

Policy Title:	Ethical Conduct For Research Involving Humans
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Contacts for Policy Interpretation:	Executive Vice President, Applied Research

1.0 Policy Overview

Fleming College (the “College”) is committed to ensuring that all research activity complies with the Agreement on the Administration of Agency Grants and Awards by Research Institutions between the College and the Tri-Agency funding body.

The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022) (the “TCPS”) is a joint policy of Canada’s three federal research agencies: the Canadian Institutes of Health Research (CIHR); the Natural Sciences and Engineering Research Council of Canada (NSERC); and the Social Sciences and Humanities Research Council of Canada (SSHRC), (“the Agencies”). Canada has created and funded these agencies to promote and assist research within their respective legislative mandates. In discharging their mandates, the agencies promote research that is conducted according to the highest ethical standards, including adopting the TCPS as a benchmark for the ethical conduct of research.

As a condition of funding, these agencies require that researchers and their institutions apply the ethical principles and the articles of the TCPS and be guided by the application sections of the articles. To be eligible to receive and administer research funds from the agencies, institutions must be compliant with specific agency TCPS policies and include them as a Memorandum of Understanding (MOU) between the agencies and institutions.

Institutions must ensure that research conducted under their auspices adheres to the TCPS requirements. Subsequently, Researchers are expected to adhere to the TCPS.

2.0 Purpose

This document constitutes Fleming’s policy guiding the review of ethical considerations arising from research involving humans.

The College, its researchers, and Research Policies and Procedures adhere to the TCPS, and revises its Research Ethics Policies and Procedure(s) to ensure compliance with the most current guidelines and requirements.

3.0 Definitions and Acronyms

TCPS 2 (2022) contains a Glossary intended to assist in the understanding of its revised Policy Statement. The following definitions have been selected from this Glossary and apply to this Policy and its linked Procedures. This abbreviated list of definitions does not intend to replace the complete Glossary but apply to this Policy and its linked Procedure(s).

Capacity: The ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate.

Delegated Research Ethics Board Review: The level of REB review assigned to minimal risk research projects. Delegated reviewers are selected from among the REB membership with the exception of student course-based research ethics review, which may be conducted by delegates from the student's department, faculty, or an equivalent level.

Diversity: respect for and appreciation of differences, in any dimension that can be used to differentiate groups and people from each other.

Equity: fairness to people of all identities and ensuring that the processes of allocating resources and the decision-making do not discriminate on the basis of identity.

Full Research Ethics Board Review: The level of REB review assigned to above minimal risk research projects. Conducted by the full membership of the research ethics board, it is the default requirement for the ethics review of research involving humans.

Harm: Anything that has a negative effect on participants' welfare. The nature of the harm may be social, behavioral, psychological, physical or economic.

Inclusion: the practice of actively ensuring all individuals are valued and respected for their contributions and are supported to achieve excellence in research and training.

Indigenous Peoples: The First Nations (status and non-status), Inuit and Métis peoples of Canada, each themselves comprised of many unique languages, cultural practices, beliefs and histories.

Minimal Risk Research: Research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in the aspects of their everyday life that relate to the research.

Participant: An individual whose data, response to interventions, stimuli, or questions by a researcher are relevant to answering a research question; also referred to as "human participant," and in other policies/guidance as "subject" or "research subject."

Proportionate Approach to Research Ethics Review: The assessment of foreseeable risk to determine the level of scrutiny a research proposal will receive (i.e.: delegated review for minimal risk research or full REB review for research above minimal risk), as well as the consideration of foreseeable risks, potential benefits, and ethical implications of the research in the context of initial and continuing review.

Reciprocal Research Ethics Board Review: An official agreement between two or more institutions, in which they accept, with an agreed level of oversight, the research ethics reviews of each other's REBs.

Research: An undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation.

Research Ethics Board (REB): A body of researchers, community members, and others with specific expertise (i.e.: in ethics, in relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

Research Ethics Protocol: A document submitted by the applicant for consideration by the Research Ethics Board. This document contains a detailed description of the rationale/purpose of the study, procedures to be followed in soliciting participants for the research, obtaining their informed consent when possible, collecting their information or data, protecting their privacy or anonymity, and providing feedback regarding the study at its conclusion.

4.0 Scope

The Executive Vice President, Applied Research of the College establishes the REB, defines the appropriate reporting relationship with the REB and ensures the REB is provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties. The latter include storage space for research data as well as the establishment of appropriate institutional security safeguards to protect privacy of data for the life cycle of information.

