



**Addendum: The Tri-Council Policy Statement:
Ethical Conduct for Research Involving Humans,
and other Canada Law Governing Research
Involving Human Participants**

Domain I: Organization

Standard I-1: The Organization has a systematic and comprehensive Human Research Protection Program that affords protections for all research participants. Individuals within the Organization are knowledgeable about and follow the policies and procedures of the Human Research Protection Program.

Element I.1.A. The Organization has and follows written policies and procedures for determining when activities are overseen by the Human Research Protection Program.

“Research” is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

- The term “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.
- Policies and procedures should describe how the organization interprets “disciplined inquiry.”

REB review is required for research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals.

Embryo means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being. Fetus means a human organism during the period of its development beginning on the 57th day following fertilization or creation, excluding any time during which its development has been suspended, and ending at birth. Fetal tissue includes membranes, placenta, umbilical cord, amniotic fluid and other tissue that contains genetic information about the fetus. Human reproductive materials mean a sperm, ovum or other human cell, or a human gene, as well as a part of any of them. The term “human biological materials” may be considered to include materials related to human reproduction.

Theses and other equivalent student research projects require REB review.

TCPS2:2.1

Guidance regarding a proportionate approach to research ethics review, consent, privacy, confidentiality, research with human biological materials and other ethical guidance described in TCPS2 apply equally to human genetic research.

TCPS2:13.1

Element I.1.B. The Organization delegates responsibility for the Human Research Protection Program to an official with sufficient standing, authority, and independence to ensure implementation and maintenance of the program.

The highest body within an institution shall: establish the REB or REBs, define an appropriate reporting relationship with the REBs, and ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfil their duties. REBs are independent in their decision making and are accountable

	<p>to the highest body that established them for the process of research ethics review.</p> <p>TCPS2: 6.2</p> <p>Institutions shall have an established mechanism and a procedure in place for promptly handling appeals from researchers when, after reconsideration, the REB has refused ethics approval of the research.</p> <p>The appeal committee shall have the authority to review negative decisions made by an REB. In so doing, it may approve, reject or request modifications to the research proposal. Its decision on behalf of the institution shall be final.</p> <p>TCPS2:6.19,6.20</p>
<p>Element I.1.D. The Organization has and follows written policies and procedures setting forth the ethical standards and practices of the HRPP. Relevant policies and procedures are made available to Sponsors, Researchers, Research Staff, research participants, and the IRB or EC, as appropriate.</p>	<p>In collaboration with their researchers, institutions and their REBs should develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices.</p> <p>TCPS2:6.21</p> <p>Research ethics policies and procedures for emergencies take effect once an emergency has been publicly declared. They should cease to apply as soon as is feasible after the end of the publicly declared emergency.</p> <p>TCPS2:6.22</p> <p>REBs should give special care to requests for exceptions to the principles and procedures outlined in this Policy during publicly declared emergencies.</p> <p>TCPS2:6.23</p>
<p>Standard I-2: The Organization ensures that the Human Research Protection Program has resources sufficient to protect the rights and welfare of research participants for the research activities that the Organization conducts or oversees.</p>	
	<p>Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality.</p> <p>TCPS2:5.1</p>
<p>Standard I-3: The Organization’s transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization’s principal location while complying with local laws and taking into account cultural context.</p>	
	<p>When conducting research outside the jurisdiction of their home institution, whether at a site abroad, or in Canada, researchers shall provide their home REBs with:</p> <ul style="list-style-type: none"> • The relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist;

