POLICY AND PROCEDURE MANUAL

Policy Title:	**RESEARCH ETHICS POLICY**	**Area of Responsibility:** **VICE PRESIDENT, ACADEMIC**
Policy Section:	**APPLIED RESEARCH**	**Policy No: 10.5**
Effective Date:	**2021 02 11**	**Page: 1 of 25**
Supersedes:	**2014 08 26**	
Mandatory Review Date:	**2026 02 11**	**Last Review Date:** **2021 02 11**

10.5 RESEARCH ETHICS POLICY

Table of Contents

1.	Acknowledgements and Definitions	2-3
2.	Purpose	4
3.	Application	7
4.	Scope of Research Requiring Review	8
5.	Multi-Jurisdictional Research	8
6.	Research Exempt from REB Review	9
7.	Research Ethics Core Principles	10
8.	Responsibility of REB	12
9.	Procedures for the Ethical Review of Research Involving Human Participants	12
10.	Procedural Guidelines	13
11.	Procedural Guidelines Concerning REB Review	15
12.	REB Decision Making	16
13.	Conflict of Interest	18
14.	Consent Process	19
15.	Privacy and Confidentiality	23
16.	Research & Emergency Health Situations	23
17.	Research Involving the First Nations, Inuit and Métis Peoples of Canada	24
18.	Qualitative Research	25
19.	Clinical Trials	25

1.0 Acknowledgements and Definitions

1.1 Acknowledgements

This policy is based on policy documents relating to ethical research created by Niagara College, George Brown College and Fanshawe College.

1.2 Definitions:

Authorized Third Party – A representative of an individual who is not competent to provide free and informed consent. The authorized third-party acts in the interest of that individual.

Capacity – The ability of prospective participants to give informed consent in accord with their own fundamental values. It involves the ability to understand information presented, appreciate the potential consequences of the decision, and provide free and informed consent.

Clinical Trial – Any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes.

Confidentiality – An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss, or theft.

Conflict of Interest – The incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another.

Consent – An indication of agreement by an individual to become a participant in a research project. Throughout this Policy, the term "consent" means "free (also referred to as voluntary), informed and on-going consent".

Core Principles – The three core principles of the Policy that together express the overarching value of respect for human dignity: Respect for Persons, Concern for Welfare and Justice. See "Respect for Persons", "Concern for Welfare" and "Justice".

Free and Informed Consent – The dialogue, information sharing, and general processes through which prospective participants choose to participate in research.

Harm – Anything that has a negative effect on participants' welfare, broadly construed. The nature of the harm may be social, behavioural, psychological, physical, or economic. See "Welfare".

Identifiable Information – Information that may reasonably be expected to identify an individual, alone or in combination with other available information. Also referred to as "personal information".

> **Directly Identifying Information** – The information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).

Indirectly Identifying Information – The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence, or unique person characteristic).

Coded Information – Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g. the Principal Investigator retains a list that links the participants' code names with their actual names so data can be re-linked if necessary).

Anonymized Information – The information is irrevocably stripped of direct identifiers, a code is not kept allowing future re-linkage, and risk of re-identification of individuals from remaining in-direct identifiers is low or very low.

Anonymous Information – The information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low.

Legal Incompetence – A legal state defined by provincial law, that an individual is unable to consent for him or herself.

Minimal risk – occurs when potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life.

Participant – A person who, by virtue of his/her involvement in a data-gathering situation or activity, is a source of primary data or information. Research participants bear the risks of the research in any study involving humans.

Principal Investigator/Principal Researcher – A person designated as the primary representative of a research project by virtue of their involvement and scholarly merit. The Principal Researcher bears responsibility for the research project including members of the research team and the reporting process.

Research –An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.[1]

Subject - In human research is a person, who by virtue of his/her involvement in a data- gathering situation or activity, is a source of primary data or information.

[1] TCPS2 (2018) defines research as "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation," p. 1

2.0 Purpose

St. Clair College is committed to the highest ethical and academic standards for its students, faculty, and staff. It is committed to respect for academic freedom for all research conducted under the auspices of the College, as well as to ensuring this research meets the highest academic standards. Not without limits, these academic freedoms include freedom of inquiry and the right to disseminate the results thereof, freedom to challenge conventional thought, freedom from institutional censorship, and the privilege of conducting research on human participants with public monies, trust and support. St. Clair College is also committed to ensuring that research conducted involving employees, students and/or College equipment and facilities is carried out using ethical and moral research practices. For these reasons, the College requires that all research using St. Clair employees, students and/or College equipment and facilities, irrespective of the source of financial support or location of the project, undergo a Research Ethics Review (RER), as set out in this policy.

All research conducted by St. Clair College staff, faculty or students that involves human participants shall comply with the standards stipulated in the TCPS2 (2018). In addition, all research involving human participants shall be subject to RER by the St. Clair College Research Ethics Board (REB). The St. Clair College REB is a properly constituted REB under the TCPS2 (2018). The TCPS2 (2018) shall be consulted for guidance by the REB members and all researchers. St. Clair College typically requires all researchers on a research team and (staff, faculty or students) to complete the online TCPS2 (2018) Tutorial Course on Research Ethics (CORE), as amended from time to time found on the Interagency Panel on Research Ethics website. Prior to ethical clearance, a printed certificate shall be submitted the REB chair upon completing the course and. All Principal Investigators and student researchers shall submit this certificate of completion as part of their application package for proposed research.

2.1 Research Ethics Board

The responsibility of the St. Clair College REB is to ensure that any research involving human participants is conducted ethically and in accordance with the core principles of the TCPS2 (2018). Any research involving human participants at St. Clair College must be reviewed and approved by the College's REB. Ultimately, the REB is responsible for ensuring that the physical safety and personal integrity of all human participants in research are protected and respected. In addition, the REB shall ensure that researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information.

2.2 REB Authority and Mandate

The REB reviews applications for research activities involving human participants as described in this policy. The REB has the authority to review and make decisions on any proposed or ongoing research. The REB also serves the St. Clair College research community as a consultative body, thus contributing to education in research ethics. Additionally, the REB operates at an arm's length from the senior administration. A senior administrator shall not serve as a member of the REB or indirectly influence the REB decision-making process.