Fleming's REB shall be the sole Research Ethics Board of the College and shall apply the principles and articles set out in the TCPS guideline "Ethical Conduct for Research Involving Humans" according to this Policy and its linked Procedure.

The College grants the REB the mandate to review the ethical acceptability of research on behalf of the institution, including approving, rejecting, proposing modifications to, or terminating any proposed or ongoing research involving humans. The College's REB is independent in its decision-making and is accountable to the Executive Vice President, Applied Research for the process of research ethics review. The College shall respect the authority delegated to the REB. The College cannot override an REB decision to reject a research proposal but may appeal a decision.

All research projects involving humans undertaken by members of, or conducted at the College - including all faculty, staff and students, including students carrying out research as part of class assignments - shall fall within the jurisdiction of the College's REB. This jurisdiction is irrespective of the source of financial support (if any) and irrespective of the location of the project so long as the investigator represents the work as College research.

Projects conducted by researchers from outside the College community who access College resources (either equipment or personnel) will also fall within the jurisdiction of the College's REB.

5.0 General Principles

The Ethics Framework of the TCPS acknowledges that research can benefit human society and that researchers must have academic freedom in order to maximize such benefits. At the same time the College requires that any research involving humans meets high scientific and ethical standards that respect and protect the participants.

Respect for human dignity has been an underlying value of the TCPS and is expressed through the core principles of respect for persons, concern for welfare, and justice. These core principles are considered the compass to navigate the course between the importance of research and its ethical conduct. The Policy is applied through a proportionate approach to REB review. The TCPS aims to assist those who use it, including Research Ethics Boards, to identify ethical issues in the design, conduct and oversight of research and to point the way to arriving at reasoned and ethical responses to those issues.

5.1 Requirement for Ethics Review: Except for the exemptions that follow, all research projects involving human participants, conducted at, in collaboration with, or under the auspices of the College require prior ethics review and approval by the REB. This requirement of obtaining prior ethics review and approval applies to:

- a) All research involving living human participants conducted by the College's academic staff, administrative and support staff, or students, persons with adjunct appointments, visiting instructors, visiting professional associates, and research associates;
- b) All research involving living human participants conducted by the College's academic staff, administrative and support staff, or students, persons with adjunct appointments, visiting instructors, visiting professional associates, and research associates;
- c) All research involving living human participants conducted by the College's academic staff, administrative and support staff, or students, persons with adjunct appointments, visiting instructors, visiting professional associates, and research associates;
- d) All research carried out on College premises or using College facilities, equipment, or human, financial or material resources;
- e) Research conducted elsewhere under the auspices of the College;
- f) The research activities of formally affiliated organizations as a condition of affiliation;
- g) The research activities of organizations or individuals (whether formally affiliated or not) while on College premises or using College facilities, equipment or resources, including off-campus sites. When research takes place in a foreign country, the researcher must also assure that his/her procedures meet all legal requirements of that country, as well as the requirements of this policy;
- h) All types of research involving humans. Specifically, prior ethics review and approval is required when research data are derived from, but not exclusively restricted to:
 - Information collected through intervention or interaction with a living individual(s);
 - Identifiable private information about individuals;
 - Information collected through naturalistic observation of humans, except as

stipulated below.

- Human organs, remains, tissues and body fluids, cadavers, embryos or fetuses; and/or
 - Written or recorded information derived from individually identifiable humans.
- i) Ethics review is required for the following categories of research that may be overlooked or raise questions about the necessity for such a review:
- j) Pilot and feasibility studies, even those involving only one human participant, require the same scrutiny as full-scale research projects involving many human participants.
- k) Projects that involve the secondary use of data on human participants gathered in earlier projects.
- l) Research conducted by administrative and academic units that involves the collection of survey replies or the use of records as correlates of survey replies from humans (e.g. students, staff and/or faculty members).
- m) Research projects in which the researcher is a consultant **unless** the researcher has a strict consulting relationship in which **all** of the following are true:
- The Researcher is hired on his or own time;
 - The Researcher holds no rights in the work; and
 - Neither the researcher nor the College retains any data

If any one of these three criteria is not met, prior ethics review and approval is required.

- n) All independent student research projects conducted in partial fulfillment of certificate/diploma/degree requirements.
- o) Research projects conducted as part of formal course requirements may, in certain instances require REB review and approval. It is incumbent on the instructor to check the applicability of this requirement with the REB Chair.