	<ul style="list-style-type: none"> • The names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site; and • Relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers' home REB. <p>TCPS2:8.4</p>
<p>Standard I-6: The Organization has and follows written policies and procedures to ensure that research is conducted so that financial conflicts of interest are identified, managed, and minimized or eliminated.</p>	
<p>Element I.6.A. The Organization has and follows written policies and procedures to identify, manage, and minimize or eliminate financial conflicts of interest of the Organization that could influence the conduct of the research or the integrity of the Human Research Protection Program.</p>	<p>Institutions should ensure that real, potential or perceived institutional conflicts of interest that may affect research are reported to the REB through established conflict of interest mechanisms. The REB shall consider whether the institutional conflict of interest should be disclosed to prospective participants as part of the consent process.</p> <p>TCPS2:7.2</p>
<p>Standard I-7: The Organization has and follows written policies and procedures to ensure that the use of any investigational or unlicensed test article complies with all applicable legal and regulatory requirements.</p>	
<p>Element I.7.A. When research involves investigational or unlicensed test articles, the Organization confirms that the test articles have appropriate regulatory approval or meet exemptions for such approval.</p>	<p>All clinical trials shall be registered before recruitment of the first trial participant in a recognized and easily web-accessible public registry.</p> <p>TCPS2:11.3</p>
<p>Standard I-9: The organization has written policies and procedures to ensure that, when sharing oversight of research with another organization, the rights and welfare of research participants are protected.</p>	
	<p>An institution that has established an REB may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with this Policy. The institution remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.</p> <p>This authorization should be based on an official agreement that includes, but is not limited to, the following minimum components:</p> <ul style="list-style-type: none"> • all institutions or equivalent organization(s) involved agree to (1) adhere to the requirements of this Policy, (2) formalize the cross-institutional agreement, and (3) document the existence of this agreement in their institutional policies; • the highest institutional level, the body that originally defined the jurisdiction of the REB and its relationship to other relevant bodies or authorities within the institution, makes the decision to allow an

	<p>REB to recognize research ethics review decisions made by another REB (in accordance with Article 6.2); and</p> <ul style="list-style-type: none"> • approvals based on cross-institutional agreement should be documented and reported to the full REB, through the REB Chair, in each institution. The point in reporting is informational. It should not necessarily trigger a duplicate research ethics review. <p>TCPS2: 8.1</p> <p>When planning a research project involving multiple institutions and/or multiple REBs, researchers and REBs should select the most appropriate research ethics review model from among those authorized by their institution.</p> <p>Organizations and Researchers should consider:</p> <ul style="list-style-type: none"> • the discipline and content area of the research, and the availability of appropriate experience and expertise within, or available to, the reviewing REB; • the scope of the project to be reviewed and appropriateness of the proposed research ethics review model; • the vulnerability of the study population overall and/or the particular characteristics of the local population at individual sites, differences in values and cultural norms, and the level of risk associated with the research under review; • any relevant differences in laws and/or guidelines pertaining to the research in question if the institutions are in different provinces, territories and/or countries; • relationships between institutions and REBs, and conflict resolution mechanisms related to REB decisions; • the potential for conflicts of interest and undue influence, including those that may arise from funding sources; • any differences in the standard of care normally followed, or access to services at the participating institutions that might be relevant to the conduct of the research; and any operational issues that might affect the research. <p>TCPS2: 8.2</p>
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Domain II: Institutional Review Board or Ethics Committee

Standard II-1: The structure and composition of the IRB or EC are appropriate to the amount and nature of the research reviewed and in accordance with requirements of applicable laws, regulations, codes, and guidance.