2.3 St. Clair College Research Ethics Board Authority & Responsibilities

The President of St. Clair College has mandated the St. Clair College REB to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within, or by members of, the institution, per the policies and guidelines set forth in this document. The REB is the final authority, and the College may not override REB decisions reached on the grounds of ethics without a formal appeal mechanism. In this context the REB is responsible for:

2.3.1 Developing policies regarding ethical issues relating to the use of human participants in research and experimental teaching protocols;

2.3.2 Reviewing all protocols requiring the participation of human participants for ethical approval;

2.3.3 Reviewing annually all policies regarding ethical issues relating to the use of human participants in research projects to ensure that policies remain current;

2.3.4 Dealing with matters concerned with human-based research referred to the REB by the President of St. Clair College;

2.3.5 Preparing an annual report for submission to the St. Clair College President

2.3.6 Participating in continuing education organized by St. Clair College research administrators for the College community in matters relating to ethics and the use of human participants.

The policies and practices adopted by the REB will be consistent with the current approved Tri-Council Policy Statement, "Ethical Conduct for Research Involving Humans."

2.4 Composition of the Board

2.4.1 Standing Membership – at least five members:
The normal term of office for REB members is three years (shorter or longer terms may be necessary from time to time). These members, including the Chair, shall be appointed by the President in accordance with the TCPS2 (2018). The Board shall consist of both men and women, of whom:

(a) faculty members who have broad research experience;
(b) at least one member is knowledgeable in the area of ethics;
(c) one is a lawyer, who is not the College legal counsel and knowledgeable in the relevant law. For biomedical research, it is mandatory that the REB member should be knowledgeable in the relevant law;
(d) at least one community member with no current affiliation to the institution;
(e) Ideally membership should include a variety of disciplines from around the college (e.g., schools, departments, etc.), in which research with human participants is considered part of the disciplinary practice;
(f) A student representative if possible (ideally SRC president or member)

2.4.2 Substitute Membership:
Substitute members may be appointed by the Chair to serve as replacements for standing members when they are unable to attend. Such substitute members shall be nominated in advance to avoid the potential for ad hoc substitutes. The appointment of nominated substitute members for a specific review shall not alter the membership structure. In all cases REB members must be competent to judge the acceptability of proposals and shall be knowledgeable of the TCPS2 (2018).

2.4.3 Ad Hoc Membership:
The REB Chair may appoint ad hoc members as necessary to consult on research within their field of expertise and when such expertise is lacking on the REB. The REB Chair may, and should nominate appropriate ad hoc members for the duration of the review when the REB is reviewing a project that:

2.4.3.1. requires particular community or research subject representation

2.4.3.2. requires specific expertise not available from the regular REB members. Such ad hoc members will not be voting members of the REB but may participate in the REB's deliberations. However, the membership structure should be altered accordingly if this occurs on a regular basis. In addition, a senior administrator may not directly or indirectly influence the REB decision-making process.

2.4.4 Appointing Members:
Education and training opportunities shall be provided to members of the REB to enable them to fulfill their duties throughout their term. The training shall be at a minimum in the following areas:
(a) Core Principles
(b) Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans TCPS2 (2018)
(c) basic ethics standards
(d) applicable institutional policies

2.5 Quorum

A quorum for the REB is 50% plus one of the members. Decisions shall be adopted only if the members in attendance have sufficient background and expertise to conduct the review(s) required. Normally consensus will be sought; when required, decisions will be by majority vote of the appointed members.

2.6 Meetings

The REB members shall meet regularly at dates and times that are publicly announced in September of every year (preferably for the entire academic year) to discharge their responsibilities. Normally, the REB meets monthly, however this may not be required at certain times of year (July and August). Regularly scheduled REB meetings may be canceled if no protocols have been received by the submission deadlines. The schedule of REB meetings shall be made available to all College researchers.

Attendance at regular REB is necessary to ensure effective communication and decision-making. Under unexpected circumstances, such as emergencies, member participation through technology is acceptable. Additionally, the REB should hold general meetings, retreats, and workshops to:

(a) enhance the operation of the REB;
(b) facilitate the discussion of arising issues;
(c) review, understand, and/or improve relevant policies; and
(d) ensure the proper training of REB members.
(e) attend professional development activities if applicable.

2.7 Record Keeping

Minutes of all REB meetings shall be prepared and maintained by the REB. This is essential in order to demonstrate that the REB is acting fairly and reasonably; failure to do so could expose the College and the researchers to legal liability.

The minutes shall clearly document the REB's decisions and any dissents, and the reasons for them.

2.8 Responsibility of the REB Chair

The responsibility of the REB Chair is to ensure that the RER process conforms to the requirements of the TCPS2 (2018) and those of the College. The Chair shall also provide overall leadership for the REB and to facilitate the REB review process. In addition, the Chair shall be responsible for:

(a) calling and Chairing regular meetings of the REB and other meetings as required;
(b) maintaining and coordinating communication with REB members and the Applied Research Office;
(c) communicating decisions to the research applicant;
(d) assisting in determining delegated reviews of proposed research;
(e) recommending experts to the REB where appropriate;
(f) ensuring that appropriate documentation of REB meetings and decisions are kept;
(g) monitoring and ensuring the REB's decisions are consistent;
(h) ensuring that REB's decisions are recorded accurately;
(i) ensuring that the REB's decisions are communicated clearly to researchers by him/her or by his/her designate;
(j) preparing an annual report for submission to the St. Clair College President on REB activities.

2.9 REB Removal

If a member cannot fulfill his/her responsibilities as an REB member, their term will be terminated. Some circumstances that will lead to termination include, but are not limited to, excessive absences to meetings and inability to attend related research ethics training. The REB Chair will provide the President with circumstances that may lead to removal. The College President will make the final decision.

3.0 Application

All research involving human participants conducted by faculty, staff, and students at St. Clair College, regardless of where the research is conducted requires REB clearance. It also applies to research conducted on St. Clair College premises by researchers who are not members of the St. Clair College community. If there are any questions about the

applicability of this practice to a particular research project, the advice of the Research Ethics Board (REB), through its Chair, shall be sought.

