# UNIVERSITY OF MANITOBA
# POLICY

| | |
|---|---|
| **Policy[1]:** | **THE ETHICS OF RESEARCH INVOLVING HUMANS** |
| **Effective Date:** | January 28, 2025 |
| **Revised Date:** | |
| **Review Date:** | January 28, 2035 |
| **Approving Body:** | Board of Governors |
| **Authority:** | *The University of Manitoba Act, Section 3(c), 16(1)* |
| **Responsible Executive Officer:** | Vice-President (Research and International) |
| **Delegate: (If applicable)** | Associate Vice-President (Research) |
| **Contact:** | Associate Vice-President (Research) |
| **Application:** | Board of Governors members, Senate members, Faculty/School Councils, Students, All Employees, All REB Members |

## Part I
## Reason for Policy and Establishment of Research Ethics Boards

1.1 In 1994, the Tri-Council Working Group on Ethical Conduct for Research Involving Human Subjects was created by the Presidents of the three major national research funding councils (the "Agencies"). This multi- disciplinary working group was commissioned to develop consistent guidelines across the three councils with respect to ethical conduct for research involving humans, resulting in the 1998 Tri-Council Policy Statement (TCPS): Ethical Conduct for Research Involving Humans. The TCPS was revised in 2010 (TCPS2) and most recently in 2022 (TCPS2 (2022)). As a condition of funding, the Agencies require that Researchers and their institutions adhere to the principles and articles stipulated in the TCPS2 (2022).

1.2 The University of Manitoba (the University) is committed to complying with the TCPS2 (2022), which articulates the core principles governing the conduct of human research at the University. These core principles are respect

[1] If the Governing Document is a By-Law or Regulation use the applicable term in place of the "Policy" reference throughout the document.

for persons, concern for welfare, and justice. Under this policy, all Research involving human Participants conducted at, or under the auspices of the University require prior ethics review and approval by a Research Ethics Board ("REB").

1.3 The Vice-President (Research & International) is responsible for establishing or appointing the REBs which have the mandate to review the ethical acceptability of all Research involving human Participants conducted within the University's jurisdiction or under its auspices on its behalf.

## Part II
## Policy Content

2.1 Definitions

(a) **Advisor** means an academic staff member of the University who is responsible for instructing a student Researcher on the ethical conduct of Research, assisting in the preparation of the Protocol, reviewing and approving the Protocol before submission to an REB, attesting to the scholarly merit of the Research, acknowledging their responsibility to uphold University policy, and taking an active role in ensuring the Research is conducted in accordance with the approved Protocol.

(b) **Anonymized information** means information that has been irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of Participants from remaining indirect identifiers is low or very low.

(c) **Anonymous information** means information which never had identifiers associated with it and risk of identification of Participants is low or very low.

(d) **Coded Information** means information in which direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific Participants.

(e) **Delegated Board Review** means the level of REB review assigned to Minimal Risk Research Projects.

(f) **Department** means a Department in a faculty, college or school established by the University. For a faculty, college, or school not organized into Departments, "Department" means faculty, school or college.

(g) **Directly Identifying Information** means information that identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

(h) **Director** means the Director, Human Research Ethics and Compliance.

(i) **Ethics Review Agreement** means an official agreement between two or more institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's REBs or in which they appoint an external, specialized or multi-institutional REB where one exists.

(j) **Full Board Review** means the level of review assigned to above Minimal Risk Research Projects. Conducted by the full membership of the REB, it is the default requirement for the ethics review of Research involving humans.

(k) **Human Ethics Resource Committee or "HERC"** means a committee responsible for providing advice and consulting to OHRE and REBs on matters related to human research ethics including recommendations on policies, procedures, and processes.

(l) **Indirectly Identifying Information** means information that can reasonably be expected to identify an individual, including through a combination of indirect identifiers (e.g., date of birth, place of residence, unique personal characteristic).

(m) **Minimal Risk Research** means Research in which the probability and magnitude of possible harms implied by participation in the Research are no greater than those encountered by Participants in those aspects of their everyday life that relate to the Research.