<p>Element II.1.A. The IRB or EC membership permits appropriate representation at the meeting for the types of research under review, and this is reflected on the IRB or EC roster. The IRB or EC has one or more unaffiliated members; one or more members who represent the general perspective of participants; one or more members who do not have</p>	<p>The REB shall consist of at least five members, including both men and women, of whom:</p> <ul style="list-style-type: none"> (a) At least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB; (b) At least one member is knowledgeable in ethics; (c) At least one member is knowledgeable in the relevant law (but that member should not be the institution’s legal counsel or risk manager). This is mandatory for biomedical research
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<p>scientific expertise; one or more members who have scientific or scholarly expertise; and, when the IRB or EC reviews research that involves vulnerable participants, one or more members who are knowledgeable about or experienced in working with such participants.</p>	<p>and is advisable, but not mandatory, for other areas of research; and</p> <p>(d) At least one community member who has no affiliation with the institution. To maintain effective community representation, the number of community members should be commensurate with the size of an REB and should increase as the size of an REB increases. Institutions should provide training opportunities to community members</p> <p>TCPS2:6.4</p>
<p>Element II.1.B. The IRB or EC has qualified leadership (e.g., chair and vice chair) and qualified members and staff. Membership and composition of the IRB or EC are periodically reviewed and adjusted as appropriate.</p>	<p>The REB Chair is responsible for ensuring that the REB review process conforms to the requirements of TCPS2.</p> <p>TCPS2:6.8</p>
<p>Standard II-2: The IRB or Ethics Committee evaluates each research protocol or plan to ensure the protection of participants.</p>	
<p>Element II.2.A. The IRB or EC has and follows written policies and procedures for determining when activities are exempt from applicable laws and regulations, when permitted by law or regulation and exercised by the IRB or EC. Such policies and procedures indicate that exemption determinations are not to be made by Researchers or others who might have a conflict of interest regarding the studies.</p>	<p>Exempt research includes:</p> <ul style="list-style-type: none"> • Research that relies exclusively on publicly available information does not require REB review when: <ul style="list-style-type: none"> (a) The information is legally accessible to the public and appropriately protected by law; or (b) The information is publicly accessible and there is no reasonable expectation of privacy. • Research that is non-intrusive, and does not involve direct interaction between the researcher and individuals through the Internet, also does not require REB review. • REB review is not required for research involving the observation of people in public places where: <ul style="list-style-type: none"> (a) It does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; (b) Individuals or groups targeted for observation have no reasonable expectation of privacy; and (c) Any dissemination of research results does not allow identification of specific individuals. • Policies and procedures should include the organization’s definition of “public places.” • REB review is not required for research that 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. • 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.

	<ul style="list-style-type: none"> • Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review. <p>TCPS2:2.2-2.6</p>
<p>Element II.2.D. The IRB or EC has and follows written policies and procedures for conducting meetings by the convened IRB or EC.</p>	<p>After initial REB review and approval, research ethics review shall continue throughout the life of the project. TCPS2:2.8</p> <p>The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year). TCPS2: 6.14</p> <p>Institutions shall establish quorum rules for REBs that meet the minimum requirements of membership representation outlined in Article 6.4. When there is less than full attendance, decisions requiring full review should be adopted only when the members in attendance at that meeting have the specific expertise, relevant competence and knowledge necessary to provide an adequate research ethics review of the proposals under consideration.</p> <p>TCPS2:6.9</p>
<p>Element II.2.E. The IRB or Ethics Committee has and follows written policies and procedures to conduct reviews by the convened IRB or Ethics Committee.</p> <ol style="list-style-type: none"> 1. Element II.2.E.1. – Initial review 2. Element II.2.E.2. – Continuing review 3. Element II.2.E.3. – Review of proposed modifications to previously approved research 	<p>Research ethics policies and procedures for emergencies take effect once an emergency has been publicly declared. They should cease to apply as soon as is feasible after the end of the publicly declared emergency. REBs should give special care to requests for exceptions to the principles and procedures outlined in this Policy during publicly declared emergencies.</p> <p>TCPS2:6.22,6.23</p> <p>In studies using emergent design in data collection, researchers shall provide the REB with all the available information to assist in the review and approval of the general procedure for data collection.</p> <p>TCPS2:10.5</p> <p>For projects lasting less than one year an end-of-study report is required to be submitted for review by the REB.</p> <p>TCPS2:6.14</p>
<p>Element II.2.F. The IRB or Ethics Committee has and follows written policies and procedures to conduct reviews by the expedited procedure, if such procedure is used.</p> <ol style="list-style-type: none"> 1. Element II.2.F.1. – Initial review 2. Element II.2.F.2. – Continuing review 	<p>After initial REB review and approval, research ethics review shall continue throughout the life of the project. TCPS2:2.8</p> <p>The REB shall make the final determination as to the nature and frequency of continuing research ethics review in accordance with a proportionate approach to research ethics review. At minimum, continuing research ethics review shall consist of an annual status report (for multi-year research projects), and an end-of-study report (projects lasting less than one year). TCPS2:6.14</p>

