

**UNIVERSITY OF MANITOBA
POLICY**

Policy:	THE ETHICS OF RESEARCH INVOLVING HUMANS
Effective Date:	December 7, 2011
Revised Date:	July 2, 2013
Review Date:	December 7, 2021
Approving Body:	Board of Governors
Authority:	<i>The University of Manitoba Act, Section 3 (c), 16(1)</i>
Responsible Executive Officer:	Vice-President (Research and International)
Delegate:	Associate Vice President (Research)
Contact:	Associate Vice-President (Research)
Application:	Board of Governors members, Senate members, Faculty/School Councils, Students, All Employees

**Part I
Reason for Policy**

- 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 Medical Research Council of Canada (MRC, now the Canadian Institutes of Health Research, CIHR), the Social Sciences and Humanities Research Council of Canada (SSHRC) and the Natural Sciences and Engineering Research Council of Canada (NSERC)). 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". After subsequent drafts were presented to the Canadian research community for feedback and revision, the 2010 Tri-Council Policy Statement (TCPS 2) Ethical Conduct for Research Involving Humans was released. The TCPS 2 replaces the previous TCPS. It is mandated by the granting Councils that, in order to receive research funding from these agencies, all publicly-funded Canadian institutions involved in human research must adhere to the principles and articles stipulated in this document.
- 1.2 The University of Manitoba is committed to complying with the intent of the Tri-Council's policy statement. The present policy affirms the TCPS 2 and articulates the core principles governing the conduct of human research at the University of Manitoba. Under this policy, all research projects involving human participants

conducted at, or under the auspices of, the University of Manitoba require prior ethics review and approval by a Research Ethics Board (REB).

Part II Policy Content

Definitions

2.1 The following definitions are from the TCPS 2:

- (a) **Human research** is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation involving participants. It refers to any project that involves the collection of specimens, data or information from persons, through intervention or otherwise. Included are procedures that have a low degree of invasiveness (e.g. surveys, interviews, naturalistic observations, exercise or psychometric testing, examination of patient records), as well as more invasive procedures (e.g. blood sampling, insertion of a cannula, administration of a substance).
- (b) A **participant in human research** is a person whose data, or responses to interventions, stimuli, or questions by a researcher are relevant to answering a research question.
- (c) A **research ethics protocol** is a document submitted by the applicant for consideration by the REB. This document contains a detailed description of: the rationale/purpose of the study; procedures to be followed in soliciting participants for the research, obtaining their informed consent when possible, collecting, handling and storing their information, data or biological specimens, protecting their privacy, anonymity and safety; disclosing conflicts of interest; and providing feedback regarding the study at its conclusion.
- (d) **Minimal risk** means that the risks of harm anticipated in the proposed research are not greater nor more likely, considering probability and magnitude, than those ordinarily encountered in life, including those encountered during the performance of routine physical or psychological examinations or tests.
- (e) **Identifiable or personal information** is defined as information that may reasonably be expected to identify an individual, alone or in combination with other available information.
- (f) **Directly identifying information** identifies a specific individual through direct identifiers (name, social insurance number, personal health number, etc.)

- (g) **Indirectly identifying information** can be reasonably expected to identify an individual through a combination of indirect identifiers (date of birth, place of residence, unique personal characteristic, etc.)
- (h) **Coded information** has been stripped of direct identifiers and replaced with a code.
- (i) **Anonymized information** has been irrevocably stripped of direct identifiers.
- (j) **Anonymous information** is not associated with any direct identifiers.

2.2 **Applicable Ethics Principles.** The University of Manitoba 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 TCPS 2 articulates minimal standards, however, and this University policy, those of a sponsoring agency, discipline, or for a category of research may have more applicable or more restrictive requirements for the protection of human participants. In such cases, the more applicable or restrictive requirements shall apply and take precedence in the review and approval of research projects conducted at the University of Manitoba.

2.3 **Requirement for Ethics Review.** Except as provided for in Policy section 2.4, all research projects involving humans conducted at, or under the auspices of, the University of Manitoba require prior ethics review and approval by a Research Ethics Board (REB) that reports to a standing Human Ethics Resource Committee (HERC, see Appendix I), which in turn reports to the Senate Committee on University Research (SCUR). This requirement of prior ethics review and approval applies to:

- (a) All research involving humans conducted under the auspices of the University of Manitoba by the University's academic staff (including G.F.T. academic staff), administrative and support staff, or students, both graduate and undergraduate, persons with adjunct appointments, visiting professors, visiting professional associates, research associates, and post-doctoral fellows.
- (b) All research carried out on University premises using University facilities, equipment or resources; research conducted elsewhere under the auspices of the University; the activities of formally affiliated organizations as a condition of affiliation; and the activities of organizations or individuals whether formally affiliated or not, while on University premises or using University facilities, equipment or resources, including off-campus sites. When research takes place in a foreign country, the researcher must also assure that his/her procedures meet all legal requirements of that country, as well as the requirements of this policy.

