Fonds de recherche du Québec

Nature et technologies *Santé* *Société et culture*

Research Ethics Policy

2026

Version 1

Québec

This document is a translation of the French original, which constitutes the official version. In the event of any discrepancy between the English and French texts, the French version prevails.

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Table of Contents of the Policy

A. Background

The mission of the Fonds de recherche du Québec (hereinafter, “FRQ”) is to support the strategic and coherent development of scientific research in Québec and to promote the training of the next generation in research as well as excellence in research[1]. To fulfil this mission, the FRQ provides financial support for research across all scientific disciplines. As a single funding project often involves several disciplines, the Research Ethics Policy (hereinafter, “the Policy”) applies to all three sectors of the FRQ: Society and Culture, Nature and Technologies, and Health. Funded research must be carried out in a responsible manner, in accordance with the FRQ’s commitment to promoting a global culture of ethics and preserving public trust in science.

Engaging in research involving humans, animals or the environment raises ethical questions inherent to the very nature of the activity. The Policy promotes a holistic approach to research ethics that recognizes that these three spheres are interdependent and inseparable. They influence one another, and each may be affected by impacts affecting the others. Thus, the Policy embraces ethics in a broad sense and aims to ensure respect for **humans, animals** and the **environment**[2].

Public trust in research is the cornerstone to ensuring that a society values scientific advancement and accords credibility to scientific findings. This trust is fundamentally rooted in the assurance that research adheres to established ethical standards. Moreover, the right to share in scientific advancement and its benefits[3] can only fully be exercised when appropriate conditions are in place, among which adherence to research ethics plays a central role. Finally, the acceptability of the risks inherent in certain research projects is based not only on the prospect of potential benefits, but also on the conviction that these risks will be minimized by applying recognized ethical standards.

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1 Section 22.8, Act respecting the Ministère de l’Économie, de l’Innovation et de l’Énergie, CQLR, c. M-14.1.

2 Article 34 d, Recommendation concerning the Status of Higher-Education Teaching Personnel, UNESCO General Conference (1997).

3 Article 27, Universal Declaration of Human Rights, United Nations General Assembly (1948).

The responsibility to conduct research with respect for ethical principles is the counterpart to freedom of scientific research, which is not absolute[4]. Indeed, academic freedom must be exercised in accordance with recognized standards of ethics[2, 5].

Here, research ethics refers to a reflective process aimed at guiding conduct that respects humans, animals and the environment with a view to the production of scientific knowledge. It is based on principles that consider, within a given context, the risks and benefits to individuals and communities as well as impacts on animals and the environment. Basing research ethics on detailed standards should not prevent a reflective approach nor lead to a mere exercise in compliance.

B. Structure and scope of the Policy

Each of the spheres covered by the Policy (humans, animals and the environment) is addressed in a separate section. Each of these sections comprises the following two subsections:

- **"Introduction"**: this subsection references a range of international and local standards to support reasoning and guide ethical reflection. Drawing on these standards, the FRQ establishes core principles in each of the spheres.
- **"Requirements imposed by the FRQ"**: this subsection sets out the requirements specifically imposed by the FRQ. These include both requirements established by the FRQ and those of other organizations that the FRQ has chosen to impose because they have become accepted standards.

In addition to the Policy, research is governed by other ethical, legal, administrative and contractual standards[6]. Where divergences exist between these standards, it becomes necessary to reconcile their application. This includes applying the various standards according to hierarchy, meaning that legal requirements always take precedence. This task can prove complex for the scientific community and may require assistance from individuals with the necessary expertise[7]. Ethical deliberation can also help to resolve normative tensions. To facilitate compliance with legal and administrative standards applicable to research involving humans in Québec, the annex to the Policy sets out certain requirements arising from these standards with which compliance is mandatory. This annex may also include requirements imposed by the FRQ that reflect its position on a particular ethical issue.