5.2 Research Excluded: Some research is exempt from REB review where protections are available by other means. The policy allows the following exemptions from the requirement for REB review, as follows:

- a) **Research that relies exclusively on publicly available information** does not require REB review when:
- the information is legally accessible to the public and appropriately protected by law, e.g. any existing stored documentary material, records or publications, which may or may not include identifiable information such as death registries, publicly available archives; or
 - the information is publicly accessible and there is no reasonable expectation of privacy, e.g. identifiable information disseminated in the public domain through print or electronic publications; film, audio or digital recordings; press accounts; artistic installations.
- b) **Research that is non-intrusive and does not involve direct interaction** between the researcher and individuals through the Internet does not require REB review i.e.: cyber-

material to which the public is given uncontrolled access on the Internet for which there is no expectation of privacy is considered to be publicly available information.

- c) **Archival analysis of records** by College departments normally engaged in the collection, maintenance, and analysis of such records does not require REB review. Nevertheless, it is incumbent on such units to ensure that the anonymity of individuals and confidentiality of their records are maintained. **The exception** for this type of research is where individuals to whom the information refers have reasonable expectations of privacy, then REB review is required.
- d) **Research involving the observation of people in public places** where:
- it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
 - individuals or groups targeted for observation have no reasonable expectation of privacy; and
 - Any dissemination of research results does not allow identification of specific individuals.
- e) **Class research projects which involve human participants**, and which are conducted by students on other members of the class as exercises to learn how to conduct research.
- f) **Quality assurance and quality improvement studies**, program evaluation activities (such as evaluations of courses or training programs that are designed to provide feedback), and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research and do not fall within the scope of REB review.
- g) **Preliminary, informal interviews or casual conversations** carried out to help clarify the design of a research project.
- h) **Information gathering procedures** in support of the general administration of the College where the primary purpose(s) are:
- To diagnose problems, identify appropriate solutions, provide advice for operation management, or assess performance.
 - To collect data primarily designed to affect the operations of the College through affirming satisfaction with the status quo or leading to quality improvements.
- Note:** Most administrative information gathering procedures and practices are not conducted in the context of research or embedded in a research framework. Rather they are conducted for the purpose of assessing choices, ascertaining satisfaction of clients, identifying service enhancements or for similar quality objectives. All such projects must also be done in accordance with the highest research ethical practices. However, in those cases where information gathering through such vehicles as surveys or interviews conducted by administration have a clear research direction, are on sensitive topics, are collected from vulnerable populations or where there may be an issue with the confidentiality of individual responses, REB review would be required.
- i) **Research undertaken as a teaching exercise** and entailing minimal risk shall be reviewed by a College or department level committee on behalf of the REB.

- j) **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.

5.3 Uncertainty About the Need for REB Review: 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.

5.4 Compliance: The College requires all faculty members, staff and students, as well as external researchers conducting research at the College, to adhere to this policy and the procedures that are derived from it. The College considers the improper treatment of research to be a serious offence, subject to severe penalties, including but not limited to the withdrawal of privileges to conduct research involving humans, or disciplinary action. The College is committed to maintaining high standards of research integrity as outlined in College Policy 9-906 Integrity in Research and Scholarship Policy.

5.5 Responsibilities of Researchers: Whenever research involving humans is to be performed under the auspices of the College or by any College researcher, the researcher is responsible for meeting the following requirements:

5.6 Qualitative Research Proposals: Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, or access to data. REB review is not required for the initial exploratory phase intended to discuss the feasibility of the research, establish research partnerships, or the design of a research proposal.

Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent. In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent.

If researchers plan to disclose the identity of participants, researchers shall discuss with prospective 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.

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.

5.7 Free and Informed Consent of Subjects: The researcher is responsible for obtaining free and informed consent given voluntarily from all prospective human participants or authorized third parties prior to commencing research activities. Free and informed consent is ongoing throughout participation in the research. Incentives are neither recommended nor discouraged by the TCPS. Incentives ought not be so large or attractive as to encourage reckless disregard of risks. Similarly, the offer of incentives in some contexts may be perceived by prospective participants as a way for them to gain favour or improve their situation. This may amount to undue inducement and thus negate the voluntariness of

participants' consent.