- (c) All types of research conducted with humans. Specifically, prior ethics review and approval is required when research data are derived from, but not exclusively restricted to:
- (i) information collected through intervention or interaction with a living individual(s);
 - (ii) identifiable private information about individuals (information is identifiable if it may reasonably be expected to identify an individual);
 - (iii) human biological materials (derived from living or deceased individuals), human embryos or fetuses, human fetal tissue, human reproductive materials and stem cells, and/or
 - (iv) written or recorded information derived from individually identifiable human participants. In addition, ethics review is required for the following categories of research that may be overlooked or raise questions about the necessity for such a review:
 - (1) Pilot studies and feasibility studies, even those involving only one human participant, require the same scrutiny as full-scale research projects involving many participants.
 - (2) Projects that involve the secondary use of data on humans gathered in earlier projects.
 - (3) Research conducted by administrative and academic units that involves the collection of survey replies or the use of records as correlates of survey replies from human participants, e.g. students, staff and/or faculty members.
 - (4) Research projects in which the researcher is a consultant unless the researcher has a strict consulting relationship in which: (a) the researcher is hired on his or her own time; (b) the researcher holds no rights in the work; and (c) neither the researcher nor the University retains any data. If any one of these three criteria is not met, prior ethics review and approval is required.
 - (5) All graduate and undergraduate independent student research projects conducted in partial fulfillment of degree requirements (see Procedures section 2.4). Research projects conducted as part of formal course requirements may, in certain instances (see Procedures section 2.4(b)), require REB review and approval. It is incumbent on the

instructor to check the applicability of this requirement with the REB Chair.

2.4 Research Excluded, i.e. Not Subject to REB Review. Prior ethics review and approval from an REB will not normally be required for:

- (a) A limited type of research most often found within the humanities, fine arts, and in some historical research, relying exclusively on publicly available information, which involves:
 - (i) information which is legally accessible to the public and appropriately protected by law, such as a public database where aggregated data that cannot be associated with any individual are obtained;
 - (ii) information already in the public domain (e.g. autobiographies, biographies or public archives) where there is no reasonable expectation of privacy; and/or
 - (iii) research involving a living individual in the public domain, or an artist, based exclusively on publicly available information, and as long as the subject is not approached directly for interviews or access to private papers. Nevertheless, it is the responsibility of the researcher to ascertain that any information used from these sources is presented in an accurate fashion. There are exceptions; research involving publicly accessible digital sites (such as Internet chat rooms or self-help groups with restricted membership) should undergo REB review.
- (b) Archival analysis of records by University departments normally engaged in the collection, maintenance, and analysis of such records. Nevertheless, it is incumbent on such units to ensure that the anonymity of individuals and confidentiality of their records are maintained.
- (c) Class research projects which involve humans and which are conducted by students on other members of the class as exercises to learn how to conduct research.
- (d) Research involving the observation of people in public places where intervention by or interaction with the researcher is not involved, there is no reasonable expectation of privacy, and the research results will not allow identification of specific individuals.
- (e) Creative practice activities, unless employed in the context of research to obtain responses from participants used to analyze a research question.
- (f) Quality Assurance or Quality Improvement studies, program evaluation, performance reviews or testing within normal educational requirements

when used exclusively for assessment, management or improvement purposes.

- 2.5 **Uncertainty About the Need for REB Review.** For research/scholarly work where the researcher is uncertain whether REB review is required, it is the responsibility of the researcher to obtain the written opinion of the Chair of the appropriate REB as to whether the research should be subjected to prior ethics review and approval.
- 2.6 **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.
- 2.7 **Compliance.** The University requires all faculty members, staff and students 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 and all employees are responsible for complying with this Policy.

Part IV Authority to Approve Procedures

- 4.1 The Vice-President (Research and International), in consultation with the Senate Committee on University Research, may approve Procedures, if applicable, which are secondary to 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 December 7, 2021.

- 5.2 In the interim, this Policy may be revised or repealed if:
- (a) the Vice-President (Research and International) or 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 will be reviewed as soon as reasonably possible in order to ensure that they:
- (a) comply with the revised Policy; or
 - (b) are in turn repealed

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) [Procedures: The Ethics of Research Involving Humans](#)