

**Politique relative à l'éthique
de la recherche avec des
êtres humains**

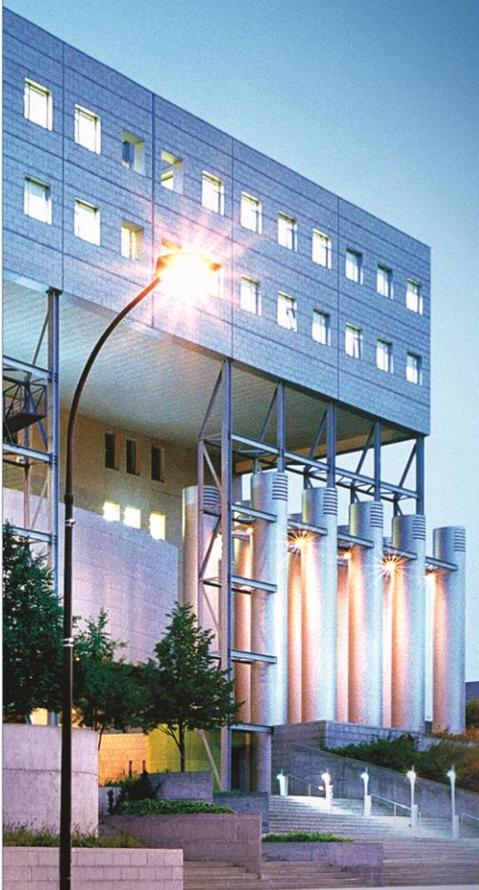
**Policy on Ethical Conduct for
Research Involving Humans**

Adoptée par le Conseil pédagogique le 13 mars 2001

Mise à jour le 23 mai 2012 et le 22 mai 2013

**Adopted by the Academic Council
March 13, 2001**

Updated May 23, 2012 and May 22, 2013



Policy on Ethical Conduct for Research Involving Humans

Preamble:

In 2001, HEC Montréal adopted its first Policy on Ethical Conduct for Research Involving Humans, the aim of which was to ensure respect for the life, autonomy, dignity and integrity of persons in research involving human beings.

In 2008, HEC Montréal signed the Memorandum of Understanding on the Roles and Responsibilities in the Management of Federal Grants and Awards with the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC).

Under this Memorandum of Understanding, HEC Montréal agrees to comply with a set of basic requirements for its researchers and faculty in order to be eligible to obtain research grants and awards from the federal granting agencies. Among these requirements, HEC Montréal reaffirms its commitment to comply with the standards and procedures established by the federal granting agencies for the ethical review of research involving humans. These rules also apply to research funded by the Canadian Institutes of Health Research (CIHR) in addition to certain other granting agencies.

In December 2010, the three federal granting agencies published the document entitled Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, or TCPS 2. The federal granting agencies will fund only those researchers, institutions and organizations that adhere to the ethical principles and clauses set out in the TCPS 2.

This Policy was adopted in order to ensure that HEC Montréal is in compliance with the requirements of the TCPS 2. This Policy replaces the Policy on Ethical Conduct for Research Involving Humans adopted on March 13, 2001.

1. Purpose

- 1.1 The primary purpose of this Policy is to implement a process for the ethics review of research projects based on the three core principles set out in the TCPS 2 – namely, respect for persons, concern for welfare and justice.

2. Scope and Application

- 2.1 All research projects involving humans, regardless of whether or not they are funded by the federal granting agencies, shall be subject to a continuing ethics review by HEC Montréal's Research Ethics Board (REB) in accordance with TCPS 2 guidelines.

- 2.2 The REB shall certify the compliance of research projects involving humans with the ethical principles set out in the TCPS 2 by issuing certificates of ethics approval.
- 2.3 Research is defined in the TCPS 2 as “an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.”
- 2.4 The TCPS 2 defines human participants as “those individuals whose data, or responses to interventions, stimuli or questions by a researcher, are relevant to answering the research question.”
- 2.5 Research that relies exclusively on publicly available information does not require REB review when:
 - 2.5.1 the information is legally accessible to the public and appropriately protected by law; or
 - 2.5.2 the information is publicly accessible and there is no reasonable expectation of privacy.
- 2.6 REB review is not required for research involving the observation of people in public places where:
 - 2.6.1 the research does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
 - 2.6.2 the individuals or groups targeted for observation have no reasonable expectation of privacy; and
 - 2.6.3 any dissemination of research results does not allow identification of specific individuals.
- 2.7 Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for such purposes if the REB is satisfied that:
 - 2.7.1 identifiable information is essential to the research;
 - 2.7.2 the use of identifiable information without the participants’ consent is unlikely to adversely affect the welfare of individuals to whom the information relates;
 - 2.7.3 the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;

- 2.7.4 the researchers will comply with any known preferences previously expressed by individuals about any use of their information;
- 2.7.5 it is impossible or impracticable to seek consent from individuals to whom the information relates;
- 2.7.6 The researchers have obtained any other necessary permission for secondary use of information for research purposes.

If a researcher satisfies all the conditions in Article 2.7.1 to 2.7.6, the REB may approve the research without requiring consent from the individuals to whom the information relates.

- 2.8 REB review is not required for research that relies exclusively on secondary use of anonymous information so long as the process of data linkage or recording or dissemination of results does not generate identifiable information. However, where the researcher seeks data linkage of two or more anonymous sets of information and there is a reasonable prospect that this could generate identifiable information, then REB review is required in accordance with the provisions of Article 2.7.
- 2.9 Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of the TCPS 2, and therefore do not fall within the scope of REB review.