5.8 Research Ethics during Emergencies

- a) Publicly Declared Emergencies – This section addresses research ethics review within the context of the official declaration of public emergencies. The College, in collaboration with their researchers and REB should develop preparedness plans for emergency research ethics review. Research ethics review during publicly declared emergencies may follow modified procedures and practices.
- b) Emergency Health Situations – 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 advance of the research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the participant (or prospective participant) or of his or her authorized third party if **ALL** of the following apply:
 - A serious threat to the prospective participant requires immediate intervention; and
 - Either no standard efficacious care exists, or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
 - Either the risk of harm is not greater than that involved in standard efficacious care, or it is not clearly justified by the direct benefits to the subject; and
 - The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
 - Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
 - No relevant prior directive by the participant is known to exist. When a previously incapacitated participant regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

5.9 Governance of Research Ethics Review: The College's REB is responsible to the Executive Vice President, Applied Research for:

- a) Developing policies regarding ethical issues relating to the use of humans in research and experimental teaching protocols;
- b) Conducting research ethics review of all research involving humans;
- c) Ensuring adherence of the College's research ethics policy with the most current version of the TCPS;
- d) Dealing with matters concerned with research involving humans referred to the REB by the Executive Vice President, Applied Research;
- e) Preparing an annual report for submission to the Executive Vice President, Applied Research, as outlined in Section 5.13 of this policy;
- f) Ensuring REB members participate in initial and ongoing training relevant to their responsibilities and duties to the REB.

5.10 Quorum: Quorum rules must meet the minimum requirements of membership. As long as the College's REB is minimally constituted and whereby individual members contribute a single critical attribute of REB membership then quorum is full attendance. To maintain quorum when REB members are geographically dispersed or in unexpected circumstances input from member(s) is allowed by other means, such as the use of technology e.g. videoconferencing, teleconferencing. Use of such technologies requires the Chair to ensure active participation of members not physically present.

5.11 Meetings: The REB members shall meet regularly at dates and times that are publicly announced in advance (preferably for the entire academic year) to discharge their responsibilities and will normally meet face to face or virtually to review proposed research that is not assigned to delegated review. 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.

5.12 On-going Training: The College will provide REB members (including community members) with the necessary training opportunities to effectively review the ethical issues raised by research proposals that fall within the mandate of their REB. This includes training opportunities for all members in core principles and understanding of the TCPS, basic ethics standards, the College's policy, and legal or regulatory requirements. This training should be tailored to the types and complexities of the research the REB reviews and should be offered both upon the appointment of new members, and periodically throughout a member's tenure.

5.13 Reports of Research Ethic Board Committee Decisions: An annual activity report from the REB will be submitted to the Executive Vice President, Applied of Fleming College, the Senior Management Team and Academic Leadership.

5.14 Adverse Events Reports: Normally it is anticipated that research will proceed with little (or no) special costs or harm to participants, beyond those noted in the protocol. However, unanticipated negative reactions by subjects or other unexpected events may occur. Researchers are obliged to immediately report, in writing, any known serious adverse event to the REB.

5.15 Administration:

- a) Administrative Support: The work involved in the ethical review process should be distributed appropriately among faculty members, staff, researchers, and administrators. The College will provide administrative support to the REB including:
- Distribution of forms and materials necessary for submission of research proposals to the REB;
 - Collection of submissions and distribution of submissions to REB members;
 - Keeping minutes of REB meetings;
 - Storing submissions and related materials in a secure location;
 - Supporting the REB in its educational activities;
 - Acting as the point of contact for the Tri-Council Advisory Group;
 - Other duties related to the support of the REB in carrying out its mandate.
- b) Deans: Provide significant support to the REB, with respect to:

- Ensuring that research projects requiring ethical review are submitted to the REB;
 - Advising their faculty members about the need to comply with the TCPS.
- c) College Departments: Support and train students so that their research projects are ethical and those that exceed minimal risk may be efficiently reviewed by the REB. Departments should screen student applications for ethical review prior to submission to the REB where such review is required. The REB may return applications to the department if they do not conform to the requirements of the TCPS.
- d) College Support: Supports the administrative processes and educational activities required by the REB so that the College as a whole remains in compliance with TCPS.
- e) Reporting of Non-Compliance: the REB role is limited to reporting cases of failure to comply with the provisions of the TCPS and the College research policies to the Executive Vice President, Applied Research.
- f) Interpretation: Questions of interpretation or application of this policy or its procedures shall be referred to the Executive Vice President, Applied Research whose decision shall be final.

5.16 Forms: Ethical Guidelines and the required forms for submission to the REB will be made available from the Office of Applied Research & Innovation.

6.0 Related Documents

- Government of Canada. (2022). Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans – TCPS 2 (2022). Government of Canada.
- 9-903 Intellectual Property Policy & Procedure
- 9-904 Copyright Policy & Procedure
- 9-906 Integrity in Research and Scholarship Policy
- 9-907 Commercialization Policy & Procedure

7.0 History of Amendments/Reviews

Date	Activity
2008	Originally approved; replaced Policy 2-214 and associated procedures
2009	Reviewed and updated
2016	Reviewed and updated, replaced 2-216
2024	Reviewed and updated, Procedure separated from Policy