to their responsibilities. In addition, the University PI shall ensure that all individuals under their supervision have the requisite knowledge, training, and competence to carry out their Research Proposal to ensure compliance with the TCPS2, applicable guidelines and associated regulations.

11.5. University Member PIs who supervise undergraduate or graduate students accept the responsibility for overseeing the ethical conduct of the student's Research Proposal, regardless of whether the student is considered the primary researcher.

12. Student Researchers

12.1. All student Research Proposals must have a PI who is an individual that is employed by the University and/or holds an appointment with the University, where it will be a joint responsibility of the University Member PI and the student researcher to ensure that the Proposal receives Ethics Approval prior to the start of Research activities, complies with the provisions of this policy, and applicable ethical guidelines and regulations.

13. Reconsideration and Appeals

13.1. Where University Members disagree with the REB over a decision regarding a Research Proposal that cannot be resolved through discussions, the PI is entitled to a reconsideration by the REB (TCPS2, Article 6.18).

13.2. University Members and REBs should make every effort to resolve disagreements through a reconsideration process. If a disagreement between the University Member and the REB cannot be resolved through reconsideration, the University Member has the option of appealing the REB decisions through the REB's appeal process (TCPS2, Article 6.18 to 6.20).

13.3. In consultation with the REB, the VPRI shall select an external REB with requisite knowledge and expertise that meets the procedural requirements of the TCPS2 as an ad-hoc appeal board to ensure an arm's length review.

13.4. The decisions of the appeal board shall be final and binding and will be adopted by the University REB.

14. Non-Compliance and Responsible Conduct of Research

14.1. The VPRI, in consultation with the REB, may stop any Research action or activity involving Human Participants that fails to comply with the approved Research Proposal, current federal and provincial regulatory requirements, and/or University research policies and procedures. In such cases, the matter will be dealt with in accordance with applicable REB procedures. Issues of Non-Compliance that constitute a breach of responsible conduct of research shall be addressed through the University's Policy on the Responsible Conduct of Research and Scholarship.

MONITORING AND REVIEW

15. This policy will be reviewed as necessary and at least every three years (unless another timeframe is required for compliance purposes). The VPRI, or successor thereof, is responsible to monitor and review this policy.

RELEVANT LEGISLATION

16. Part C, Division 5 of the Food and Drug Regulations of Health Canada;

17. Food and Drug Administration (FDA) in the USA;

18. US Code of Federal Regulations (CFR);

19. Ontario Personal Health Information Protection Act 2004 (PHIPA) and its applicable regulations; Other regulatory body that guides research using Human Participants.

RELATED POLICIES, PROCEDURES

20. Conflict of Interest in Research

21. Payments to Research Participant

22. Policy and Procedures on Expenses

23. Policy on the Responsible Conduct of Research and Scholarship

24. Responsibilities of Graduate Program Directors, Faculty Advisors, Research Supervisors and Graduate Students

25. Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans;

26. The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) Consolidated Guideline.

27. Tri-Agency (the Agreement on the Administration of Agency Grants and Awards by Research Institutions). Term of Agreement from April 1, 2023 to March 31, 2028.

RELATED FORMS AND & DOCUMENTS

28. REB Application for Ethical Review Form;
Course-Based Research Request Form;
Secondary Use of Data Form;
Human Tissue Samples in Research;
Multi-Jurisdictional Research (MJR) Form;
Request for Exemption Form;
Adverse/Unanticipated Event Report Form;
Change Request;
Study Renewal Form; and
Research Project Completion Form

RESEARCH ETHICS BOARD TERMS OF REFERENCE

PURPOSE

1. The University Research Ethics Board (REB) was established to ensure that all research involving human participants meets the research ethical standards, requirements and responsibilities in accordance with the most recent Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2), associated regulations (TCPS2, Article 6.1) and the University's Research Involving Human Participants Policy. The TCPS2 is 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). The Tri-Councils only provide funding to researchers and institutions that are compliant with the TCPS2. The REB endorses the core ethical principles of the TCPS2, which includes respect for persons, concern for welfare, and justice.

DEFINITIONS

2. For the purposes of this Policy the following definitions apply:

"Auspices" stands for any support, guidance, sponsorship or approval from a person or organization in which the research is being conducted under.

"Human Biological Materials" refers to any human tissues, organs, blood, plasma, serum, DNA, RNA, proteins, cells, skin, hair, nail clippings, urine, saliva and other body fluids, embryos, fetuses, fetal tissues, reproductive materials and stem cells collected from participants for research purposes.

"Jurisdiction" means the limits or territory of power, right or authority that may be exercised.