4.0 Scope of Research Requiring Review

All research involving human participants requires the review and approval of the Research Ethics Board of St. Clair College prior to the start of the research. In this context, research involving human participants refers to research where humans are participating in studies where the College has the responsibility to regulate legal or ethical aspects, or where databases will be used containing specific information about the human participants. Research that requires REB review and approval are in accordance with Article 2.1[2] of the TCPS2 (2018).

If a researcher working under the auspices of an organization that is not Tri-Council eligible, seeks to conduct research at St. Clair College, with the use of St. Clair College resources and/or with personnel (e.g., staff and students) from St. Clair College, they will be required to adhere to the ethical principles and guidelines laid out in the TCPS 2 (2018) and submit an application along with all requisite documents to the SCC-REB for review.

5.0 Multi-Jurisdictional Research

For multi-jurisdictional research, the participating REBs may choose to coordinate their review of multi-centred projects through an agreed-upon coordination method or review model. St. Clair College may introduce the most appropriate alternative review model (e.g., independent ethics review by several REBs', research ethics review delegated to an external, specialized or multi-institutional REB, reciprocal REB review)[3] for research that will involve multiple REBs or institutions. However, St. Clair College shall "remain 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."[4]

If the research is being conducted at more than one centre or site, there may be more than one REB involved. All REBs with jurisdiction over the research project must approve the planned research. When conducting research in Canada outside the REBs jurisdiction or abroad, researchers shall:

(a) provide to their REB the rules and ethics requirements of the research site;
(b) names and information of all REBs involved; and
(c) "relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researchers' home REB."[5]

In addition, the researcher shall distinguish between core elements of the research (those that cannot be altered without invalidating the combined data from the participating institutions or centres) and those elements that may be altered to comply with local requirements without invalidating the research project.

In cases where a research team is working together from different institutions, the board of record (BOR) is normally the board of the principal investigator. All co-investigators will need to have the project vetted by the REB or equivalent (e.g., administrative approval) at their institution. For multi-site research involving SCC researchers, the research is not permitted to proceed until such clearance is received.

[2] Article 2.1 of the TCPS2 (2018), Research Requiring Review, p. 15.
[3] See pp. 99-100 of the TCPS2 (2018) for further details of each model.
[4] Article 8.1 of the TCPS2 (2018), Adoption of Alternate Review Models – An Institutional Responsibility, p.98.
[5] Article 8.4 of the TCPS2 (2018), Ethics Review of Research Conducted Outside the Institution, p. 103.

Exceptions to this rule include a researcher collaborating with a research team after data collection is complete and all data has been rendered de-identifiable or any research collaboration not including human or animal participants (e.g., a discussion paper).

Furthermore, all members of a research team will need to have the project vetted by their institution if not then by St. Clair College.

6.0 Research Exempt from REB Review

The decision regarding whether a project is exempt from review is the responsibility of the REB. Researchers shall consult with the REB when considering exemptions. A RER is not required when the research relies exclusively on publicly available information that is legally accessible to the public and appropriately protected by law, and when the information is publicly accessible and there is no reasonable expectation of privacy. This may include, but is not limited to:

(a) research involving public policy issues, the writing of modern history, or literary or artistic criticism; and
(b) research about a living person involved in the public arena, or about an artist, if such research is exclusively based on publicly available information, documents, records, works, performances, archival materials, or third-party interviews.

If the participant is to be approached directly for interviews or for access to private papers, then a RER is required to ensure that such approaches are conducted following ethical research protocols.

6.1 Observation of People

A RER is not required when research involving the observation of people in public places does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups. As a result, the individuals or groups targeted for observation should not have reasonable expectation of privacy and any dissemination of research results do not allow identification of specific individuals.

However, if any of the activities listed above are conducted in the context of a research framework, they may require RER. In addition, a RER is not required where the secondary use of anonymous information for which its dissemination, collection and linkage of data do not generate identifiable information.

For research/scholarly work where the researcher is uncertain whether REB review is required; it is the responsibility of the researcher to obtain the written opinion of the Chair of the REB as to whether the research should be subjected to prior ethics review and approval.

6.2 Other Activities

Any activity that refers to the performance of employees or students of the organization that are required within the mandate of the organization, according to its terms and conditions of employment, shall not be subject to a REB review. These activities may include, but are not limited to:

(a) quality assurance and improvement studies;
(b) assessing the performance of the College;
(c) staff performance reviews;
(d) testing that occurs within normal educational requirements.

However, if any of the activities listed above are conducted in the context of a research framework, they may require RER. In addition, a RER is not required where the secondary use of anonymous information for which its dissemination, collection and linkage of data do not generate identifiable information.

7.0 Research Ethics Core Principles

Respect for human dignity is the cardinal principle of the Tri-Council Policy Statement. It forms the basis of the ethical obligations in research involving human participants. The TCPS2 (2018) has consolidated the original eight guiding principles to three core principles (i.e., Respect for Persons, Concern for Welfare, and Justice).

These three core principles are stipulated in Article 1.1[6] of the TCPS2 (2018).
In addition to the three core principles, research shall be inclusive in regard to the benefits of research and shall have a fair distribution of its burdens to distinct individuals, groups or communities. There shall only be valid reasons to exclude individuals to participate in research based on their attributes (e.g. "culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age,"[7] etc.). For example, some research that is focused on a specific "religious order that is restricted to one sex."[8] Therefore researchers hold the responsibility to justify the exclusion of participants and such justification shall answer the research question.

7.1 Respect for Persons

This principle encompasses the treatment of persons involved in research as participants. It recognizes the value of human beings and the respect that they should be given as individuals. This includes respecting a person's autonomy[9] and protecting those with developing or impaired autonomy. A person shall be free and capable to choose, without interference. In order to accomplish this, it is important to seek the free, informed, and ongoing consent[10] of participants.

When an individual does not have the capacity to make a free and informed decision they are still protected by this principle. Respect for persons translates in practice into the dialogue, process, rights, duties, and requirements for free and informed consent by the research participant. This ensures that the participant is able to decide for themself whether they would like to participate based on being informed of the following:

(a) the purpose of the research;
(b) its potential risks and benefits to the participant and others; and
(c) what is involved in the research.