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4 Article 2 d, Universal Declaration on Bioethics and Human Rights, UNESCO General Conference (2005).

5 Section 3, Act respecting academic freedom in the university sector, CQLR, c. L-1.2.

6 The Policy should be regularly updated to reflect changes in these standards.

7 Anyone faced with this situation should consider seeking advice — of an ethical, legal, administrative or contractual nature — in order to make informed decisions. Resources within an institution that have the expertise to provide such advice include the research support office, legal affairs office, contracts office, research ethics boards and responsible conduct of research officers.

The Policy applies to all research whose support comes — in whole or in part — from FRQ funding. The Policy also applies to all research conducted under the authority or auspices of a managing institution[8], regardless of its funding. Managing institutions must therefore ensure that the research conducted under their authority or auspices adheres to the Policy.

C. Human dignity

i) Introduction

Generally speaking, research involving humans entails the use of data relating to individuals, their biological materials, and their reactions or responses to interventions, stimuli or questions for research purposes. The opportunity to carry out research involving human participants carries with it the responsibility to conduct such research with respect for human dignity[4].

Respect for human dignity is the core value of ethics in research involving humans. Those conducting such research have a moral obligation to ensure that it is carried out in ways that uphold human rights, and respect, protect, and are fair to human participants and the communities in which the research is conducted[9]. Research must be subject to ethical standards that ensure respect for participants and protect their health and rights[10].

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8 Institution recognized by the FRQ to administer FRQ funding. A list of managing institutions is available on the FRQ website (in French).

9 Guideline 1, International Ethical Guidelines for Health-related Research Involving Humans, Council for International Organizations of Medical Sciences in collaboration with the World Health Organization (2016).

10 Article 6, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, World Medical Association (2024).

In the Policy, respect for human dignity is expressed through three complementary and interdependent core principles[11] :

- **Respect for persons:** research must be conducted with due regard for the intrinsic value of every human being. This principle entails recognizing every person's right to equal consideration and appropriate protection. Respect for persons encompasses a dual moral obligation: to respect autonomy and to afford special consideration to those with developing, impaired or diminished autonomy. Respecting autonomy means giving due deference to the judgment of a person capable of exercising their autonomy and ensuring that they are free to make choices without interference. Obtaining free, informed, and ongoing consent protects this autonomy and contributes to respect for persons.
- **Concern for welfare:** research must consider all aspects of a person's welfare, including their physical, mental, and spiritual health, as well as their physical, economic, and social circumstances. Privacy and the control of information about a person also contribute to the person's welfare. The impacts of research on the welfare of groups and of society as a whole must also be considered.
- **Justice**: research must be conducted in a way that treats all people with equal respect and concern. Justice also requires equity in the distribution of the benefits and the burden of research participation, so that no group is unduly exposed to the disadvantages of the research or excluded from the benefits that may result from it. People or groups whose circumstances cause them to be vulnerable or marginalized must be afforded special consideration in the context of the research.

ii) Requirements imposed by the FRQ

Under this Policy, the FRQ requires that research activities incorporate considerations designed to guide conduct that respects human dignity, based on the core principles set out in the previous paragraph.

In its Politique sur la conduite responsable en recherche (hereinafter, "Policy for the Responsible Conduct of Research"), the FRQ calls for research participants to be treated with justice, respect and beneficence[12].

Through this Policy, the FRQ demands that research involving humans comply with the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans[11]

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[11] These principles were adapted from Chapter 1 of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (hereinafter, "TCPS"), which was adopted by the Social Sciences and Humanities Research Council of Canada (SSHRC), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Canadian Institutes of Health Research (CIHR) in 2022.

[12] Section 4 k), Politique sur la conduite responsable en recherche, Fonds de recherche du Québec – Nature et technologies, Fonds de recherche du Québec – Santé et Fonds de recherche du Québec – Société et culture (2022).