<p>3. Element II.2.F.3. – Review of proposed modifications to previously approved research</p>	<p>Delegated REB review of minimal risk research: An REB may authorize a delegated research ethics review in accordance with its institutional policies and written procedures. Delegated reviewer(s) shall be selected from the REB membership: the REB Chair or another member (see Article 6.4 on the appointment of research ethics administration staff to the REB as non-voting members). Research ethics review may also be undertaken by non-REB members for student course-based research. Delegated reviewers who are non-members or non-voting members of the REB must have experience, expertise and knowledge comparable to what is expected of an REB member.</p> <p>TCPS2:6.12</p>
<p>Element II.2.I. The IRB or EC has and follows policies and procedures for managing multi-site research by defining the responsibilities of participating sites that are relevant to the protection of research participants, such as reporting of unanticipated problems or interim results.</p>	<p>When planning a research project involving multiple institutions and/or multiple REBs, researchers and REBs should select the most appropriate research ethics review model from among those authorized by their institution.</p> <p>TCPS2:8.2</p>
<p>Standard II-3: The IRB or EC approves each research protocol or plan according to criteria based on applicable laws, regulations, codes and guidance.</p>	
<p>Element II.3.A. The IRB or EC has and follows written policies and procedures for identifying and analyzing potential sources of risk and measures to minimize risk. The analysis of risk includes a determination that the risks to participants are reasonable in relation to the potential benefits to participants and to society.</p>	<p>Risks in research are not limited to participants. In their conduct of research, researchers themselves may be exposed to risks that may take many forms (e.g., injury, incarceration). Risks to researchers may become a safety concern, especially for student researchers who are at a learning stage regarding the conduct of research, and who may be subject to pressures from supervisors to conduct research in unsafe situations.</p> <p>While it is not a formal part of its responsibilities, an REB may raise concerns about the safety of student researchers as part of its communication to the student researchers, and to their supervisors. Based on the level of risk, the REB may consider referring these concerns for review by an appropriate body within the institution.</p> <p>TCPS2:2.9</p> <p>REBs shall ensure that clinical trial budgets are reviewed to ensure that conflicts of interest are identified and minimized, or otherwise managed.</p> <p>TCPS2:11.11</p>
<p>Element II.3.B. The IRB or EC has and follows written policies and procedures for reviewing the plan for data and safety monitoring, when applicable, and determines that the data and safety monitoring plan provides adequate protection for participants.</p>	<p>REBs shall develop procedures to review safety reports and other new information arising from clinical trials that may affect the welfare or consent of participants, and to take appropriate steps in response.</p> <p>TCPS2:11.9</p>

<p>Element II.3.C. The IRB or EC has and follows written policies and procedures to evaluate the equitable selection of participants.</p> <p>1. Element II.3.C.1. The IRB or EC has and follows written policies and procedures to review proposed participant recruitment methods, advertising materials, and participation payment arrangements and determines whether such arrangements are fair, accurate, and appropriate.</p>	<p>An experiment may not give rise to any financial reward other than the payment of an indemnity as compensation for the loss and inconvenience suffered.</p> <p>Civil Code of Quebec: Article 25</p>
<p>Element II.3.E. The IRB or EC has and follows written policies and procedures to evaluate proposed arrangements for maintaining the confidentiality of identifiable data, when appropriate, preliminary to the research, during the research, and after the conclusion of the research.</p>	<p>Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.</p> <p>Factors relevant to the REB’s assessment of the adequacy of the researchers’ proposed measures for safeguarding information include:</p> <ul style="list-style-type: none"> (a) The type of information to be collected; (b) The purpose for which the information will be used, and the purpose of any secondary use of identifiable information; (c) Limits on the use, disclosure and retention of the information; (d) Risks to participants should the security of the data be breached, including risks of re-identification of individuals; (e) Appropriate security safeguards for the full life cycle of information; (f) Any recording of observations (e.g., photographs, videos, sound recordings) in the research that may allow identification of particular participants; (g) Any anticipated uses of personal information from the research; and (h) Any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records. <p>TCPS2:5.3</p> <p>In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed, researchers shall record each participant’s consent.</p> <p>TCPS2:10.4</p> <p>Every person who establishes a file on another person shall have a serious and legitimate reason for doing so. He may gather only</p>