"Minimal risk" is defined as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

"Multi-Jurisdiction Research" is research involving humans that may require the involvement of multiple Canadian institutions and/or multiple Canadian REBs, but is not limited to, the following situations:

a) A research proposal conducted by a team of University Members affiliated with different institutions.
b) Several research proposals independently conducted by a University Member affiliated with different institutions, with data combined at some point to form one overall research proposal.
c) A research proposal conducted by a University Member, where the research proposal involves collecting data or recruiting participants at different institutions.

d) A research proposal conducted by a University Member who has multiple institutional affiliations. For example, two universities, a university and a college, or a university and a hospital.
e) A research proposal conducted by a University Member that requires the limited collaboration of individuals affiliated with different institutions or organizations (e.g.,
statisticians, lab or x-ray technicians, social workers, or school teachers).
f) A research proposal that a University Member conducts under the auspices of a Canadian research institution in another province, territory, or country.

"Non-University Member" means any individual involved in a Research Proposal who is not directly affiliated with the University.

"Principal Investigator (PI)" is the head of the research team who has overall responsibility for the ethical conduct of the study, and for the actions of any member of the research team. The PI is responsible for communicating any changes to the study, material incidental findings, new information, and/or unanticipated events to their own REB as well as to local site PI for multi-site studies, who must then inform their respective local REBs.

"Research" is defined as an undertaking intended to extend knowledge through disciplined inquiry and/or systematic investigation. Research involving human participants may include, but is not limited to, proposals where data are derived through:

a. the collection of information through any interaction or intervention with a living individual;
b. the secondary use of data previously collected from human participants;
c. identifiable private information about an individual; and/or
d. human remains, cadavers, human organs, tissues and biological fluids, embryos, or fetuses.

"Research Ethics Administrators" are members of the Office of Research Services which includes the Research Ethics Assistant, Research Ethics Coordinator, Research Ethics Officer and Manager of Research Ethics.

REB staff are ex-officio non-voting members. Provide administrative and operational support for the REB to fulfill its mandate.

"REB" refers to the Research Ethics Board authorized by the University.

"Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2)" is 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). This policy outlines ethical norms related to the conduct of research involving humans.

"University" refers to the University of Ontario Institute of Technology.

"University Member" means any individual who is:

a. employed by the University;
b. registered as a student, in accordance with the academic regulations of the University;
c. holding an appointment with the University, including paid, unpaid and/or honorific appointments; and/or
d. otherwise subject to University policies by virtue of the requirements of a specific policy and/or the terms of an agreement or contract.

MANDATE

3. The REB reviews and oversees all research involving human participants conducted within the University's jurisdiction or under the auspices of University members, which includes off-site and multi-jurisdiction research, to ensure that it meets ethical principles and that it complies with all applicable regulations and guidelines pertaining to human participant protection. These activities may be conducted on- or off-campus and may be funded or unfunded research. The REB shall determine the ethical acceptability of research involving human participants or human biological materials, with a primary objective of protecting the rights and welfare of participants who take part in research conducted within the jurisdiction and/or under the auspices of the University.

3.1. The REB was established and is empowered by the President of the University to review the ethical acceptability of research on behalf of the University, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans (TCPS2, Article 6.2).

4. Accountability and Reporting Relationships

4.1. The President has delegated decision-making authority to the REB in accordance with the TCPS2 standards (TCPS 2, Article 6.3).

4.2. The Chair, Vice-Chair, and members of the REB are accountable to the President for the integrity of its research ethics review process.

4.3. The Chair, Vice-Chair, and members of the REB shall report everyday administrative matters to the Vice-President Research and Innovation (VPRI).

4.4. The REB shall function independently in the decision-making process to carry out its role effectively and apply the core principles of the TCPS2 and application procedures and regulations (TCPS2, Article 6.2).

4.5. The President, other University Members and/or non-University members shall respect the independence, accountability, and authority delegated to the REB and may not override a REB decision to a research proposal that was made on ethical grounds and in accordance with the TCPS2 (TCPS 2, Article 6.3).

5. Composition and Appointment of Members

5.1. The membership of the REB is designed to ensure competent and independent research ethics review (TCPS2, Article 6.4). Voting members of the REB shall consist of:

a) A minimum of one member from each faculty within the University with expertise in relevant research disciplines, fields, and methodologies covered by the REB. As needed, additional members may be added to the membership.
b) A minimum of one community member who has no affiliation with the University.
c) One member knowledgeable in ethics. This can be someone who has a teaching or research specialization in ethics, or someone who has had extensive experience in research ethics.
d) One member whose research involves Indigenous people, if available.
e) A minimum of one member with a biomedical background.
f) One member knowledgeable in Canadian laws relevant to the research being reviewed (but the member should not be the University's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research (TCPS2 Article 6.4c).