6Article 1.1 of the TCPS2 (2018), Core Principles, provides details and an explanation for each core principle, pp. 8 – 11.
7Article 4.1 of the TCPS2 (2018), Fairness and Equity Research Participation, Appropriate Inclusion, p. 48.
8Article 4.1 of the TCPS2 (2018), Fairness and Equity Research Participation, Appropriate Inclusion, p. 48.
9TCPS2 (2018) defines autonomy as "the ability to deliberate about a decision and to act based on that deliberation," p. 8.
10TCPS2 (2018) defines consent as "an indication of agreement by an individual to become a participant in a research project," p. 190. The TCPS2 (2018) refers to consent as being voluntary or "free, informed and ongoing consent," p. 27.

For some research, participation is requested from individuals incapable of exercising autonomy due to their youth, cognitive impairment or illness. Additional measures are necessary to protect those participants. This may generally include seeking consent from an authorized third party.[11]

7.2 Concern for Welfare

The TCPS2 (2018) states that welfare of participants consists of how individuals, either as distinct persons or as a group, may be impacted by various circumstances such as their physical, economic and social status. This could also include their mental and spiritual health. For example, housing, employment, security, family life, community membership and social participation are determinants of welfare.

The researcher(s) must demonstrate that the benefits of the research outweigh the potential risks to the person(s) who is/are participating in the research. This may require the researcher to demonstrate how potential risk is being managed and/or mitigated in the conduct of research.

The privacy and control of information about the person is another contributing factor to welfare. This may include protecting the access, control, and dissemination of personal information and materials. Concern for welfare is fundamental to the principle of respect for human dignity. In addition, the treatment of human biological materials, according to the free, informed, and ongoing consent of the person who was the source of the information or materials may be another contributing factor to welfare.

The Principal Investigator shall protect the welfare of participants and promote the welfare in view of any foreseeable risk. Participants must be provided with enough information to be able to assess the risks and potential benefits associated with the research with which they will be involved as participants.

Moreover, the analysis and balance of harms and benefits are critical to the ethics of research involving human participants. Therefore, foreseeable harms should not outweigh anticipated benefits of the research. The balance must respect human dignity and impose strict ethical obligations on the validity, design, and conduct of research. It is the duty of those conducting research involving human participants to avoid, prevent or minimize harm to others. Research participants must be fully aware of any potential for harm, at any stage of the research, to both individual participants and to groups of participants.

7.3 Justice

According to this principle, humans shall be treated fairly and equitably, that is treating all people with respect and concern. This includes not segmenting a group or population to be burdened by the harms of research or denied the benefits of the knowledge generated from it.

[11] TCPS2 (2018) defines an authorized third party as "any person with the necessary legal authority to make decisions on behalf of an individual who lacks the capacity to consent to participate or to continue to participate in a particular research project," p. 27.

It is important to know the vulnerability of individuals due to their limited capacity or access vulnerable persons, including children, elderly, and institutionalized persons, are entitled to special protection against exploitation, discrimination, or abuse.

Treating people fairly and equitably does not necessarily mean treating people exactly the same, thus special procedures may be required to protect these persons. Therefore, the ethics review process and research shall have fair methods, standards, and procedures.

In practice the principle of justice translates into researchers demonstrating that inclusion/exclusion criteria do not unnecessarily target individuals or groups of individuals. In addition, research must demonstrate that the benefits and risks of the research are distributed equitably.

8.0 Responsibility of REB

8.1 The REB shall adopt a proportionate approach to ethics review, (as defined in Section 11 of this policy).

8.2 REB review shall be based upon fully detailed research proposals or, where applicable, progress reports. The REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions. The REB shall accommodate reasonable requests from the Principal Investigator to participate in discussions about their proposals, but not be present when the REB is making its decision. When an REB is considering a negative decision, it shall provide the researcher with all the reasons for doing so and give the researcher an opportunity to reply before making a final decision.

8.3 It is the responsibility of the REB to uphold the principle of distributive justice: "members of society should neither bear an unfair share of the direct burdens of participating in research, nor should they be unfairly excluded from the potential benefits of research participation." For example, those who do not have the capacity to consent for themselves shall not be automatically excluded from research, which is potentially beneficial to them as individuals, or to the group that they represent.

9.0 Procedures for the Ethical Review of Research Involving Human Participants

For research involving human participants, a St. Clair College application package for "Research Involving Human Participants"[12] shall be completed and signed by the Principal Investigator and submitted to the office of Applied Research.
No research is permitted to begin until the REB review process has been completed.

Ongoing research is also subject to an ethics review, based on the proportionate approach to assessment which includes the level of risks, the potential benefits, and the implications of the proposed research.[13]

[12] The St. Clair College application package for "Research Involving Human Participants" may be downloaded from

the St. Clair Research website or requested directly via email from research@stclaircollege.ca.

[13] For further explanation of the proportionate approach to assessment, refer to the TCPS2 (2018) Ethics Framework, p. 11 and to Article 2.9, pp. 24-25 of the TCPS2 (2018).

If the researcher is unsure whether their research requires REB approval, they should reach out the REB chair for clarification.

10.0 Procedural Guidelines

10.1 Determining the Level of Research Ethics Board Review

The Research Ethics Board Chair will review the proposed research and determine the level of the ethical review ("Full" or "Delegated" Board review). The more invasive the research, the greater should the care of assessing that research be. According to Article 6. 12[14] of the TCPS2 (2018), a full or delegated research ethics review may apply.

10.2 Full REB Review

Research ethics review by the full REB should be the default requirement for research involving humans. If the applicant elects a full review or if the Chair determines that a delegated review is not appropriate, the application will be copied and distributed to the members of the REB for consideration at the next scheduled REB meeting. A full REB review must take place in an REB meeting. The applicant may be present, if the Chair requests this, to discuss the proposed research and answer questions the REB may have about the research but may not be present when the REB is making its decision. Researchers must submit their application in full using the checklist by the posted deadline to have their documents considered for the next meeting.

10.3 Delegated REB review of minimal-risk research

In some instances, the Research Ethics Board Chair (in consultation with the REB) will delegate review to a subset of the REB member(s) or the REB has delegated the review to the REB Chair (known as executive review). In some cases, the REB Chair may elect to use full board, delegated or executive review processes. The review level may change based on discussions with the REB. The typical level of review for revisions shall be executive review.