	<p>information which is relevant to the stated objective of the file, and may not, without the consent of the person concerned or authorization by law, communicate such information to third persons or use it for purposes that are inconsistent with the purposes for which the file was established. In addition, he may not, when establishing or using the file, otherwise invade the privacy or damage the reputation of the person concerned.</p> <p>Civil Code of Quebec: Article 37</p>
<p>Element II.3.F. The IRB or EC has and follows written policies and procedures to evaluate the consent process and the consent document and to require that the Researcher appropriately document the consent process.</p>	<p>The option to withdraw information is required unless adequate justification for limiting or removing this option is provided. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials. The consent form should set out any circumstances that do not allow withdrawal of data or human biological materials once collected. Where the terms of the research do not allow for withdrawal of their data or human biological materials, the identity of the participants shall be protected at all times during the project and after its completion. In some research projects, the withdrawal of data or human biological materials may not be feasible (e.g., when personal information has been anonymized and added to a data pool). Participants shall also be informed that it is difficult, if not impossible, to withdraw results once they have been published or otherwise disseminated.</p> <p>TCPS2:3.1</p> <p>The information generally required for informed consent includes:</p> <ul style="list-style-type: none"> • A statement of the research purpose in plain language, the identity of the researcher, the identity of the funder or sponsor, the expected duration and nature of participation, a description of research procedures, and an explanation of the responsibilities of the participant. • An assurance that prospective participants will be given information on the participant's right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal. • Information concerning the possibility of commercialization of research findings, and the presence of any real, potential or perceived conflicts of interest on the part of the researchers, their institutions or the research sponsors. • The measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly. • An indication of what information will be collected about participants and for what purposes; an indication of who will have access to information collected about the identity of participants, a description of how confidentiality will be protected (see Article 5.2), a description of the anticipated uses of data; and information indicating who may have a duty to disclose information collected, and to whom such disclosures could be made.

- In clinical trials, information on stopping rules and when researchers may remove participants from trial.

TCPS2:3.2

In addition, researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research, when applicable. A researcher may request an exception to the obligation to disclose material incidental findings, based on the impracticability or impossibility of disclosing such findings to the participant. Disclosure may be impossible or impracticable when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. The onus is on the researcher to justify to the REB the need for the exception. REBs should decide whether exceptions apply on a case-by-case basis.

TCPS2: 3.4

Permission is not required from an organization in order to conduct research on that organization. If a researcher engages the participation of members of an organization without the organization's permission, the researcher shall inform participants of any foreseeable risk that may be posed by their participation.

TCPS2:3.6

Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Written consent in a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory (e.g., Health Canada regulations under the Food and Drugs Act, the Civil Code of Québec). However, there are other means of providing consent that are equally ethically acceptable. In some types of research, and for some groups or individuals, written signed consent may be perceived as an attempt to legalize or formalize the consent process and therefore may be interpreted by the participant as a lack of trust on the part of the researcher. In these cases, oral consent, a verbal agreement or a handshake may be required, rather than signing a consent form. In some cultures, the giving and receiving of gifts symbolizes the establishment of a relationship comparable to consent. Where consent is not documented in a signed consent form, researchers may use a range of consent procedures, including oral consent, field notes and other strategies, for documenting the consent process. Consent may also be demonstrated solely by the actions of the participant (e.g., through the return of a completed questionnaire).

Where there are valid reasons for not recording consent in writing, the procedures used to seek consent must be documented (see Article 10.2).

TCPS2:3.12

Researchers shall also inform participants and seek their consent if their personal information may be shared with government departments or agencies, community partners in the research, personnel from an agency that monitors the research, a research sponsor (such as a pharmaceutical company), the REB or a regulatory agency.

TCPS2:5.2

When secondary use of identifiable information without the requirement to seek consent has been approved by the REB, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.