The membership composition outlined above does not include the Chair, Vice-Chair and Research Ethics Administrators.

5.2. University student members, while optional, may be included in the REB membership. Priority is given to graduate students due to their advanced academic standing and research experience. Undergraduate students with relevant research experience may also be considered for membership.

5.3. To ensure the independence of REB decision-making, senior University administrators (e.g. vice-president of research, director general, director of business development or members of the Board of Governors) shall not serve on the REB, or directly or indirectly influence the REB decision-making process (TCPS2, Articles 6.2 and 6.10).

5.4. Members of the REB shall be appointed by the President on recommendation of the members of the REB and VPRI. The REB and/or VPRI may consult with faculty Deans and department Chairs in maintaining appropriate REB membership. In addition, University administration, REB members, and the broader community can nominate potential members. Self-nominations can also be accepted by sending a letter to the Chair, Vice-Chair of the REB and/or the Research Ethics Administrators. The President is responsible for replacing members. As needed, the President can delegate this responsibility to the VPRI.

5.5. Appointments of general members shall range from two to three years to allow for continuity of membership during transition periods among member(s).

5.6. The VPRI through the Office of Research Services (ORS) will provide the REB with necessary and sufficient ongoing financial, administrative resources and Research Ethics Administrators for the effective and efficient operation of the REB to fulfill its mandate (TCPS2, Article 6.2). The Research Ethics Administrators are ex-officio non-voting members and primarily provide administrative and operational support for the REB to fulfill its mandate. Research Ethics Administrators shall have the necessary qualifications, as well as initial and continuing training, to appropriately perform their roles and responsibilities (TCPS2, Article 6.2).

6. Responsibilities

6.1. The REB ensures compliance to the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (TCPS2), the University's Research Involving Human Participants Policy and associated procedures. For clinical trials, the REB follows Health Canada's Food and Drugs Act, the International Conference on Harmonization (ICH) Good Clinical Practice: Consolidated Guideline, and where applicable, U.S. federal regulations. The University REB also operates under applicable federal and provincial regulations.

6.2. Specifically, the REB's responsibilities include:

a. Ethics review:
   i. review all research proposals and make decisions on the ethical acceptability of all research involving human participants and/or human biological materials;
   ii. request, receive, and share any information involving the research that the REB considers necessary to fulfil its mandate, while maintaining confidentiality and respecting privacy. This may include research tools/materials and supporting documentation;

b. Compliance and monitoring:
   i. provide research ethics oversight to ensure the ethical conduct of the research;
   ii. ensure that all research proposals have a favorable risk/benefit ratio for research participants and respect a person's right for self-determination and autonomy;
   iii. ensure equitable distribution of the benefits and burdens of the research proposal;
   iv. monitor and review ongoing activities such as adverse events, unanticipated problems, continuing review, and change requests before the changes are implemented;
   v. suspend, terminate, or place restrictions on any ongoing research that has been associated with unexpected serious harm/risk to participants, ethical breaches, and/or research that is not being conducted in accordance with associated University policy, Standard Operating Procedures, applicable federal and provincial legislation, standards, and guidelines;

vi. take any actions considered reasonably necessary and consistent with the TCPS2 and University policies and procedures to ensure the protection of the rights, safety, and well-being of participants in research conducted under the REB's jurisdiction;

c. Education:
   i. act as a resource on matters of research ethics for the University;
   ii. develop and review policies and procedures regarding ethical issues of human participants in research and teaching proposals through a coordinated effort with the VPRI and/or delegate;
   iii. participate in continuing education organized by the University research administrators for the University community in matters relating to research ethics and the use of human participants in research. All REB members are required to complete the TCPS2 online tutorial.

d. Confidentiality: respect the confidentiality of the research proposals, submission materials, REB deliberations related to any research proposal, and participant complaints; and,

e. Reporting: provide an annual report summarizing the nature and volume of REB activities to the President.