10.4 Scholarly Review

The REB has the responsibility to "review the ethical implications of the methods and design of the research."[15] Scholarly reviews are different amongst various fields of research. This includes the stage at which a scholarly review may occur. Researchers shall demonstrate to their REB when and how scholarly reviews have been or will be undertaken for their research. In addition, the REB may request the full documentation of the scholarly reviews already completed.

Approvals of the delegated reviews must be reported to the REB by the next scheduled meeting. In addition, an application cannot be rejected without full REB review and validation before communicating the decision to the researcher.

[14] Refer to Article 6.12, pp. 77 – 79, for further explanation of the two levels of research ethics review.

[15] Article 2.7 of the TCPS2 (2018), Relationship between Research Ethics Review and Scholarly Review, p. 20.

10.5 Course-based Research REB Review

According to the TCPS2 (2018), course-based research requires REB review. In such instances, instructors are required to complete the course-based research application form. Course-based research may be delegated if its activities are intended solely for pedagogical purposes. For example, the objectives of these activities are to provide students exposure to research methods in their field of study. In contrast, faculty engaged in course-based research for the purpose of research or with intentions of sharing the data outside of the classroom shall undergo regular REB procedures.

For course-based research, REB review authority may be delegated to selected reviewers that are not members of the REB or to the REB subcommittee for delegated reviews, at the discretion of the Chair. Course-based research reviewers shall have the experience, expertise, training and resources required to review the ethical acceptability of research within the proposed field of research, according to this practice, and the guidelines of the TCPS2 (2018).

10.6 Continuing Research Ethics Review

On-going research is subject to an ethics review at the level consistent with the level of risk in the research. As part of the research proposal submitted for REB review, the Principal Investigator shall propose a process for on-going review of the research. For minimal risk research, at minimum, multi-year research will require an annual status report, and projects lasting less than one year will require an end-of-study report. Where there is more than minimal risk, a more stringent review process may be required. Continuing REB review is independent of reporting requirements for funded research required by funding agencies.

10.7 Reporting Unanticipated Issues

Researchers shall report any adverse or unanticipated events as soon as it is possible to do so. Unanticipated or adverse events that do not change the level risk for any given participant shall be reported to the Chair of the research ethics board within 3 days of becoming aware of the incident. In such instances, the researcher shall notify the Chair of the research ethics board indicating the nature of the unanticipated event along with a plan for resolving the issues surrounding the event and a mechanism to prevent similar such events moving forward. Research should communicate this using the unanticipated/adverse event form.

In those cases where the unanticipated events are adverse (e.g., has caused real or perceived harm to participants or has rendered participants more vulnerable) researchers shall notify the Chair of the REB within 24 hours of the event being discovered by the research team. Data collection should also cease until the REB and the Principal Investigator have settled on a plan for the research.

11.0 Procedural Guidelines Concerning REB Review

11.1 Submission

Contact with potential participants (e.g., recruitment) and data collection cannot begin prior to REB clearance (regardless of funding applications). Submissions for review should be submitted to the REB using the appropriate forms and by following the instructions on those forms.

11.2 Guidelines for Proportionate Review

The SCC-REB is constituted according to and follows the guidelines in the TCPS2 (2018) regarding review. As such, the SCC-REB will use a proportionate approach based on the general principle of risk. Risk is a function of the magnitude or seriousness of the harm, and the probability that it will occur, whether to participants or to third parties. A proper ethical analysis of research should consider both the foreseeable risk and the available methods of eliminating or mitigating the risk. Proportionate review shall be evaluated by assessing the character, magnitude, and probability of potential harms inherent in the research, from the point of view of the potential participants. Following this initial assessment, the REB may nonetheless choose from the following possible levels of review:

- Full REB review
- Delegated REB review by an individual or sub-group of the REB
- Faculty/Divisional (Departmental) level review of projects carried out within formal course requirements and posing no more than minimal risk.

Additionally, informal meetings between REBs and Principal Investigators are appropriate to expedite the process but shall not substitute for the formal review process.

11.3 REB Records

The SCC-REB will maintain a file for a period of five years as records demonstrating compliance with the TCPS2 (2018). The files remain the property of St. Clair College and cannot be removed from the secure location by the researchers. Upon request files may be subject to audit by authorized representatives of St. Clair College, members of Appeal Boards, and funding agencies. The REB file on applications for ethical review shall contain the following documents:

- Application form
- Project protocol and amendments (if any)
- Any other documents the REB may need to fulfill its responsibilities

Additionally, a record of correspondence between the REB and the researcher will be kept. All research requiring ethical approval, regardless of the level of review, shall require a proper file showing compliance with the St. Clair College Ethics Review Policy. Insufficient information in the file is grounds for refusing or delaying ethical approval.

11.4 Full Review

11.4.1 Full review shall be the default type of review.

11.4.2 The REB shall accommodate reasonable requests from the Principal Investigator to participate in discussions about their proposals, but not be present when the REB is making its decision.

11.5 Delegated Review

11.5.1 After an initial assessment of an application submission for consistency and completeness, the REB Chair will determine the level of review appropriate for the application. The Chair must report requests for delegated review and results of such reviews to the full REB.

11.5.2 Delegated review is review by a subset of the REB. It is available only in cases, which fulfill one of the following criteria:

11.5.2.1 Research involves no more than minimal risk as required by the TCPS2 (2018).

11.5.2.2 The review is an annual renewal of a project previously approved by the REB, and the file is up to date.

11.5.2.3 The research involves only review of patient records by hospital personnel

12.0 REB Decision Making

All REB submissions shall have an impartial and fair hearing.

The REB shall endeavour to reach consensus on decisions and may wish to request external advice if it lacks expertise in the area of research being proposed. If a consensus cannot be reached, a decision shall be made by majority vote. In case of a tie vote, the Chair will break the tie.

12.1 Decisions of the REB

12.1.1 After review by a REB, the protocol submission may be:

12.1.1.1 Approved as submitted

12.1.1.2 Approved with conditions that must be met before final approval is granted

12.1.1.3 Deferred pending receipt of additional information and/or revisions

12.1.1.4 Not approved

12.1.2 All decisions must be recorded and communicated in writing, either by print or electronically, with reasons for the decision by the Chair or by his/her selected designate. The applicant will be notified of the decision normally within 10 working days of the reviewed date of the proposed research. If a protocol submission is approved with minor changes or conditions, the Principal Investigator can either accept the proposed modification or offer a counter-proposal to the Chair of the REB. To facilitate the continuing process of such research ethics protocols between meetings, the REB should specify conditions that should be met to enable the Chair to review and grant approval on behalf of the REB.

