

## POLICY 7.14 – Research Involving Human Participants

<b>Policy Category:</b>	Research
<b>Subject:</b>	Human Ethics
<b>Approving Authority:</b>	Board of Governors
<b>Responsible Officer:</b>	Vice-President (Research)
<b>Responsible Office:</b>	Office of the Vice-President (Research)
<b>Related University Policies:</b>	<a href="#">MAPP 7.0 – Academic Integrity in Research Activities</a>
<b>Effective Date:</b>	June 17, 2021
<b>Supersedes:</b>	June 30, 2009

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### I. PURPOSE

To cultivate an environment in which the conduct of Research involving Human Participants, performed by faculty, staff or students of or in affiliation with The University of Western Ontario (Western), follows the highest ethical standards.

To promote an awareness and understanding of how the Core Ethical Principles of Respect for Persons, Concern for Welfare, and Justice are applied within the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) as well as all applicable regulations, guidelines, and standards pertaining to human participant protection: and

To establish an independent human research ethics review process charged with the task of promoting the ethical pursuit of Western's research objectives.

### II. SCOPE

This policy applies to all research involving humans conducted by faculty, staff or students of or in affiliation with Western (Western Human Research).

### III. AUTHORITY AND RESPONSIBILITY

- a) The Research Ethics Boards (REBs) are accountable to the Board of Governor's with respect to the processes the REBs follow in pursuit of their mandates.
- b) The Vice-President (Research) is designated as the senior administrative officer of Western responsible to ensure Western's REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their regulatory duties.

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- c) Western's Research Ethics and Compliance Office (RECO) is responsible to provide administrative support and to facilitate the REBs' management of the approval and monitoring processes for Western Human Research.
- d) The REBs shall act independently of the Board of Governors when making decisions regarding the ethics of Western Human Research. Neither the Board of Governors nor any other entity may override a REB's decision to approve, reject, request modifications to, or terminate any proposed or ongoing research. Notwithstanding this point, the REBs are accountable to the Board of Governors with respect to the processes the REBs follow in pursuit of this policy.
- e) For the final meeting of the Board of Governors each year, Director of Research Ethics and Compliance shall submit a report to the Board of Governors through the University Research Board (URB) regarding the REBs' activities. This report shall include information regarding the number of protocols reviewed by both REBs, the efficiency of the review process, and related procedural matters.
- f) The RECO is responsible to provide leadership to serve Western's research community of faculty, staff and students who share responsibility for undertaking human participant research in alignment with all external and institutional requirements and statutory requirements.
- g) Western's REBs may be designated as another institution's REB of Record or, conversely, another institution's research ethics board may be designated as the Western REB of Record (e.g. for the purpose of multi-centre research). In each case, it is subject to approval by one of the relevant Western REB and the Vice-President (Research). The designated REB acting as the Board of Record carries out the mandate of the designating institution's REB provided it meets and maintains acceptable research ethics review qualification or accreditation standards.

### **IV. RESPONSIBILITY OF THE RESEARCH ETHICS BOARDS**

- a) Western's REBs are established to protect the rights and welfare of human participants who take part in Western Human Research.
- b) The REBs shall review the ethical acceptability of all Western Human Research, regardless of where the research is conducted.
- c) The REBs will provide initial review and ongoing oversight of research projects to ensure that they meet the ethical principles and that they comply with all applicable regulations, guidelines, and standards pertaining to human participant protection. The REBs shall comply with and apply:
  - i. The principles of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) for all research;
  - ii. As applicable to the research, the requirements of the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations, the provisions of the Ontario Personal Health Information Protection Act (PHIPA) and research requirements under O. Reg. 329/04;

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- iii. When applicable to the research, the requirements of the *U.S. federal regulations* to the extent that they exceed the applicable Canadian regulations and guidelines.
- d) Western's REBs have the authority to ensure that all research they review is designed and conducted in an ethically acceptable manner.

This includes:

- i. rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans that the REB deems to be noncompliant with the applicable regulations, guidelines, and standards pertaining to human participant protection, or
- ii. approving any research that the REBs deems to comply with the applicable regulations, guidelines, and standards pertaining to human participant protection.

### V. NON-COMPLIANCE

- a) Failure to comply with Western's policies and procedures may prevent approval of pending ethics applications and/or may result in the revocation of approval of current studies being revoked by the REBs. As warranted by the severity of circumstances, an REB may also send notification of such failure to comply to the Vice-President (Research), the researcher's Dean, Chair or Director, Institute Heads, and appropriate funding and licensing agencies.
- b) Failure to comply with this policy may result in the revocation of grant funding.

All guidelines, forms and instructions are accessible on the website at <http://www.uwo.ca/research/ethics>

### Glossary of Terms

**Core Ethical Principles of Respect for Persons, Concern for Welfare, and Justice** – Respect for human dignity requires that research involving humans be conducted in a manner that is sensitive to the inherent worth of all human beings and the respect and consideration that they are due. Respect for human dignity is expressed through three core principles: Respect for Persons, Concern for Welfare, and Justice. These core principles transcend disciplinary boundaries and, therefore, are relevant to the full range of research covered by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2018)

**Human Participant** – An individual whose data, biological materials, or responses to interventions, stimuli, or questions by a researcher are relevant to answering the research question(s). Also referred to as a “human participant,” and in other policies/guidance as “subject” or “research subject (as defined by TCPS2 [2018] [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_glossary-glossaire.html](https://ethics.gc.ca/eng/tcps2-eptc2_2018_glossary-glossaire.html) ).

**Multi-centre** – The research is reasonably expected to be conducted at more than one centre participating in the delegated REB model.

**Research** – An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation (as defined by TCPS2 [2018] [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_glossary-glossaire.html](https://ethics.gc.ca/eng/tcps2-eptc2_2018_glossary-glossaire.html) ).

**Research Ethics Board of Record (REB of Record)** – The qualified Research Ethics Board that has been delegated authority for the ethics review and ethical oversight of a research study.

**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”. The TCPS covers research involving human participants in person, by mail-out or internet. TCPS also applies to research involving human tissue and personal data collected from human participants. (see: [https://ethics.gc.ca/eng/tcps2-eptc2\\_2018\\_introduction.html#1](https://ethics.gc.ca/eng/tcps2-eptc2_2018_introduction.html#1))

**Western’s Research Ethics Boards (REBs)** –

- Non-Medical Research Board (NMREB): reviews research studies that predominately deal with social, behavioral, and cultural research in a non-clinical, non-patient-based population.
- Health Science Research Ethics Board (HSREB): reviews research studies that take place predominately inside a medical or health care environment or involve a patient population.