(hereinafter, “TCPS”) and with any subsequent amendments to this statement. However, as stipulated in the TCPS, its application must comply with the legal framework. Accordingly, the FRQ requires that the application of the TCPS to research conducted in Québec comply with applicable legal and administrative requirements, in particular those set out in the annex to the Policy.

D. Animal welfare

i) Introduction

Animals are sentient beings with biological needs[13]. The protection of animal welfare relies on legal and ethical considerations that reflect society’s respect for living beings capable of feeling pain. It is founded on the recognition that sentient animals deserve a life free from unnecessary suffering. Animal welfare is a concept used to characterize an animal’s state of health and how it experiences the conditions in which it lives[14].

The human species has an individual and collective responsibility to ensure animal welfare and safety[15]. As such, science involving animals must be conducted with due regard for their welfare[16] and within an appropriate ethical framework[17]. Furthermore, everyone working in research in contact with animals has an ethical responsibility for the animals’ welfare[18].

Research involving animals must strike a balance between the imperative of animal welfare and the importance of advancing knowledge for society. While research involving animals may be necessary in the pursuit of knowledge, its acceptability depends, among other things, on the ability to ensure their protection and welfare[19]. The “Three Rs” approach, an internationally recognized ethical framework for the protection of animal welfare, sets out three core principles aimed at achieving this balance[20]:

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13 Article 898.1, Civil Code of Québec.

14 CCAC guidelines: Animal welfare assessment, Canadian Council on Animal Care (2021), p. 3.

15 Preamble, Animal Welfare and Safety Act, CQLR, c. B-3.1.

16 Article 21, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, World Medical Association (2024).

17 Article 1, Use of Animals in Science – Position Statement, Canadian Veterinary Medical Association (2021).

18 Preamble, Chapter 7.8, Terrestrial Animal Health Code, Volume 1, 32nd edition, World Organization for Animal Health (2024).

19 CALAM Position Statement on the use of animals in science, Canadian Association for Laboratory Animal Medicine (2025).

20 These principles were adapted from Ethics of Animal Investigation, Canadian Council on Animal Care (1989); CALAM Position Statement on the use of animals in science, Canadian Association for Laboratory Animal Medicine (2025); Use of Animals in Science – Position Statement, Canadian Veterinary Medical Association (2021). The following revised ethics principles will come into force on

- **Replacement**: the involvement of animals in research must be replaced by alternative methods wherever possible and where these methods enable the scientific objectives to be achieved.
- **Reduction**: the number of animals required for research must be reduced to the minimum necessary to achieve the scientific objectives.
- **Refinement**: procedures to reduce or eliminate pain, suffering, and distress in animals must be refined in order to optimize their welfare.

ii) Requirements imposed by the FRQ

Under this Policy, the FRQ requires that research activities incorporate considerations designed to guide conduct that respects animal welfare, based on the core principles set out in the previous paragraph.

In its Policy for the Responsible Conduct of Research, the FRQ calls for animals to be treated with respect[21].

Through this Policy, the FRQ demands that research involving animals be subject to ethical approval by an animal care committee in accordance with the current standards of the Canadian Council on Animal Care and with any subsequent amendments to these standards[22]. Furthermore, the FRQ demands that such research be conducted under the authority or auspices of an institution with an animal care committee that holds a Good Animal Practice certificate from the Canadian Council on Animal Care[23].

January 1, 2030: CCAC Ethics Principles for Animal Use in Science, Canadian Council on Animal Care (2026).

21 Section 4 l), Politique sur la conduite responsable en recherche, Fonds de recherche du Québec (2022).

22 CCAC policy statement on: scientific merit and ethical review of animal-based research, Canadian Council on Animal Care (2013). This organization's standards determine which activities do or do not constitute a use of animals requiring ethical approval.

23 Certification of Ethical Animal Care and Use Programs, Canadian Council on Animal Care (2022).

E. Respect for the environment

i) Introduction

Like other types of activities, research activities can have environmental impacts. The environment is a collective and public asset, and its protection is in the general interest[24]. From this perspective, when the scientific community carries out research activities, it shares a responsibility towards protecting the environment in the collective interest.