12.1.3 Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project.

12.1.4 If the REB does not approve a research activity for ethical reasons, the notification shall include a statement of the reasons for its decision and the Principal Investigator shall be given an opportunity to respond in writing or in person. The REB may, at its discretion, review and reconsider its decision to not approve the research activity.

12.1.5 In the case of ongoing research, the REB has the authority to terminate research that deviates from an approved research protocol and as a result no longer complies with the criteria set forth in these policies or the TCPS2 (2018).

12.2 Requests of Research Changes to Approved Decisions

Researchers shall submit to the REB request for substantive changes to an approved research proposal. The request shall include an explanation of the reasons for the request and shall be submitted using the appropriate REB form. Depending on the level of risk to participants, the changes may receive delegated or full review. The REB shall decide on the ethical acceptability of the proposed changes and may determine that the changes are substantial, which may require a new REB review.

12.3 Deferred Decisions

Upon a communication of a deferred REB decision the Principal Investigator will have an opportunity to consider the decision and to provide a response to the REB. The final decision of the REB will depend upon the response from the researcher and any additional information required to make a final decision. The process of communication between the REB and PI is not subject to a set number of communications, however, it is the aim of the REB to work proactively with researchers to ensure a reasonable start of the research project.

12.4 Appeal of REB Decisions

After the researcher and REB have exhausted the reconsideration process, and the REB has issued a final decision, the researcher may initiate an appeal. The researcher must initiate the appeal within 30 days of the receipt of the written decision. The appeal must be made in writing to the Chair of the Research Ethics Board and include all supporting documents.

The Research Ethics Appeal Board may sustain, modify, or reverse a decision of the REB. The decision of the Research Ethics Appeal Board is final and will be communicated promptly to the applicant. A decision of the REB to disallow research on ethical grounds, unless reversed on reconsideration by the REB, may be reversed through the appeal process.

12.4.1 The Principal Investigator must apply in writing to the President to appeal a negative decision of the REB. A copy of the appeal letter should be sent to the REB Chair. Appeals may be requested to the President, who will then appoint an appeal board. The President shall appoint an Appeals Board (REAB) in accordance with the guidelines set out in the TCPS2 (2018). Non-compliance with the substance of the TCPS2 (2018) is a valid reason for refusing to grant an appeal.

12.4.2 Upon granting an appeal, the President shall forward the appeal letter and all relevant documents to the St. Clair College Research Ethics Appeal Board within ten days of receiving the request for appeal.

12.4.3 The Research Ethics Appeal Board shall review the appeal at their next scheduled meeting and notify the Principal Investigator in writing of their decision no later than 40 days after receiving the appeal from the President.

12.4.4 The protocol submission may be approved or rejected. The decision of the Appeal Board shall be binding.

13.0 Conflict of Interest

Researchers hold a relationship of trust with research participants, sponsors, professional bodies, and society. Trust relationships must not be put at risk by a conflict of interest. The REB review process is also based upon a trust relationship between the REB and the researchers. According to the TCPS2 (2018), "researchers, their institutions and REBs should identify and address conflicts of interest – real, potential or perceived – to discharge professional and institutional obligations, maintain public confidence and trust, and ensure accountability."[16] This includes developing a process that will identify the steps taken to manage the conflict. All researchers and REB members have the responsibility to review the St. Clair College policy on Research Integrity and the guidelines stipulated in the TCPS2 (2018) to avoid or prevent being in a position of conflict of interest, as well as to understand how to minimize or manage the conflict.[17]

13.1 Institutional Conflict of Interest

St. Clair College shall identify, eliminate, minimize, or manage conflicts of interest that affect research. This includes for researchers, administrators, REB members, faculty, and all other parties involved to act in a transparent manner while identifying and addressing conflicts of interests. In addition, any institutional conflict of interest that may affect research shall be reported to the REB according to established conflict of interest policies. Institutional conflict of interest is consistent with Article 7.1 and 7.2 of the TCPS2 (2018).

13.2 REB Member Conflict of Interest

A member of the REB or Research Ethics Appeal Board (REAB) shall not be part of any discussion or decision regarding a research project in which the member has a personal or financial conflict of interest (e.g.,review of a member's research project). The REB member conflict of interest is consistent with Article 7.3 of the TCPS2 (2018).

---

[16] TCPS2 (2018), Chapter 7, Conflicts of Interest.

[17] Refer to Chapter 7, Conflict of Interest of the TCPS2 (2018).

14.0 Consent Process

There are three general principles to the consent process.[18] These are:

(a) consent shall be given voluntarily;
(b) consent can be withdrawn at any time; and
(c) if a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

Furthermore, the consent process is ongoing. That is, the consent process applies to every point of contact with participants and endures until project completion. Participant re-consent may also be required in instances where participant information is subsequently used in another research project. Research may begin only if prospective participants, or authorized third parties, have been provided with the opportunity to give free and informed consent about

participation, and their free and informed consent has been given. The inclusion of a participant's data or human biological materials in the research is contingent on their free and informed consent being maintained throughout their participation in the research.

Participants must have freely agreed to participate in the research study on the basis of well-understood information about the objectives of the research and the nature of their participation. Additionally, they must be fully informed of any and all known risks associated with the research, as well as possible benefits of their participation. They must have the opportunity and ample time to evaluate the relative weight of any known risks and benefits.[19]

14.1 Informed Consent

To make an informed decision regarding participation in a research project, researchers shall provide to prospective participants, or authorized third parties, all information necessary for making such decision.

Throughout this process, the researcher must ensure that prospective participants are given adequate opportunities to discuss and contemplate their participation by giving them enough time and the opportunity to ask questions. The information generally required for informed consent includes [20]:

(a) information that the individual is being invited to participate in a research project;
(b) 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;
(c) a plain language description of all reasonably foreseeable risks and potential benefits, both to the participants and in general, that may arise from research participation;

[18] For further explanation for each principle of the consent process, refer to Article 3.1 of the TCPS2 (2018) and its applications.