7. Chair of the Research Ethics Board

7.1. The Chair of the REB is responsible for:

a) Ensuring that the REB review conforms to the requirements of the TCPS2 (TCPS 2, Article 6.8), University policies, Standard Operating Procedures (SOPs), applicable federal and provincial legislation, standards, and guidelines.
b) Providing leadership and knowledge dissemination to the REB members on research ethics literature and debates, national and international guidelines, statutes and regulations, as well as University policies and procedures.
c) Monitoring the REB's decisions for consistency.
d) Approving all REB decision letters unless otherwise delegated.
e) Ensuring that REB decisions are recorded accurately and communicated to the PI in writing as soon as possible by the Chair or the Chair's delegate (TCPS2 Article 6.8).
f) Informing the full REB of any urgent actions taken to suspend or terminate any ongoing research associated with unexpected serious harm/risk to participants, ethical breaches and/or research that is not being conducted in accordance with associated University policies, SOPs, applicable federal and provincial legislation, standards, and guidelines for ratification as soon as possible, no later than 30 days after the action was taken.
g) Advising the President and/or VPRI on the evaluation of the performance of members of the REB.

8. Vice-Chair of the Research Ethics Board

8.1. The Vice-Chair of the REB shall fulfill the same responsibilities as the Chair of the REB, as outlined in section 11.1, in a manner proportionate to their role.

8.2. The Vice-Chair shall assume the Chair's duties in their absence, in cases of conflict of interest, or when assigned specific responsibilities by the Chair.

9. General members of the Research Ethics Board

9.1. General REB members shall conduct timely and thorough reviews of applications involving human participants, ensuring the protection of participants' rights and welfare according to the principles of the TCPS2, associated regulations and the University's policies.

9.2. General REB members are expected to attend scheduled meetings regularly, except in cases of professional obligations, religious observances, personal emergencies, or scheduled vacations.

9.3. When the Chair and Vice-Chair are unavailable or in cases of conflict of interest, members may assume decision-making responsibilities as Acting Chair.

9.4. General REB members may be assigned additional ethical responsibilities by the Chair or Vice-Chair as needed.

10. Proportionate Approach to REB Review

10.1. The rigour of the research ethics review shall be proportionate to the level of associated risk to the research participants. The general principle of proportionate review outlines that the more invasive the research, the greater should be the care in assessing the research in accordance to Article 2.9 of the TCPS2. The REB must adopt a proportionate approach to assessing the ethical acceptability of the research. This level of review involves consideration of the foreseeable risks, the potential benefits, and the ethical implications of the research.

10.2. For studies that have been deemed as minimal risk research, the scrutiny level of review is proportionate to the risk level resulting in a delegated review. For studies that have been deemed as above minimal risk, the scrutiny level of review would be higher, resulting in a review by the full REB at a convened meeting.

11. Ad Hoc Advisors

11.1. At the REB's discretion, the REB may invite individuals as ad hoc advisors with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the Board (TCPS2, Article 6.5).

11.2. Ad hoc advisors must provide a written report on the review and participate via teleconference and/or attend the REB meeting for discussion on the review, if deemed necessary by the REB Chair and/or Vice-Chair. However, the ad hoc advisors may not participate in the REB's final deliberation about the proposal

(TCPS2, Article 6.5). The report and discussions are documented in the final REB minutes and stored in the study-specific file.

11.3. While ad hoc advisors may complement the REB through their experience, knowledge, or expertise, their input is a form of consultation that may or may not be considered in the REB's final decision. They are not considered REB members and should not be counted in the quorum for an REB, nor be allowed to vote on REB decisions (TCPS2, Article 6.5).

12. Chair and Vice Chair of the REB Selection and Appointments

12.1. The President shall appoint the Chair and Vice-Chair of the REB based in consultation with the VPRI and members of the REB. The President may consult with faculty Deans and department Chairs on the Chair and Vice-Chair selection. The Chair and Vice-Chair shall serve for a term of 2 years, renewable for one additional term.

12.2. The President can extend the Chair and Vice-Chair's term until a suitable Chair and/or Vice-Chair replacement is available to ensure leadership continuity.

12.3. The Chair of the REB must hold a tenured position from an academic institution along with research experience on human participants and knowledge of the TCPS2.

12.4. The Vice Chair of the REB may hold a tenured position from an academic institution; however, it is not necessary. The Vice Chair of the REB must have recent research experience on human participants and knowledge of the TCPS2.

13. Removal of the Chair, Vice-Chair, Members of the REB

13.1. In the event of unforeseen circumstances necessitating temporary or permanent changes with the Chair and/or Vice-Chair, the President shall identify a suitable interim Chair and/or Vice-Chair in consultation with the VPRI and members. For permanent changes to the Chair and/or Vice-Chair, the President shall initiate a transparent selection process to identify viable candidates.

13.2. The decision to remove a member due to unforeseen circumstances necessitating temporary or permanent changes shall be made by the Chair of the REB, in consultation with the Vice-Chair and/or the VPRI, with the approval of the President. Written notice of the decision will be provided to the member, along with the reasons for removal.