TCPS2: 5.6

Research involving collection and use of human biological materials requires REB review and:

- (a) Consent of the participant who will donate biological materials; or
- (b) Consent of an authorized third party on behalf of a participant who lacks capacity, taking into account any research directive that applies to the participant; or
- (c) Consent of a deceased participant through a donation decision made prior to death, or by an authorized third party.

TCPS2:12.1

To seek consent for use of human biological materials in research, researchers shall provide to prospective participants or authorized third parties, applicable information as set out in Article 3.2 as well as the following details:

- (a) The type and amount of biological materials to be taken;
- (b) The manner in which biological materials will be taken, and the safety and invasiveness of the procedures for acquisition;
- (c) The intended uses of the biological materials, including any commercial use;
- (d) The measures employed to protect the privacy of and minimize risks to participants;
- (e) The length of time the biological materials will be kept, how they will be preserved, location of storage (e.g., in Canada, outside Canada), and process for disposal, if applicable;
- (f) Any anticipated linkage of biological materials with information about the participant; and
- (g) The researchers' plan for handling results and findings, including clinically relevant information and incidental findings.

	<p>TCPS2:12.2</p> <p>A part of the body, whether an organ, tissue or other substance, removed from a person as part of the care he receives may, with his consent or that of the person qualified to give consent for him, be used for purposes of research.</p> <p>Civil Code of Quebec: Article 22</p> <p>Consent to care not required by a person's state of health, to the alienation of a part of a person's body, or to an experiment shall be given in writing. It may be withdrawn at any time, even verbally.</p> <p>Civil Code of Quebec: Article 24</p>
<p>Element II.3.G. The IRB or EC has and follows written policies and procedures for approving waivers or alterations of the consent process and waivers of consent documentation.</p>	<p>The REB may approve research without requiring that the researcher obtain the participant's consent in accordance with Articles 3.1 to 3.5 where the REB is satisfied, and documents, that all of the following apply:</p> <ul style="list-style-type: none"> (a) the research involves no more than minimal risk to the participants; (b) the alteration to consent requirements is unlikely to adversely affect the welfare of participants; (c) it is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required (“impracticable” means refers to undue hardship or onerousness that jeopardizes the conduct of the research, not just mere inconvenience); (d) in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and (e) the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B. <p>TCPS2:3.7A</p> <p>Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if the REB is satisfied that:</p> <ul style="list-style-type: none"> (a) Identifiable information is essential to the research; (b) The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates; (c) The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information; (d) The researchers will comply with any known preferences previously expressed by individuals about any use of their information;

	<p>(e) It is impossible or impracticable to seek consent from individuals to whom the information relates; and</p> <p>(f) The researchers have obtained any other necessary permission for secondary use of information for research purposes.</p> <p>TCPS2:5.5, 12.3A</p> <p>If a researcher satisfies all the conditions in Article 5.5(a) to (f), the REB may approve the research without requiring consent from the individuals to whom the information relates.</p> <p>TCPS2:5.5</p> <p>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 information.</p> <p>TCPS2:5.5B</p> <p>When secondary use of identifiable information without the requirement to seek consent has been approved under Article 5.5, researchers who propose to contact individuals for additional information shall, prior to contact, seek REB approval of the plan for making contact.</p> <p>TCPS2:5.6</p>
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Standard II-4: The IRB or EC provides additional protections for individuals who are vulnerable to coercion or undue influence and participate in research.

