

POLICY 2500-028

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FOREWORD

In 1989, Université de Sherbrooke adopted the *Politique institutionnelle en matière de déontologie de la recherche sur l'humain*. This policy was amended when the *Civil Code of Québec* came into force in 1994, and again in 1998 with the implementation of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The policy was then renamed the *Policy on Ethical Conduct for Research Involving Humans* (hereinafter referred to as “the Policy”) to better reflect the ethical dimension of the approach adopted by Université de Sherbrooke in its institutional policy.

In 2010, a major revision of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS-2) was published to highlight current and emerging ethical issues and new areas of research. The TCPS-2 was subsequently updated in 2014. Université de Sherbrooke (the “University”) has since revised the Policy’s content to better reflect these changes.

The Policy henceforth considers, among other things, the following elements:

- *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*¹ (Interagency Advisory Panel on Research Ethics, 2014);
- The *Charter of Human Rights and Freedoms* (R.S.Q., c. 12);
- The *Civil Code of Québec*;
- The *Act respecting Access to documents held by public bodies and the Protection of personal information* (R.S.Q., c. A-2.1);
- The *Plan d'action ministériel en éthique de la recherche et en intégrité scientifique* (Ministère de la Santé et des Services sociaux, 1998);
- The *Entente pour la reconnaissance des certificats d'éthique des projets à risque minimal* (Conférence des recteurs et principaux d'universités du Québec – CREPUQ, 2011);
- *Guidelines for Human Pluripotent Stem Cell Research* (Canadian Institutes of Health Research, 2007);
- The *Politique sur l'intégrité en recherche et sur les conflits d'intérêts* (Policy 2500-021, Université de Sherbrooke); and
- Other laws, regulations and standards in force.

In the event of any discrepancy between the English and French versions of this policy, the French version shall prevail.

1. ETHICAL FRAMEWORK

The University recognizes as a fundamental principle that science and technology are at the service of human beings and must respect their inalienable rights and fundamental values. To this end, the University forms, or mandates research ethics boards (REBs) to review all research involving humans conducted under its authority or auspices, i.e., by its faculty members, employees, and students, regardless of where the research is conducted.

This policy is consistent with the standards set out in TCPS-2. The TCPS-2 is the leading framework for institutions, researchers, and research ethics boards (REBs) mandated to conduct ethics reviews of research involving humans. Its aim is to propose and inspire thoughtful conduct grounded in ethical principles.

1.1 Core principles

The University embraces the core principles of respect for Persons and concern for Welfare and Justice:

¹ https://ethics.gc.ca/eng/policy-politique_tcps2-epc2_2018.html

- **Respect for Persons** recognizes the intrinsic value of human beings and the respect and consideration that they are due. It encompasses the treatment of persons involved in research directly as participants, and for those who are participants because their data or human biological materials are used in research. Respect for Persons includes the dual moral obligation to respect autonomy and to protect those with developing, impaired or diminished autonomy;
- **Concern for Welfare** means that researchers and REBs should aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research;
- **The principle of Justice** refers to the obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

These principles are complementary and interdependent. How they apply and the weight accorded to each will depend on the nature and context of the research being undertaken.

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.

2. SCOPE AND APPROACH

This Policy applies to all research involving humans that is conducted or supervised by faculty, staff, or students at the University (hereinafter referred to as “researchers”). The research may be funded by grants, contracts, awards, etc., or it may be non-funded.

The TCPS-2 defines research as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. Disciplined inquiry refers to an inquiry that is conducted with the expectation that the method, results, and conclusions will be able to withstand the scrutiny of the relevant research community.

2.1 Research requiring research ethics board review

Projects involving the following require ethics review and approval by an REB before the research commences:

- Living human participants;
- Any human biological materials, as well as embryos, fetuses, fetal tissue, human reproductive materials (including human genetic materials) and stem cells. This applies to materials derived from living or deceased individuals;
- The creation or use of data banks or tissues from either of these groups.