[19] Refer to the sample consent form on the REB website (www.stclaircollege,ca/reb) for all components of consent.

[20] Derived directly from Article 3.2, TCPS2 (2018).

(d) an assurance that prospective participants:
- are under no obligation to participate and are free to withdraw at any time without prejudice to pre-existing entitlements;
- will be given, in a timely manner throughout the course of the research project, information that is relevant to their decision to continue or withdraw from participation; and
- will be given information on their right to request the withdrawal of data or human biological materials, including any limitations on the feasibility of that withdrawal;

(e) 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;

(f) the measures to be undertaken for dissemination of research results and whether participants will be identified directly or indirectly;
(g) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
(h) the identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
(i) the identity and contact information of the appropriate individual(s) outside the research team whom participants may contact regarding possible ethical issues in the research;
(j) 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 (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;
(k) information about any payments, including incentives for participants, reimbursement for participation-related expenses and compensation for injury;
(l) a statement to the effect that, by consenting, participants have not waived any rights to legal recourse in the event of research-related harm; and
(m) in clinical trials, information on stopping rules and when researchers may remove participants from trial.

14.2 Voluntary Consent

Free and informed consent must be given voluntarily, without manipulation, undue influence, or coercion. There shall not be incentives offered that are so large as to become an undue influence and undermine the voluntary nature of their participation. The researcher has the responsibility to justify the intended use of incentives. Researchers must take care to avoid problems of informed consent based on a special relationship between researcher and participant, so that such relationship does not unduly influence the participant's free and informed consent.

14.3 Modification of Consent

14.1 and 14.2 outline the default requirements for seeking consents from individuals to participate in research. Some research projects may require an alteration to these requirements. Modifications to consent requirements may require providing to prospective participants only partial disclosure of the purpose of the study according to Article 3.7 of the TCPS2 (2018).

Free and informed consent should normally be provided in writing. It is the responsibility of the researcher, at all times, to justify the consent process (whether written or not).

The REB must ensure that all of the following apply:[21]

(a) the waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
(b) the research could not practicably be carried out without the waiver or alteration;

(c) whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
(d) the waiver or altered consent does not involve a therapeutic, clinical or diagnostic intervention.

14.4 Capacity of Individuals

The competence of the potential participants to provide free and informed consent is an important factor in the validity of the consent. Competence refers to the ability to understand the information presented about the research, to appreciate the potential consequences of a decision, and to provide free and informed consent to participate in a specific research project.

The prospective participants do not need to have the capacity to make every kind of decision, only the informed decision about participation in the specific research.

Some individuals may permanently or temporarily lack the capacity to decide for themselves to participate in a research project. Researchers must justify to the REB's satisfaction that individuals who lack the capacity to consent are safeguarded and protected, nonetheless. [22]

In some circumstances, a person may have some ability to understand the importance and implications of the research. Although some individuals lack the legal capacity and are required to have an authorized third party, they may still be able to express their wishes, either by verbally or physically disagreeing to participate in research. The researcher shall respect the wishes of these individuals in regard to their participation.

14.5 Individuals Who Lack the Capacity to Consent

"Individuals who lack the capacity to decide whether to participate in research shall not be inappropriately excluded from research." [23] In such instances, the researcher shall satisfy the REB that:

[21] Article 3.7A and 3.7B of the TCPS2 (2018) sets out the conditions that must be satisfied for an REB to approve research involving any alterations to consent requirements. These may include the lack of prior consent or of fully informed consent, and subsequent requirements for debriefing. It is clear in the TCPS2 (2018) that what is important is the consent process rather than whether the consent is written or not.

[22] Article 3.9 of the TCPS2 (2018) lists the minimum conditions that must be met involving individuals who lack the capacity to make an informed decision to participate in a research project.

(a) the research question can only be addressed using the identified group(s);
(b) free and informed consent is sought from their authorized representatives, such as parents or legal guardians; and
(c) the research does not expose them to more than minimal risk without the potential for direct benefits to them.

14.6 Reporting Concerns and Incidental Findings

Where any research participant expresses questions or concern that cannot be immediately resolved by the researcher, shall be reported to the REB. The REB may request from the researcher, a plan for the resolution of these concerns and at the discretion of the REB, may temporarily halt the research. Researchers also have the duty to "disclose to the participant any material incidental findings discovered in the course of research."[24]

14.7 Activities That May Not Require Informed Consent Procedure

REB review is normally required for research involving naturalistic observation, except for observation of participants in public meetings, demonstrations, political rallies or like activities where participants are expected to be seeking or are aware of public visibility. Naturalistic observation is used to study behaviour in a natural environment. If the naturalistic observation does not allow for the identification of the participants, and is not staged, then the research will normally be considered as of minimal risk. However, naturalistic observation still raises the concerns of privacy and the dignity of those being observed.

According to Article 10.3 of the TCPS2 (2018), the "REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection.

14.8 Consent During Individual Medical Emergencies

The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant or of his or her authorized third party, if all of the following apply:[25]

(a) a serious threat to the prospective participant requires immediate intervention;
(b) no standard efficacious care exists, or the research offers a real possibility of direct benefit to the subject in comparison to the standard of care;
(c) either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the participant;
(d) the prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research;
(e) third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts; and
(f) no relevant prior directive by the participant is known to exist.

[23] See Article 4.6 of the TCPS2 (2018), Research Involving Participants Who Lack the Capacity to Consent for Themselves.

[24] Article 3.4 of the TCPS2 (2018), Incidental Findings. The TCPS2 (2018) defines "incidental findings" as "unanticipated discoveries made in the course of research but that are outside the scope of the research,".

[25] Derived directly from Article 3.8 of the TCPS2 (2018), p. 42.

If a previously incapacitated participant regains capacity, or when an authorized third party is found, the free and informed consent of the participant or authorized third party shall be sought promptly for the participant's continuation in the project and for subsequent examinations or tests related to the study to be conducted.

15.0 Privacy and Confidentiality

Researchers shall comply with all applicable privacy legislation of the jurisdiction in which the research takes place. Wherever possible, participants must be guaranteed privacy[26] and anonymity, and their responses must be treated with confidentiality[27]. If anonymity and confidentiality cannot be assured or guaranteed, potential participants must be made aware of the limitations and possible consequences before they are asked for their consent to participate.