<p>Element II.4.A. The IRB or EC has and follows written policies and procedures for determining the risks to prospective participants who are vulnerable to coercion or undue influence and ensuring that additional protections are provided as required by applicable laws, regulations, codes, and guidance.</p>	<p>Research involving First Nations, Inuit and Metis peoples of Canada shall be reviewed under the requirements of TCPS2 Chapter 9.</p> <p>Research on in vitro embryos already created and intended for implantation to achieve pregnancy is acceptable if:</p> <ul style="list-style-type: none"> (a) The research is intended to benefit the embryo; (b) Research interventions will not compromise the care of the woman, or the subsequent fetus; (c) Researchers closely monitor the safety and comfort of the woman and the safety of the embryo; and (d) Consent was provided by the gamete donors. <p>TCPS2:12.7</p> <p>Research involving embryos that have been created for reproductive or other purposes permitted under the Assisted Human Reproduction Act, but are no longer required for these purposes, may be ethically acceptable if:</p> <ul style="list-style-type: none"> (a) The ova and sperm from which they are formed were obtained in accordance with Article 12.7; (b) Consent was provided by the gamete donors;
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	<p>(c) Embryos exposed to manipulations not directed specifically to their ongoing normal development will not be transferred for continuing pregnancy; and</p> <p>(d) Research involving embryos will take place only during the first 14 days after their formation by combination of the gametes, excluding any time during which embryonic development has been suspended.</p> <p>TCPS2:12.8</p> <p>Researchers who intend to conduct research to derive or use pluripotent stem cells shall follow the Guidelines for Human Pluripotent Stem Cell Research,⁵ as amended from time to time and published by the Canadian Institutes of Health Research.</p> <p>TCPS2:12.10</p> <p>Every decision concerning a child shall be taken in light of the child's interests and the respect of his rights. Consideration is given, in addition to the moral, intellectual, emotional and physical needs of the child, to the child's age, health, personality and family environment, and to the other aspects of his situation.</p> <p>Civil Code of Quebec: Article 33</p>
<p>Element II.4.B. The IRB or EC has and follows written policies and procedures requiring appropriate protections for prospective participants who cannot give consent or whose decision-making capacity is in question.</p>	<p>So long as it does not conflict with any laws governing research participation, the decision about whether a child is able to provide consent to research should be based on decision-making capacity rather than age. Some children begin participation in a project on the basis of consent from an authorized third party (due to the determination that they lacked capacity to decide on their own behalf) and on the basis of their own assent (see Article 3.10). In these cases, if the children mature sufficiently to decide on their own behalf (subject to legal requirements), the researcher must seek the children's autonomous consent in order for their participation to continue. Similarly, in the case of children who are unable to assent to research participation (e.g., infants) at the beginning of a project, the researcher must seek their assent to continue their participation once they are able to understand the purpose of the research as well as its risks and benefits.</p> <p>TCPS2: 3.3</p> <p>For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met:</p> <p>(a) The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;</p> <p>(b) The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;</p>

(c) The authorized third party is not the researcher or any other member of the research team;

(d) The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research; and

(e) When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation.

TCPS2:3.9

Where an authorized third party has consented on behalf of an individual who lacks legal capacity, but that person has some ability to understand the significance of the research, the researcher shall ascertain the wishes of that individual with respect to participation. Prospective participants' dissent will preclude their participation.

TCPS2:3.10

Subject to applicable legal requirements, individuals who lack capacity to consent to participate in research shall not be inappropriately excluded from research. Where a researcher seeks to involve individuals in research who do not have capacity to consent for themselves, the researcher shall, in addition to fulfilling the conditions in Articles 3.9 and 3.10, satisfy the REB that:

(a) The research question can be addressed only with participants within the identified group; and

(b) The research does not expose the participants to more than minimal risk without the prospect of direct benefits for them; or

(c) Where the research entails only minimal risk, it should at least have the prospect of providing benefits to participants or to a group that is the focus of the research and to which the participants belong.

TCPS2:4.6

Where individuals have signed a research directive indicating their preferences about future participation in research in the event that they lose capacity or upon death, researchers and authorized third parties should be guided by these directives during the consent process.

TCPS2:3.11

Research involving a fetus or fetal tissue:

(a) requires the consent of the woman; and

	<p>(b) shall not compromise the woman’s ability to make decisions regarding continuation of her pregnancy.</p> <p>TCPS2: 12.9</p>
<p>Element II.4.C. The IRB or EC has and follows written policies and procedures for making exceptions to consent requirements for planned emergency research and reviews such exceptions according to applicable laws, regulations, codes, and guidance.</p>	<p>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:</p> <p>(a) a serious threat to the prospective participant requires immediate intervention;</p> <p>(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;</p> <p>(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;</p> <p>(d) the prospective participant is unconscious or lacks capacity to understand the risks, methods and purposes of the research project;</p> <p>(e) third party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and</p> <p>(f) no relevant prior directive by the participant is known to exist.</p> <p>When a previously incapacitated participant regains decision-making capacity, or when an authorized third party is found, consent shall be sought promptly for continuation in the project, and for subsequent examinations or tests related to the research project.</p> <p>TCPS2:3.8</p>

Domain III: Researchers and Research Staff

Standard III-1: In addition to following applicable laws and regulations, Researchers adhere to ethical principles and standards appropriate for their discipline. In designing and conducting research studies, Researchers have the protection of the rights and welfare of research participants as a primary concern.