(n) **Multi-Jurisdictional Research** means Research involving multiple institutions and/or multiple Research Ethics Boards (REBs). It is not intended to apply to ethics review mechanisms for Research involving multiple REBs within the jurisdiction or under the auspices of a single institution. Research involving humans that may require the involvement of multiple institutions and/or multiple REBs includes, but is not limited to, the following situations:

(i) a Research project conducted by a team of Researchers affiliated with different institutions;

(ii) several Research projects independently conducted by Researchers affiliated with different institutions, with data combined at some point to form one overall research project;

(iii) a Research project conducted by a Researcher affiliated with one institution, but that involves collecting data or recruiting Participants at different institutions;

(iv) a Research project conducted by a Researcher who has multiple institutional affiliations (e.g., two universities, a university and a college, or a university and a hospital);

(v) a Research project conducted by a researcher at one institution that requires the limited collaboration of individuals affiliated with different

institutions; or organizations (e.g., statisticians, lab or X-ray technicians, social workers, and school teachers); or

(vi) a Research project that researcher(s) working under the auspices of a Canadian research institution conduct in another province, territory or country.

(o) **Office of Human Research Ethics or "OHRE"** means the office responsible for providing administrative support for the University's constituted REBs.

(p) **Participant** means an individual whose data, biological materials, or responses to interventions, stimuli, or questions by a Researcher are relevant to answering the Research question(s).

(q) **Principal Investigator** means the Researcher who is responsible for the ethical conduct of the Research, and for the actions of any member of the Research team at a local site.

(r) **Research** is defined as an undertaking intended to extend knowledges through a disciplined inquiry or systematic investigation involving Participants.

(s) **Researcher** means any individual associated with and under the auspices of the University who engages in or supports Research including, but not limited to, faculty, staff, students, post-doctoral fellows, research associates, community researchers, research assistants, lab assistants, visiting researchers and anyone holding an academic appointment with the University (including geographic full time, nil salaried and adjunct appointments).

(t) **Research Ethics Board or "REB"** means a body of Researchers, community members, and others with specific expertise established to review the ethical acceptability of all Research involving humans. The University may constitute an REB or appoint an REB by agreement.

(u) **Research Ethics Protocol or "Protocol"** means information submitted in the appropriate format to the REB by the Researcher for review and approval of the ethical acceptability of the Research prior to the start of recruitment of Participants, data collection, access to data, or collection of human biological materials.

(v) **The Agencies** means the Canadian Institutes of Health Research, (CIHR and originally the Medical Research Council of Canada), the Social Sciences and Humanities Research Council of Canada (SSHRC) and the Natural Sciences and Engineering Research Council of Canada (NSERC).

(w) **University** means The University of Manitoba.

2.2 **Applicable Ethics Principles.** The University hereby affirms The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as embodying principles that apply in the discharge of its responsibilities for protecting the rights and welfare of human Participants. The TCPS2 (2022) articulates minimal standards. The University recognizes that certain laws and regulatory requirements, policies of a sponsoring agency, specific disciplines, and/or particular categories of Research may have more restrictive requirements for the protection of human Participants. In such cases, the more restrictive requirements shall apply and take precedence in the review and approval of Research conducted at, or under the auspices of, the University.

2.3 The University recognizes that in order to ensure the integrity of the Research ethics review process and to safeguard public trust in this process, REBs operate independently in their decision-making so as to be free of inappropriate influence.

2.4 **Academic Freedom**. A fundamental premise of the TCPS2 and this Policy is that Research can benefit human society. In order to maximize the benefits of Research, Researchers must have academic freedom. All REBs and all persons involved in the ethics review process shall act in such a manner as to ensure that there is no infringement of the academic freedom of Researchers.

2.5 With academic freedom comes responsibility, including the responsibility to ensure that Research involving humans meets high scientific and ethical standards that respect and protect the Participants. Thus, Researchers' commitment to the advancement of knowledges also implies duties of honest and thoughtful inquiry, rigorous analysis, commitment to the dissemination of Research results, and adherence to the use of professional standards.

2.6 **Requirement for Ethics Review.** Research involving human Participants that is conducted at, or under the auspices of, the University will normally require prior ethics review and approval by an REB. This includes but is not necessarily limited to Research involving human Participants:

(a) carried out by a Researcher;

(b) that is carried out on University premises when using University facilities, equipment or resources;

(c) that is conducted elsewhere under the auspices of the University;

(d) that is an activity of a formally affiliated organization as a condition of affiliation;

(e) that is an activity of organizations or individuals whether formally affiliated or not, while on University premises using University facilities, equipment or resources, including off-campus sites;

(f) where information is collected through intervention or interaction with a living individual;

(g) where identifiable private information about individuals is collected;

(h) where human biological materials (derived from living or deceased individuals), human embryos or fetuses, human fetal tissue, human reproductive materials and stem cells, are collected and/or;

(i) where written or recorded information derived from individually identifiable human Participants is collected.

When Research takes place outside of Canada, the Researcher must also ensure that the Researcher's procedures meet all legal and regulatory requirements of that country, as well as the requirements of this Policy and Procedures.