Respect for the environment is, moreover, an integral part of ethical conduct in research. As the conservation of biodiversity is a common concern of humankind, due regard must be given to the role of humans in protecting the environment, the biosphere and biodiversity[25]. The interdependence between humans and the environment requires the scientific community to design and conduct research in a manner that avoids or minimizes harm to the environment[26].

Incorporating respect for the environment into research activities relies on the following core principles:

- **Shared responsibility:** protecting the environment is the responsibility of all sectors of society, including the research community, which is called upon to contribute to collective efforts.
- **Consideration of environmental impacts:** it is essential to consider the potential impacts that research activities may have on the environment.

ii) Requirements imposed by the FRQ

Under this Policy, the FRQ requires that research activities incorporate considerations designed to guide conduct that demonstrates respect for the environment, based on the core principles set out in the previous paragraph.

In its Policy for the Responsible Conduct of Research, the FRQ calls for respect for the environment and for projects to be conducted with consideration for environmental responsibilities in research[21].

Under its Action Plan for Environmental Responsibility in Research, the FRQ demands the implementation of mitigation measures where the level of environmental risk posed by research

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[24] Preliminary provision, Environment Quality Act, CQLR, c. Q-2.

[25] Articles 2h and 17, Universal Declaration on Bioethics and Human Rights, UNESCO General Conference (2005).

[26] Article 11, Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants, World Medical Association (2024).

activities exceeds a specific threshold[27]. It also demands, in certain cases, that the FRQ be informed of the measures to be implemented to comply with environmental legal requirements[27].

F. Implementation

The Policy comes into force on July 1, 2026. However, managing institutions have a transition period until June 30, 2027 to prepare and to adapt their standards and procedures for the application of the Policy to all new research conducted under their authority or auspices.

Compliance with the Policy is an inherent condition for the awarding of funding by the FRQ. Failure to fulfil the requirements of the Policy may constitute a breach of responsible research conduct and be subject to sanctions in accordance with the FRQ's Policy for the Responsible Conduct of Research[28].

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[27] Sections 1 and 3.1, Action Plan for Environmental Responsibility in Research, Fonds de recherche du Québec – Nature et technologies, Fonds de recherche du Québec – Santé et Fonds de recherche du Québec – Société et culture (2020). See the Action Plan for detailed requirements.

[28] See, in particular, Section 6.2.3, Politique sur la conduite responsable en recherche, Fonds de recherche du Québec (2022).

G. Annex: Application of the TCPS in Québec

The requirements of the TCPS sometimes diverge from those imposed by the legal or administrative standards that are mandatory for research involving humans in Québec. This annex sets out certain legal and administrative requirements that must be complied with in Québec, notwithstanding such divergences. As this annex does not list all the divergences between the TCPS and legal and administrative standards, it is important to ascertain whether other divergences should be taken into account.

This annex may also include requirements imposed by the FRQ that reflect its position on a particular ethical issue. Where this is the case, these requirements will be clearly identified as such.

The content of this annex may be reviewed and updated annually.

Table of Contents (Annex)

1 Glossary

Assisted procreation activities – As defined in Section 2 of the Act respecting clinical and research activities relating to assisted procreation (CQLR, c. A-5.01).

Attached researcher – Depending on context, as referred to in Section 2.2 of the Act respecting the Institut de la statistique du Québec (CQLR, c. I-13.011) or Section 44 of the Act respecting health and social services information (CQLR, c. R-22.1).

Central REB of the Ministre de la Santé et des Services sociaux – REB established under Article 21 of the Civil Code of Québec (CQLR, c. CCQ-1991) and governed by the Règles de fonctionnement du Comité central d'éthique de la recherche du ministre de la Santé (2025).