<p>Element III.1.C. Researchers employ sound study design in accordance with the standards of the discipline. Researchers design studies in a manner that minimizes risks to participants.</p>	<p>Researchers shall consult with the REB when, during the conduct of the research, changes to the data collection procedures may present ethical implications and associated risks to the participants.</p> <p>TCPS2:10.5</p> <p>In the design and review of a clinical trial, researchers and REBs shall consider the type of trial (e.g., pharmaceutical, natural health product, medical device, psychotherapy), its phase (if appropriate) and the corresponding particular ethical issues associated with it, in light of the core principles of this Policy (TCPS2).</p> <p>TCPS2:11.1</p>
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	<p>As with all alternative choices of a control, a placebo control is ethically acceptable in a randomized controlled clinical trial only if:</p> <ul style="list-style-type: none"> • Its use is scientifically and methodologically sound in establishing the efficacy or safety of the test therapy or intervention; and • It does not compromise the safety or health of participants; and • The researcher articulates to the REB a compelling scientific justification for the use of the placebo control. <p>For clinical trials involving a placebo control, the researcher and the REB shall ensure the general principles of consent are respected and that participants or their authorized third parties are specifically informed (see Article 3.2):</p> <ul style="list-style-type: none"> • About any therapy that will be withdrawn or withheld for purposes of the research; and • Of the anticipated consequences of withdrawing or withholding the therapy. <p>TCPS2:11.2</p> <p>In the design and review of a clinical trial, researchers and REBs shall consider the type of trial (e.g., pharmaceutical, natural health product, medical device, psychotherapy), its phase (if appropriate) and the corresponding particular ethical issues associated with it, in light of the core principles of TCPS2.</p> <p>TCPS2:11.1</p> <p>Researchers conducting genetic research shall:</p> <ol style="list-style-type: none"> (a) In their research proposal, develop a plan for managing information that may be revealed through their genetic research; (b) Submit their plan to the REB; and (c) Advise prospective participants of the plan for managing information revealed through the research. <p>TCPS2:13.2</p>
<p>Element III.1.D. Researchers determine that the resources necessary to protect participants are present before conducting each research study.</p>	<p>Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.</p> <p>TCPS2:3.3</p>
<p>Element III.1.F. Researchers employ consent processes and methods of documentation appropriate to the type of research and the study population, emphasizing the importance of participant comprehension and voluntary participation to foster informed decision-making by participants.</p>	<p>REBs and clinical trial researchers should be conscious of the phenomenon of therapeutic misconception, and ensure that procedures for recruitment and consent emphasize which specific elements of a clinical trial are required for research purposes, as well as the differences between research and the standard clinical care patients might otherwise receive.</p> <p>TCPS2:11.6</p>

Standard III-2: Researchers meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the Organization’s policies and procedures for protecting research participants; and the IRB’s or EC’s determinations.

Element III.2.D. Researchers and Research Staff follow reporting requirements during a research study in accordance with applicable laws, regulations, codes and guidance; the Organization’s policies and procedures; and the IRB’s or EC’s requirements.

Researchers shall promptly report new information that may affect the welfare or consent of participants, to the REB, and to other appropriate regulatory or advisory bodies. When new information is relevant to participants’ welfare, researchers shall promptly inform all participants to whom the information applies (including former participants). Researchers shall work with their REB to determine which participants must be informed, and how the information should be conveyed.

TCPS2:11.8

Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research. When material incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants, and submit this plan to the REB.

TCPS2:3.4