2.7 **Research Not Subject to REB Review.** Prior ethics review and approval from an REB will not normally be required for Research when:

(a) It relies exclusively on information that is publicly available through a mechanism of legislation or regulation and that is protected by law;

(b) It is in the public domain and the individuals to whom the information refers have no reasonable expectation of privacy;

(c) It involves the observation of people in public places where it does not involve any intervention staged by the Researcher, or direct interaction with individuals or groups; those targeted for observation have no reasonable expectation of privacy; and any dissemination of Research results does not allow identification of specific individuals;

(d) It relies exclusively on secondary use of anonymous information or anonymous human biological materials so long as the process of data linkage or recording or dissemination of results does not generate identifiable information;

(e) It involves conducting quality assurance and quality improvement studies, program evaluation activities and performance reviews or testing within normal education requirements when use exclusively for assessment, management, or improvement purposes;

(f) It engages in creative practice activities as long as the creative practice activities are not used to obtain responses from Participants that will be analyzed to answer a Research question;

(g) For the initial exploratory phase of Research, which is intended to establish Research partnerships or to inform the design of a Research proposal, and may involve contact with individuals or communities.

2.8 **Uncertainty About the Need for REB Review.** When a Researcher is uncertain about the need for REB review and approval, it is the responsibility of the Researcher to obtain the written opinion of the appropriate REB Chair.

2.9 **REB of Record.** The appropriate REB of record may be:

(a) An REB constituted by the University; or

(b) An REB appointed by the University under an agreement in accordance with the TCPS2 (2022); or

(c) In the case of collaborative and/or Multi-Jurisdictional Research involving Researchers, data, or Participants from more than one institution, an REB of another institution, provided that the University has entered into an Ethics Review Agreement; or

(d) In the case of Minimal Risk Research that falls under the auspices or jurisdiction of multiple REBs or institutions, the University may follow alternative Research ethics review models without the requirement for official agreements, in accordance with the TCPS2 (2022).

2.10 **Compliance.** The University requires all Researchers to adhere to this policy and the procedures that are derived from it. The University considers the improper treatment of human Participants in Research to be a serious offence, subject to severe penalties, including but not limited to the withdrawal of privileges to conduct Research involving humans or disciplinary action.

## Part III
## Accountability

3.1 The Office of Legal Counsel is responsible for advising the Vice-President (Research and International) that a formal review of this Policy is required.

3.2 The Associate Vice-President (Research) is responsible for the implementation, administration and review of this Policy.

3.3 Board of Governors members, Senate members, Faculty/School Councils, students, employees and all REB members are responsible for complying with this Policy.

## Part IV
## Authority to Approve Procedures

4.1 The Vice-President (Research and International) may approve Procedures, if applicable, which are secondary to and comply with this Policy.

## Part V
## Review

5.1 Governing Document reviews shall be conducted every ten (10) years. The next scheduled review date for this Policy is January 28, 2035.

5.2 In the interim, this Policy may be revised or repealed if:

(a) the Vice-President (Research and International) or the Approving Body deems it necessary or desirable to do so;

(b) the Policy is no longer legislatively or statutorily compliant; and/or

(c) the Policy is now in conflict with another Governing Document.

5.3 If this Policy is revised or repealed all Secondary Documents, if applicable, shall be reviewed as soon as possible in order that they:

(a) comply with the revised Policy; or

(b) are in turn repealed.

5.4 The University recognizes that the TCPS2 (2022) will be amended from time to time. The University's policy and procedures will be reviewed on a regular basis and revised to ensure consistency with the current TCPS as required.

## Part VI
## Effect on Previous Statements

6.1 This Policy supersedes all of the following:

(a) all previous Board of Governors/Senate Governing Documents on the subject matter contained herein; and

(b) all previous Administration Governing Documents on the subject matter contained herein.

## Part VII
## Cross References

7.1 This Policy should be cross referenced to the following relevant Governing Documents, legislation and/or forms:

(a) The Ethics of Research Involving Humans Procedure

(b) The Responsible Conduct of Research Policy

(c) The Responsible Conduct of Research – Code of Research Ethics Policy

(d) Respectful Rematriation and Repatriation Ceremony Policy and Procedure

(e) Access and Privacy Policy

(f) Access and Privacy Procedure

(g) Academic Freedom and Responsibilities Policy

(h) University of Manitoba - University of Manitoba Faculty Association Collective Agreement

(i) The Tri-Council Policy Statement Ethical Conduct for Research Involving Humans

(j) Freedom of Information and Protection of Privacy Act

(k) The Personal Health Information Act (PHIA)

(l) Conflict of Interest Policy

(m) Conflict of Interest Procedure