Designated information – As referred to in Section 13.1 of the Act respecting the Institut de la statistique du Québec (CQLR, c. I-13.011).

Health and social services body – As defined in Section 4 of the Act respecting health and social services information (CQLR, c. R-22.1).

Health and social services information – As defined in Section 2 of the Act respecting health and social services information (CQLR, c. R-22.1).

Identifiable human biological materials – As defined in the TCPS Glossary.

Personal information – Depending on context, as defined in Section 54 of the Act respecting Access to documents held by public bodies and the Protection of personal information (CQLR, c. A-2.1) or Section 2 of the Act respecting the protection of personal information in the private sector (CQLR, c. P-39.1).

Private enterprise – Enterprise covered by the Act respecting the protection of personal information in the private sector (CQLR, c. P-39.1).

Public body – As defined in Section 3 of the Act respecting Access to documents held by public bodies and the Protection of personal information (CQLR, c. A-2.1).

REB – Research ethics board.

REB designated or formed by the Ministre de la Santé et des Services sociaux – As referred to in Article 21 of the Civil Code of Québec (CQLR, c. CCQ-1991).

Research access centre – As referred to in Section 56 of the Act respecting health and social services information (CQLR, c. R-22.1).

RSSS – Health and social services network as defined in the Cadre de référence ministériel pour la recherche avec les participants humains (Ministère de la Santé et des Services sociaux, 2020).

TCPS – Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, 2022).

Unattached researcher – As referred to in Section 55 of the Act respecting health and social services information (CQLR, c. R-22.1).

2 REB review

The review, approval and monitoring of research involving humans by an REB are fundamental steps in the implementation of the applicable core principles, namely respect for persons, concern for welfare, and justice. REBs therefore play a central role in ensuring a balance between the potential benefits of research and its risks. Given that they also play an educational and advisory role, it may be beneficial to engage in dialogue with REBs during the research design phase and prior to the formal review process.

2.1 Exemption – Disclosure of information without consent

Article 2.2 of the TCPS

"Research does not require REB review when it relies exclusively on information that is:

a. publicly available through a mechanism set out by legislation or regulation and that is protected by law […]."

Application of Article 2.2 of the TCPS

"An archival record or database that is subject to restrictions, such as those under access to information and privacy legislation, may also be considered publicly available for the purposes of [the TCPS]."

In Québec, research involving only publicly available information obtained without consent by a mechanism established by law is not always exempt from REB review. REB review may be required before the bodies below disclose information under such a mechanism (regardless of whether it is considered "publicly available" within the meaning of the TCPS).

- **Institut de la statistique du Québec:** when an attached researcher requests the disclosure of designated information, REB review may be required[29]. The Institut de la statistique du Québec should be consulted to ascertain when this is required.

[29] Sections 13.7 and 13.8, Act respecting the Institut de la statistique du Québec, CQLR, c. I-13.011. See also: Règles de gouvernance concernant les renseignements désignés par le gouvernement et

- **Health and social services body:** when an attached researcher requests the disclosure of health and social services information, REB review is required[30].
- **Research access centre:** when an unattached researcher requests the disclosure of health and social services information, REB review is required[31].
- **Public body:** when a person requests the disclosure of personal information, REB review may be required[32]. The public body should be consulted to ascertain when this is required.
- **Private enterprise:** when a person requests the disclosure of personal information, REB review may be required[33]. The private enterprise should be consulted to ascertain when this is required.

communiqués à des fins de recherche aux chercheurs liés à un organisme public, Institut de la statistique du Québec (2023) p. 5.

30 Sections 44 and 47, Act respecting health and social services information, CQLR, c. R-22.1

31 Sections 55 and 57, Act respecting health and social services information, CQLR, c. R-22.1

32 Sections 67.2.1 and 67.2.2, Act respecting Access to documents held by public bodies and the Protection of personal information, CQLR, c. A-2.1.