2.2 Research exempt from or not requiring research ethics board review

Some research is exempt from REB review where protections are available by other means. Research requiring REB review should be distinguished from non-research activities, even if they commonly make use of research-like methods and techniques.

In the event of any doubt about the applicability of this Policy to a specific research project, the researcher should seek guidance from the REB, which is responsible for ruling on exemptions from the requirement for ethics review.

2.2.1 Publicly available information

Research based exclusively on publicly available information does not require REB review if either of the following conditions are met:

- The information is legally available to the public and adequately protected under the law; or
- The information is publicly available and there is no reasonable expectation of privacy.

2.2.2 Observation of people in public places

Observation of people in public places does not require REB review provided that:

- The research does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
- The individuals or groups targeted for observation have no reasonable expectation of privacy; and
- No dissemination of research results allow for identification of specific individuals.

2.2.3 Secondary use of anonymous information or of anonymous human biological materials

REB review is not required for research that relies exclusively on the secondary use of anonymous information, or anonymous human biological materials, so long as that the process for linkage, recording or dissemination of results does not generate identifiable information.

2.2.4 Activities not constituting research

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 this Policy, and do not fall within the scope of REB review.

Arts activities primarily involving creative practice do not require REB review. However, REB review is required if a research project involves creative practice to obtain responses from participants that will be analyzed to answer the questions related to the research project.

2.3 Proportionate approach to research ethics board review

The REB should adopt a proportionate approach to research ethics review, such that the level of review is selected according to the level of risk associated with the research: the lower the level of risk, the lower the level of review (delegated review), and the higher the level of risk, the higher the level of review (full board review). Regardless of the level of review adopted, the proportionate approach to assessing the ethical acceptability of research is understood as taking into account the foreseeable risks, potential benefits and ethical implications of the research in question.

2.3.1 Potential benefits

Research involving humans may produce benefits that positively affect the welfare of society as a whole through the advancement of knowledge for future generations, for participants themselves or for other individuals. Often, however, a research project offers little or no direct

benefit to participants. In most research, the primary benefits produced are for society and for the advancement of knowledge.

2.3.2 Risks

Because research is a step into the unknown, its undertaking involves harms to participants or others. Harm is anything that has a negative impact on the welfare of participants, and the nature of the harm may be social, behavioural, psychological, physical or economic. Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or third parties.

Taking account foreseeable risks and the means available to eliminate or mitigate them is essential for proper ethics review of research projects.

To the extent possible, REBs and researchers should attempt to assess the harm from the perspective of the participants and consider that in some disciplines, research may present risks that go beyond the individuals and may involve the interests of communities, defined groups, or societies.

2.3.3 Balance of benefits and risks

The potential benefits may be for the participants themselves, for others or for society as a whole. However, research may cause harm to participants, hence the need to consider and balance the two elements at stake – the potential benefits and the foreseeable risks. One of the roles of the REB is to ensure that the risk/benefit balance justifies the risks of the project.

The principle of concern for welfare imposes an ethical obligation to design, review, and implement the research project in a way that protects the participants from unnecessary or avoidable risk. In their review, REBs consider whether the risks are justified by the assessment of the potential outcomes and benefits of the research.

2.4 Scientific review

REBs shall review the ethical implications of the methods and design of the research. They should normally avoid duplicating previous professional peer-review assessments unless there is a specific and defined reason to do so.

The University considers that it is the responsibility of REBs reviewing research to ensure that the methods used to answer the research questions are sufficiently reliable to avoid the futile participation of participants. They must therefore ensure that there is a scientific assessment of the research project, considering the nature and degree of risk to the participants.

It is the responsibility of researchers to inform the REB of whether the project has undergone or will undergo scientific review and, if so, the terms thereof. REBs may require the researcher to provide full documentation of previous scientific reviews.

3. DIRECTIVES

The University Executive Committee shall establish directives derived from this policy as needed.

4. RESPONSIBILITY

Responsibility for the application of this policy rests with the Vice-President, Research.

5. ENTRY INTO FORCE

This policy became effective on February 27, 1989; the latest amendments were adopted by the University Council on April 22, 2015.