3. Responsibilities of Researchers

- 3.1 Any professor who obtains funding to conduct a research project shall submit a Declaration of Ethical Responsibility to the REB.
- 3.2 Any researcher who conducts a research project involving humans, whether funded or not, is responsible for obtaining a certificate of ethics approval before commencing the research involving humans.
- 3.3 Any researcher who conducts a research project involving humans is responsible for maintaining ethics certification throughout the entire duration of research activities involving humans.
- 3.4 Any researcher who conducts a research project involving humans is responsible for informing the REB of any significant changes to the research project that may affect human participants and must obtain the REB's approval of any such changes prior to their implementation.

- 3.5 Any researcher who conducts a research project involving humans is responsible for reporting to the REB any unforeseen issues that arise that may increase the level of risk or have other ethical implications.
- 3.6 Any researcher who conducts a research project involving humans is responsible for informing the REB of the completion of the research project.

4. Research Ethics Board

a) Establishment of the REB

- 4.1 The Academic Council shall establish HEC Montréal's Research Ethics Board, which shall continue the work of the REB created under the Policy on Ethical Conduct for Research Involving Humans adopted on March 13, 2001.

b) Composition of the REB

- 4.2 The members of the REB shall be appointed by the Director for terms of three (3) years, which terms shall be renewable. In appointing REB members, the institution shall establish their terms in such a way that the terms of one-third of members are renewed or terminated each year.
- 4.3 The REB shall consist of at least the following members:
 - 4.3.1 A chairperson, who may also belong to one of the following categories;
 - 4.3.2 One professor per department;
 - 4.3.3 One M. Sc. or Ph. D. student;
 - 4.3.4 One community member;
 - 4.3.5 One person who is knowledgeable in ethics;
 - 4.3.6 Any other person who, in the opinion of the Director, should be a member of the REB in order to facilitate its work;
 - 4.3.7 Staff members of the Research Office or the REB secretariat, without voting rights.
 - 4.3.8 A secretary, without voting rights.

c) Mandates of the REB

- 4.4 The primary mandate of the REB shall be to review the ethical acceptability of research projects involving humans conducted by HEC Montréal faculty, staff or students, regardless of where the research is conducted. Research projects are deemed to include, notably, projects that give rise to the writing of a supervised project in the context of a specific research mandate, a master's or doctoral thesis, a scientific or professional article or a case used for research purposes.
- 4.5 The REB shall also have the following additional mandates:
- Promote awareness and inform the School's researchers about issues related to ethical conduct for research involving humans;
 - Develop the necessary tools and procedures for the implementation of this Policy;
 - Ensure monitoring of approved research protocols;
 - Approve, modify or, where necessary, terminate a research proposal or the continuation of a research project;
 - Submit an annual report to the Director of the School, to the Director of Research and to the Program Director summarizing the Committee's activities and decisions and presenting any recommendations that may be useful in the application of this Policy.
 - Ensure liaison with the Interagency Advisory Panel on Research Ethics and the granting agencies for all questions related to the application of this Policy.

d) Rules of Procedure

- 4.6 The REB shall meet in a plenary session at least four (4) times each year.
- 4.7 Quorum for meetings of the full committee shall consist of at least three (3) professors appointed in accordance with Article 4.3, one community member and one person who is knowledgeable in ethics. In the absence of the chairperson, one of the professors appointed in accordance with Article 4.3 may chair a full committee meeting.
- 4.8 In accordance with the principle of a proportionate approach to reviews set out in the TCPS 2, the REB may delegate the review of research projects involving minimal risk to one or more of its members.

- 4.9 “Minimal risk” research is defined as 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.
- 4.10 In the event that the delegated reviewers are unable to reach a positive decision, the decision shall be referred to a review by the full committee.
- 4.11 REB members may not review a research project which they themselves submitted or on which they are co-investigator, or which was submitted by a student under their supervision. In such circumstances, the REB member must leave the room during the meeting of the full committee.
- 4.12 The certificate of ethics approval issued by the REB shall be valid for a maximum period of one year, renewable upon request, and shall expire on the date indicated on the certificate. In exceptional or special circumstances, such as sick leave, maternity leave or an emergency, the validity of an ethics approval certificate may be extended beyond its initial expiry date.

5. Appeal of REB Decisions

a) Right of Appeal

- 5.1 The REB can recommend that changes be made to a research project in order to bring it into compliance with the TCPS 2.
- 5.2 The researcher may also suggest other modifications and request a reconsideration of the research project by the REB.
- 5.3 The REB can refuse to approve a project or to renew an ethics approval certificate.
- 5.4 A researcher can appeal a decision by the REB to the Research Ethics Appeal Committee. The researcher shall have thirty (30) days from receipt of the decision to submit a request for an appeal to the REB chair.

b) Research Ethics Appeal Committee

- 5.5 The Research Ethics Appeal Committee shall be composed of two full professors, one of whom has relevant expertise in the topic of the research project, and one person from outside HEC Montréal who is knowledgeable in research ethics. A member of the REB can not sit on the Appeal Committee.

- 5.6 The Director shall appoint the three members of the Research Ethics Appeal Committee.
- 5.7 The Research Ethics Appeal Committee shall be given access to all documents in the research project file.
- 5.8 The Research Ethics Appeal Committee shall give the researcher and the chair of the REB the opportunity to present their views regarding the refusal, either in writing, in person or both.
- 5.9 The Research Ethics Appeal Committee can either approve or refuse the granting of a certificate of ethics approval. The decision of the Research Ethics Appeal Committee shall be final and binding.