33 Section 21.0.1, Act respecting the protection of personal information in the private sector, CQLR, c. P-39.1.

2.2 Recognition of an external REB

> Article 8.1 of the TCPS
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> "An institution that has established an REB may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with [the TCPS]."
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> Application of Article 8.1 of the TCPS
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> "In consultation with its REB(s), an institution may authorize its REB(s) to accept reviews undertaken by an external REB of the ethical acceptability of research."

In Québec, certain requirements may sometimes prevent an institution from authorizing its REB to recognise a review conducted by another institution's REB, regardless of the risk level of the research. In the situations below, the institution must ensure that an external REB meets the specific requirements applicable in Québec, in addition to those set out in the TCPS.

- **Research that could interfere with the integrity of a minor or an adult incapable of giving consent:** ethics review and monitoring must be conducted by an REB designated or formed by the Ministre de la Santé et des Services sociaux[34].
- **Research conducted under the auspices of an RSSS institution:** ethics review and monitoring must be conducted by an REB from the RSSS or by the central REB of the Ministre de la Santé et des Services sociaux[35].
- **Research concerning assisted procreation activities** (or using embryos that resulted from such activities but were not used for that purpose): ethics review and monitoring must be conducted by the central REB of the Ministre de la Santé et des Services sociaux[36].
- **Disclosure without consent of health and social services information by a health and social services body to an attached researcher:** ethics review and monitoring must be conducted by an REB designated or formed by the Ministre de la Santé et des Services sociaux[37].
- **Disclosure without consent of health and social services information by the research access centre to an unattached researcher:** ethics

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[34] Article 21, Civil Code of Québec, CQLR, c. CCQ-1991.

[35] Article 2.5.3, Cadre de référence ministériel pour la recherche avec les participants humains, Ministère de la Santé et des Services sociaux (2020).

[36] Section 8, Act respecting clinical and research activities relating to assisted procreation, CQLR, c. A-5.01.

[37] Section 44, Act respecting health and social services information, CQLR, c. R-22.1.

review and monitoring must be conducted by an REB designated or formed by the Ministre de la Santé et des Services sociaux[38].

2.3 Member with knowledge of relevant law

> Article 6.4 of the TCPS
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> "The REB shall consist of at least five members, including both men and women, of whom at least: […]
>
> c. one member is knowledgeable in the relevant law. That member should not be the institution's legal counsel or risk manager. This is mandatory for biomedical research and is advisable, but not mandatory, for other areas of research […]".

In Québec, even if the research is not biomedical, it is sometimes mandatory to obtain approval from an REB that includes a member who is knowledgeable in the relevant law. Specifically, this requirement applies in the situation described below.

- **Research that could interfere with the integrity of a minor or an adult incapable of giving consent:** the initial review of such research must be conducted by an REB designated or formed by the Ministre de la Santé et des Services sociaux[34], which includes a member who is knowledgeable in the relevant law[39].

3 Consent

Free, informed and ongoing consent of research participants is a fundamental component of the core principle aimed at respecting persons and their autonomy.

3.1 Exception to consent

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[38] Section 57, Act respecting health and social services information, CQLR, c. R-22.1.

[39] Articles 2 and 9, Règles sur la composition et les conditions de fonctionnement des comités d'éthique de la recherche compétents, Order No. 2024-017 of the Ministre de la Santé (2024); articles 3.2 and 7.2, Règles de fonctionnement du Comité central d'éthique de la recherche du ministre de la Santé (2025), this article calls for a person with a legal background (in French: "personne ayant une formation en droit").

3.1.1 Secondary use of biological materials

Article 12.3A of the TCPS

"Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if they have satisfied the REB that:

a. identifiable human biological materials are essential to the research;

b. the use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;

c. the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;

d. the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;

e. it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and

f. the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes.

If a researcher satisfies all the conditions in Article 12.3A(a) to (f), the REB may approve the research without requiring consent from the individuals from whom the biological materials were collected."

Article 12.3B of the TCPS

"Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable human biological materials."

In Québec, it is not possible to conduct research involving the secondary use of human biological materials (whether identifiable or non-identifiable) collected from a person as part of the care they receive, without consent. Such research requires consent from the person concerned or from a person authorized to give consent on their behalf[40]. If the person concerned has died, consent must be obtained from the person who could give or could have given consent to any care required by their state of health[40].

[40] Article 22, Civil Code of Québec.

3.1.2 Medical emergency

Article 3.8 of the TCPS

"Subject to all applicable legal and regulatory requirements, research involving medical emergencies shall be conducted only if it addresses the emergency needs of the individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves medical emergencies to be carried out without the consent of participants, or of their authorized third party, if all of the following apply:

a. A serious threat to the prospective participant requires immediate intervention.

b. Either no standard efficacious care exists, or the research offers a realistic possibility of direct benefit to the participant in comparison with standard care.

c. Either the risk is not greater than that involved in standard efficacious care, or it is clearly justified by the prospect for direct benefits to the participant.

d. The prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project.

e. Third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so.

f. No relevant prior directive by the participant is known to exist.

When a previously incapacitated participant regains decision-making capacity, or when an authorized third party is found, consent shall be sought for continuation in the project, and for subsequent examinations or tests related to the research project."

In Québec, where research could interfere with the integrity of a person in a medical emergency situation and it is not possible to obtain their consent, consent must be obtained from a person authorized to do so, according to the situations set out below.

- **Research involving a minor:** consent must be obtained from the person having parental authority or from the tutor[34].
- **Research involving an adult:** consent must be obtained from the person's mandatary or tutor[34]. However, if the adult is not so represented and the research involves only minimal risk, consent may be given by the person qualified to consent to any care required by the state of health of an adult incapable of giving consent[34]. Consent may also be given by such a qualified person where an adult suddenly becomes incapable of giving consent and the research (regardless of risk level) must be undertaken promptly after the appearance of the condition giving rise to it[34].

4 Research involving First Nations and/or Inuit peoples

> Article 9.8 of the TCPS
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> "Researchers have an obligation to become informed about, and to respect, the relevant customs and codes of research practice that apply in the particular community or communities affected by their research. Inconsistencies between community custom and this Policy should be identified and addressed in advance of initiating the research, or as they arise."

In Québec, there are a variety of traditions, customs, codes of practice, local protocols and ethical standards that may apply where research involves First Nations and/or Inuit peoples. Such research may involve both organizations within First Nations and/or Inuit communities and individuals from those communities.

Where differences in traditions, customs, codes of practice, local protocols and ethical standards give rise to issues regarding their application, a solution must be found in collaboration with the communities involved, taking into account the following[41].

- **First:** the relevant traditions, customs, codes of practice and local protocols that apply in the First Nations and/or Inuit communities concerned by the research. When designing the research, the authorities of these communities (or individuals designated by them) must be consulted as to whether any traditions, customs, codes of practice or local protocols (whether in written form or passed down orally) will apply.

[41] Requirement imposed by the FRQ that reflects its position on a particular ethical issue (position developed in collaboration with the *Groupe de travail pour assurer le leadership des Peuples autochtones en recherche* in May 2026).

- **Second**:
    - **If the research involves First Nations peoples**: the current version of the First Nations in Québec and Labrador's Research Protocol[42] (as well as any subsequent amendments to this protocol);
    - **If the research involves Inuit peoples:** the codes of practice adopted by the Inuit.
- **Third**: the TCPS.

To come: requirements relating to other divergences with the TCPS.

[42] First Nations in Quebec and Labrador's Research Protocol, Assembly of First Nations Quebec-Labrador (2014).

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Suivez-nous sur les médias sociaux

Le Fonds de recherche du Québec

140, Grande Allée Est, 4e étage
Québec (Québec) G1R 5M8 | 418 643 8560

Fonds de recherche Québec