15.1 Safeguarding Information

The ethical duty of confidentiality by researchers and REB members includes safeguarding information. This entails the collection, use, dissemination, retention and/or disposal of the information for its full life cycle. In addition, the following, as stipulated in the

TCPS2 (2018), must apply for the proposed measures to safeguard information:[28]

(a) type of information to be collected and how it will be used;
(b) purpose of any secondary use of identifiable information;
(c) limits on the use, disclosure and retention of the information;
(d) risks to participants if the security of the data be breached; including risks of re- identification of individuals;
(e) any documentation in the research that may identify particular participants;
(f) any anticipated uses of personal information from the research; and
(g) any anticipated linkage of data gathered in the research with other data about participants, whether those data are contained in public or personal records.

Researchers "shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements."[29] This will be established during the consent process and in the application materials submitted to the REB.

15.2 Obtaining REB Approval

REB approval is not required for access to publicly available information or materials, including archival documents and records of public interviews or performances. Researchers who plan to interview a participant to secure identifiable personal information must obtain REB approval for the consent and the interview procedures used and shall ensure the free and informed consent of the participant, as required within this practice. An interview may be face- to-face, by telephone, electronic media, or through individualized questionnaires.

[26] The TCPS2 (2018) refers to privacy as "an individual's right to be free from intrusion or interference by others," p. 55.

[27] The TCPS2 (2018) refers to "confidentiality" as the "obligation of an individual or organization to safeguard trusted information," p. 56.

[28] The measures to safeguard information were derived directly from Article 5.3 of the TCPS2 (2018), pp. 60 -61

[29] Article 5.2 of the TCPS2 (2018), Ethical Duty of Confidentiality, p. 59

15.3 Secondary Use of Identifiable Information

As stipulated in Article 5.5 of the TCPS2 (2018),[30] researchers may forego obtaining the consent of participants for the secondary use of identifiable information only when the REB has determined that:

(a) the 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;

(e) it is impossible or impracticable to seek consent from individuals to whom the information relates; and
(f) the researchers have obtained any other necessary permission for secondary use of information for research purposes.

The researcher has the exclusive right to use the data collected in any study for the approved period of time that is required for the completion of the approved research. Where the secondary use of the data will not include access to any personal identifiers, an REB review may not be required.

16.0 Research in Emergency Health Situations

Publicly declared emergencies are due to unexpected circumstances (e.g., public health outbreaks, natural disasters, etc.). Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advanced of such research by the REB.

REB review shall follow modified procedures and practices during emergencies. A preparedness plan for an emergency research ethics review shall be developed in collaboration with researchers, institutions, and the REB. These plans shall take place once an emergency has been declared and must be stopped after the end of the publicly declared emergency. The REB and researchers shall consult the TCPS2 (2018) for further guidance regarding research in emergency situations.

17.0 Research Involving the First Nations, Inuit and Métis Peoples of Canada

Researchers and REB members shall apply all the principles and values stated in the TCPS2 (2018) when conducting research involving Aboriginal people of Canada and respect all other Government of Canada policies. Research involving Aboriginal people shall acknowledge their unique status and affirm the "respect for community customs and codes of research practice in researcher-community relations."[31]

[30] Derived from Article 5.5 of the TCPS2 (2018), The Consent and Secondary Use of Identifiable Information for Research Purposes, p. 62.
[31] Chapter 9, Research Involving the First Nations, Inuit and Métis Peoples of Canada, p. 106.

Furthermore, the REB and researchers hold the responsibility to interpret the ethics framework in an Aboriginal context. Where research will involve an Aboriginal community or communities, the researcher has the responsibility to engage with the relevant community. Engagement is required, but not limited, under the following conditions:[32]

(a) research conducted on First Nations, Inuit or Métis lands;
(b) recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
(c) research that seeks input from participants regarding a community's cultural heritage, artifacts, traditional knowledge or unique characteristics;
(d) research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data; and

(e) interpretation of research results that will refer to Aboriginal communities, people, language, history, or culture.

18.0 Qualitative Research

Qualitative research, including pilot studies, requires REB review and approval. Researchers shall present their research design, as well as explain their consent process and plan to document consent, prior to recruiting participants or accessing their data.

If participants choose to disclose their identity through the dissemination process, such as having their names on publications, the researcher shall record each participant's consent for disclosing information. Researchers hold the responsibility to communicate to the REB any changes to the data collection process that may present any real, perceived, or potential risks or ethical implications.

If the research requires observation in a natural or virtual setting environment, the Principal Investigator may request to be exempt from the consent process only when individuals have a "reasonable or limited expectation of privacy."[33] The REB may approve the exemption of consent after the researcher has provided a reasonable explanation for this request, and only if the REB is satisfied that there will be no breaches of privacy such as the possible identification of individuals.

19.0 Clinical Trials

For all clinical trials, the researchers and the REB hold the responsibility to consider any potential risks associated with the type of clinical trial (e.g. pharmaceutical, natural health product, medical device, psychotherapy, etc.)during the design and review of the clinical trial. Prior to the recruitment of participants, clinical trials must be registered in a "recognized and easily web-accessible public registry."[34]

---

[32] Derived directly from Article 9.1 of the TCPS2 (2018), Requirement of Community Engagement in Aboriginal Research, p. 110.

[33] Article 10.3 of the TCPS2 (2018), p. 141.

[34] Article 11.3 of the TCPS2 (2018), p. 156

All risks to participants shall be appropriately minimized and be justified by the potential benefits to be gained. In addition, researchers shall provide the REB with a plan to monitor the safety of participants and the collection, analysis, and reporting of data.

Any new findings that may threaten the welfare of participants must be reported to the REB and corresponding regulatory agencies.
The College may develop further policies and procedures for the ethical review of research involving clinical trials, as both researchers and the College wish to conduct such research. REB members and researchers shall consult the TCPS2 (2018) for further guidance to the ethical practice for research involving clinical trials.

Both researchers and REB members shall consult the TCPS2 (2018) for further guidance on the ethical conduct of research involving Aboriginal peoples (e.g. engagement with organizations and communities of interest, complex authority structures, recognizing diverse interests with communities, critical inquiry, etc.