14. Quorum

14.1. As per TCPS2 Articles 6.4 and 6.9, quorum requirements shall consist of:

a) At least two members having expertise in relevant research disciplines, fields, and methodologies covered by the REB.
b) At least one member knowledgeable in ethics.
c) At least one member knowledgeable in the relevant law (but that member should not be the university's legal counsel or risk manager).
d) At least one community member who has no affiliation with the university.

15. Meetings

15.1. The REB shall hold at most twelve meetings each year to review all proposals involving human participants and human materials that require a review by the full Board. Meetings are to be held monthly and the Chair of the REB through the Office of the VPRI shall set dates. Additional meetings will be held when necessary, at the request of the Chair, Vice-Chair or members of the REB. Research proposals receiving a delegated review will follow the applicable SOPs of the REB.

15.2. The REB meetings shall be conducted in hybrid format to allow members of the REB to participate either in person or remotely via videoconference, teleconferencing, or other technologies to attend a meeting to foster collaboration and enhance accessibility.

15.3. Attendance at REB meetings ensures active participation and contributes to the effectiveness of the ethics review process. The REB members are expected to attend all meetings; however, the Chair and Vice-Chair of the REB understands that planned and unplanned absences may arise that can prevent members from attending a scheduled meeting. The Chair and Vice-Chair of the REB will accommodate absences within reason. For planned and/or unplanned absences, members are expected to provide as much notice as possible to the Chair, Vice-Chair and/or Research Ethics Administrators about the absence.

15.4. Consistent failure to attend the REB meetings may result in a review of the membership status and/or loss of membership on the REB. The Chair and Vice-Chair of the REB understands that individual circumstances may vary and membership removal from the REB will be made on a case-by-case basis. The Chair and/or Vice- Chair of the REB will notify the President to obtain a suitable member replacement for the REB, in consultation with the VPRI.

15.5. The REB should accommodate reasonable requests from the PI and/or University member(s) to participate in discussions of their research proposal(s) at the REB meeting. However, the PI and/or project team members shall not be present during the deliberation and decision-making of the research status going forward for the study.

15.6. REB meetings are closed to the University members and general public to maintain the integrity of the REB's review process. However, the REB Chair

and/or Vice-Chair may, at their discretion and on a case-by-case basis, allow external attendance.

15.7. REB minutes must be taken at every meeting to document the following: meeting attendance (including the presence of ad hoc reviewers, guests or observers); conflict of interest declarations and recusals; summary of discussions; actions taken by the REB on each agenda item requiring full REB action; and, final voting results, including for, against, and abstentions.

15.8. REB minutes are to only be accessible to REB members, authorized ORS personnel, the VPRI and President. For internal or external audits of research monitoring, reconsideration requests, and/or appeals, the study files, minutes and other relevant documentation will be made accessible to authorized representatives of the University, sponsors and/or funding agencies.

16. Decision Process

16.1. For research proposals that qualify for a review by the full board, a fully detailed review will occur at a convened REB meeting. When a research proposal has been reviewed by the full board, the REB may delegate the responsibility to the Chair and/or Vice-Chair of the REB post-review to synthesize the clarifications/concerns raised by the REB into a decision letter and assess the PI's proposed responses to the decision letter. When the investigator addresses all clarifications/concerns of the REB, the REB delegates authority to the Chair and/or Vice-Chair to issue approval.

16.2. The Chair and/or Vice-Chair of the REB or delegate will determine which research proposals qualify for delegated versus full board review. On behalf of the full REB, the Chair and Vice-Chair of the REB are delegated the authority to review and approve delegated research proposals, change requests, ongoing activities, and monitor reports of adverse events and unanticipated problems.

16.3. The Research Ethics Administrators will communicate all decisions of the REB in writing to the PI.

16.4. Delegated decisions and actions of the Chair and/or Vice-Chair of the REB will be reported to the full REB at the next available opportunity.

17. Conflicts of Interest

17.1. Members of the REB must disclose any real, apparent, or perceived conflicts of interest regarding a proposal under review to the Chair and/or Vice-Chair of the REB. Members cannot be present for any REB discussion and cannot participate in the decision process for a proposal in which they have any vested interest and/or named as a project team member. The minutes shall reflect that a conflict of interest was declared and whether the REB member was removed from the deliberations.

17.2. Members of the REB recusing themselves due to conflicts of interest are not counted towards quorum requirements.

MONITORING AND REVIEW

18. The REB Terms of Reference will be reviewed as necessary, and at least every three years (unless another timeframe is required for compliance purposes). The REB, VPRI, and ORS are responsible to monitor and review these terms.

RELATED POLICIES, PROCEDURES & DOCUMENTS

19. Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans