Procedure Title:	Ethical Conduct for Research Involving Humans
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Contact for Procedure Interpretation:	Executive Vice President, Applied Research

1.0 – Purpose

The purpose of this procedure (the "**Procedure**") is to set out instructions for obtaining Research Ethics Board (REB) approval under Policy 9-905 Ethical Conduct for Research Involving Humans.

2.0 – Guiding Principles

The College's REB will make every effort to safeguard the well-being of research participants and ensure the integrity of the research being conducted.

Its procedures are anchored in principles that prioritize ethical conduct, transparency and the advancement of knowledge. Foremost among these principles is the commitment for autonomy, emphasizing the voluntary and informed consent of participants.

The REB committee is dedicated to upholding the principle of avoiding harm and ensuring that any potential risks are thoroughly evaluated.

Finally, the principle of accountability governs the REB's commitment to ongoing review, continuous education and responsiveness to evolving ethical standards, thereby fostering public trust in the research enterprise.

3.0 – Procedure

3.1 Composition of the Board

a) **Basic REB Membership Requirements:** The College may establish its own terms of appointment of REB members to allow for continuity of the research ethics review process. Currently, the normal term of office for REB members is three years, with no more than one-third being replaced each year; shorter or longer terms may be

necessary from time to time. Members may not serve more than six consecutive years but are eligible for re-appointment after an interval of one year.

b) Selection of REB Members: The selection of REB members, including the Chair, should be fair and impartial in accordance with the College's written policy that defines the process of appointing REB members. In appointing and renewing REB members, institutions should arrange the terms of members and their rotation to balance the need to maintain continuity with the need to ensure diversity of opinion, and the opportunity to spread knowledge and experience gained from REB membership throughout the institution and the community.

c) REB Size: The College may determine the size of its REB which will vary in accordance to institutional needs. In accordance with the TCPS, the College's REB shall consist of at least five members, including both men and women, of whom:

- At least two members have expertise in relevant research disciplines, fields and methodologies covered by the REB;
- At least one member is knowledgeable in ethics;
- At least one member is knowledgeable in the relevant law (but that member should not be the institution's legal counsel or risk manager). This is mandatory for biomedical research and is advisable, but not mandatory for other areas of research; and;
- At least one community member who has no affiliation with the institution. Their primary role is to reflect the perspective of the participant especially when participants are vulnerable and/or risks to participants are high;
- Research ethics administrative staff who have the requisite experience, expertise and knowledge comparable to what is expected of REB members may be appointed as nonvoting members.

Ad hoc advisors may be consulted in the event that the REB lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently.

At a minimum, it is advisable that each member be appointed to formally fulfill the requirements of only one of the above categories. Where the size of the REB exceeds the minimum requirements, additional members may fulfill more than one capacity.

d) To ensure the independence of REB decision making, the College's Senior Management Team shall not serve on the REB nor attend meetings even as non-voting members. However, the involvement of administrative staff dedicated to research ethics functions may be relevant and appropriate to support REB procedures. In cases where research ethics administrative staff has the requisite experience, expertise and knowledge comparable to what is expected of REB members, the College may appoint them as non-voting members.

e) Substitute Membership: The College will nominate substitute REB members so that the REB can continue to function when regular members are unable to attend due to illness or other unforeseen eventualities. The appointment of substitute members should not, however, alter the REB membership composition. Substitute members should have the appropriate knowledge, expertise and training to contribute to the research ethics review process.

f) Ad Hoc Members: From time to time, the REB may find it necessary to consult with ad hoc advisors in the event that it lacks the specific expertise or knowledge to review the ethical acceptability of a research proposal competently. In each case, the responsibility for appointing these ad hoc members will rest with the Chair. Such ad hoc members will not be counted in the quorum of the REB nor be voting members of the REB. Their input as consultation may or may not be considered in the REBs final decision. If similar ad hoc members be regularly required, the membership of the REB should be modified to ensure appropriate expertise on the REB.

g) REB Chair: Responsible for ensuring that the REB review process conforms to the requirements of the TCPS. The Chair provides overall leadership for the REB and facilitates the REB review process, based on institutional policies and procedures and the TCPS. The Chair should monitor the REB's decisions for consistency and ensure that these decisions are recorded accurately and communicated clearly to researchers in writing as soon as possible by the Chair or designate. The College shall provide the necessary resources and adequate administrative support to enable the REB Chair to fulfill his or her responsibilities.

h) Research ethics administration should maintain general records related to REB membership and qualification of members (e.g. copies of curriculum vitae, participation in relevant research ethics training).

3.2 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:

a) Ensuring that the proposed research is both ethically acceptable and, where appropriate, adheres to relevant disciplinary scholarly standards. Researchers have a role to play in demonstrating to the REB whether, when and how appropriate scholarly review has been or will be undertaken for their research. Researchers ought to be prepared to provide the REB with the full documentation of scholarly reviews already completed.

b) Reading and becoming thoroughly familiar with applicable ethical guidelines.

c) Determining if the proposed research requires ethics review. If there is any uncertainty about whether the research requires ethics review and approval, the researcher shall consult the Chair of the REB for advice. Following initial REB approval, research ethics review shall continue throughout the life of the project. Continuing ethics review by an REB provides those involved in the research process (in particular, researchers and REBS) with multiple opportunities to reflect on the ethical issues surrounding the research.

d) Notifying the REB of the proposed research by submitting a completed Research Ethics Protocol Involving Humans accompanied by any supplementary materials necessary for full ethics review, and providing any additional information requested by the REB in a timely fashion.

e) Not commencing research involving human participants in the proposed research until the REB has informed him/her of approval of the proposed research.

f) Abiding by all decisions of the REB, including following all modifications required for REB approval and not undertaking the research if it has not been approved.

g) Obtaining free and informed consent from all prospective participants as outlined in Section 5.6 of this policy and document this consent regardless of participants' signatures. Maintain ongoing informed consent. Ensure participants understand they may withdraw consent at any time during the research. Their data will be withdrawn when possible. There are exceptions to the obtainment of informed consent e.g. research involving observation in a natural environments or virtual settings where people have a reasonable or limited expectation of privacy. In this case the researcher shall explain the need for an exception to the general requirement for consent.

h) Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Fleming shall support their researchers in maintaining promises of confidentiality. Researchers shall describe measures for meeting confidentiality obligations and explain any reasonable foreseeable disclosure requirements in their application materials they submit to the REB and during the consent process with prospective participants. Maintaining the confidentiality of data obtained from subjects in the manner required by the REB and relevant organizations.

i) Promptly reporting to the Chair of the REB in a timely manner, any unanticipated issues that arise that may increase the level of risk or have other ethical implications. Researchers shall also submit to the REB in a timely manner requests for changes to their approved research.

j) Researchers have an obligation to disclose to the participants any material incidental findings discovered in the course of research. Incidental findings are findings that have been interpreted as having significant welfare implications for the participants, whether health-related, psychological, or social. If in the course of research, material incidental findings are discovered, researchers have an obligation to inform the participants.

Researchers should be inclusive in selecting participants by supporting the visibility of research from members of underrepresented groups in your field. Researchers shall not exclude individuals from the opportunity to participate in research on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age unless there is a valid reason for the exclusion. In addition, individuals or groups whose circumstances may make them vulnerable in the context of research should not be inappropriately included or excluded from participation in research on the basis of their circumstances.

k) Consider ways to ensure the equitable distribution of any benefits of participation in research.

l) Reporting to the Chair of the REB any serious or continuing non-compliance with the requirements of this policy or of the procedures stipulated by an REB by any individual associated with the research.

m) Researchers have the right to request an appeal of an REB decision. An appeal can be launched for procedural or substantive reasons. The onus is on the researchers to justify the grounds on which they request an appeal and to indicate any breaches to the

research ethics review process or any elements of the REB decision that are not supported by this Policy.

3.3 Free and Informed Consent of Subjects

a) Free and informed consent must be given voluntarily, without undue influence or coercion. Consent can be withdrawn at any time. If a participant withdraws consent, the participant can also request the withdrawal of their data or human biological materials.

b) Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

c) The REB may approve a consent procedure that differs from that outlined in 3.3a) and b) above if the REB finds that:

- The research involves no more than minimal risk to the participants;
- The alteration or waiver of the consent procedure is unlikely to adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the alteration or waiver of the consent procedure;
- Whenever possible and appropriate after participation, or at a later time during the study, participants will be debriefed and provided with additional pertinent information at which point they will have the opportunity to refuse consent;
- The alteration or waiver of consent does not involve a therapeutic intervention.

d) Researchers shall provide prospective participants or authorized third parties with full disclosure of all information necessary as is applicable to the project to inform their decision to participate.

For consent to be informed, prospective participants shall be given adequate time and opportunity to assimilate the information provided, pose any questions they may have and discuss and consider whether they will participate. The time required for this initial phase of the consent process will depend on such factors as the magnitude and probability of harms, the complexity of the information conveyed, and the setting where the information is given.

The information to be disclosed to prospective participants should include all of the following that apply to the project.:

- Information that the individual is being invited to participate in a research project and against which criteria subjects are being selected;
- A statement of the research purpose, identity of the researcher, the expected duration and nature of participation and a description of the research procedures and an explanation of the responsibilities of the participant;
- A plain language description of all reasonably foreseeable harms and potential benefits that may arise from research participation;
- An assurance that prospective subjects are under no obligation to participate and have the right to withdraw at any time without prejudice to pre-existing entitlements;
- The possibility of commercialization of the research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors. Please refer to Policy 9-907 Commercialization Policy.
- The measures to be undertaken for dissemination of research results and whether

participants will be identified directly or indirectly;
- The identity and contact information of a qualified designated representative who can explain scientific or scholarly aspects of the research to participants;
- 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;
- 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,
- 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.

e) Capacity may vary according to the complexity of the choice being made, the circumstances surrounding the decision, or the point in time at which consent is sought. The determination of capacity to participate in research, then, is not a static determination. Assessing capacity is a question of determining, at a particular point in time, whether a participant (or prospective participant) sufficiently understands the nature of a particular research project, and the risks, consequences and potential benefits associated with it.

For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, individuals who are not legally competent shall only be asked to become research subjects when:

- The research question can only be addressed using individuals within the identified group(s);
- Free and informed consent will be sought from their authorized representative(s); and
- The research does not expose them to more than minimal risks without the potential for direct benefits for them.

f) For research involving legally incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

- The researcher involves participants who lack the capacity to consent on their own behalf to the greatest extent possible in the decision-making process;
- The researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned;
- The authorized third party cannot be the researcher or any other member of the research team. The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.
- When authorization for participation was granted by an authorized third party, and a participant acquires or regains capacity during the course of the research, the researcher shall promptly seek the participant's consent as a condition of continuing participation (Section 5.7 b).;
  The researcher demonstrates that the research is being carried out for the participant's direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only

for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant's welfare will be protected throughout the participation in research.

3.4 Submission: REB applications must be submitted by the first day of the month for that month's REB meeting. The REB's monthly meeting schedule can be found on the College's website under the Office of Applied Research and Innovation, Research Ethics. Submissions for review should be submitted to the REB using the appropriate forms and by following the instructions on the forms.

The REB file on applications for ethical review should contain the following documents:

- Application to Involve Human Participants in Research form;
- Trial protocol and amendments;
- Written informed consent forms and any updates;
- Subject recruitment procedures (e.g. advertisements);
- Investigator's brochure (if one exists);
- Available safety information;
- Information about payments and compensation available to subjects;
- Investigator's current curriculum vitae and/or other document on qualifications;
- Any other documents that the REB may need to fulfill its responsibilities.

All researchers are required to complete the free online TCPS Ethics Tutorial and submit their certificate along with the application and supporting documents to REB@flemingcollege.ca.

If approval has been obtained from another institution's REB, please include the corresponding documentation along with the approval letter. Ensure that all necessary information and forms are provided. Incomplete submissions will not be considered for processing.

Visiting researchers should contact the Chair of the College's REB well in advance of the anticipated start date of research. Prospective applicants may approach the REB Chair or any REB member for assistance in selecting the appropriate forms for submission.

REB approval must be obtained before the researcher begins any component of their research that directly involves human participants.

3.5 Normal Review Process: Review and approval of REB applications occurs as follows:

a) The REB shall meet face to face or virtually in order to review submitted research proposals. In case of controversial research proposals, the REB may meet face to face or virtually with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies.

b) The REB shall meet face to face or virtually in order to review submitted research proposals. In case of controversial research proposals, the REB may meet face to face or virtually with researchers in order to consider the ethical solutions proposed by researchers for problems arising in their studies.

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

d) Minutes will be kept for these meetings and inserted into the appropriate case files. Meeting minutes shall clearly document the REB's decisions, any dissents, and the reasons for them. REB decisions should be supported by clear references (e.g. date of decision, title of project), documentary basis for decision (i.e. documents or progress reports received and reviewed), the plan for continuing ethics review and timelines, reasons for decisions, and any conditions or limitations attached to the approval. Providing reasons for REB decisions is optional when ethics approval is granted.

e) The REB shall keep an "open file" in a secure location determined by the Chair of the REB, for researchers applying for ethical approval. The file shall be opened by the Chair when sufficient information has been submitted by the researcher to start the review process. The original application, descriptions of research and methodology, correspondence, relevant documents, ethical certificates, revised materials, and any comments from the public or other information relevant to the research project shall be kept in the file.

f) It is the responsibility of the researcher to address all of the recommendations made by the REB. The REB will ensure the file is complete and up to date at all times. The researcher is to notify the REB when the project is completed, and the REB shall "close" the file and be kept for a period of at least five years by the REB as records demonstrating compliance with the TCPS. The files remain the property of the College and cannot be removed from their secure location by the researchers. These files shall be subject to audit by authorized representatives of the College (research administrators), members of Appeal Boards, and funding agencies.

All research receiving ethical approval, following a full or delegated review, as well as that receiving departmental level review shall require a proper file showing compliance with the TCPS. Insufficient information in the file is grounds for refusing or delaying ethical approval.

3.6 Scholarly Review

a) In cases of research proposals that present more than minimal risk, the design of the project must be peer reviewed to assure that it can address the question(s) being asked in the research. Sufficient peer review may be any one of the following:

- Successful approval by the REB (if research is in the REB's field of expertise).
- Successful funding of grant proposal by a funding agency.
- Ad hoc independent external review reporting directly to the REB.

b) The extent of the review required for biomedical research that does not involve more than minimal risk will vary according to the research being carried out.

c) Research in the humanities and the social sciences, which poses, at most, minimal risk shall not normally be required by the REB to be peer reviewed. The REB will undertake review of qualitative research studies in accordance with the TCPS; in particular its particular aspects such as emergent research design, planned disclosure of participants'

identities, absence of signed consents or exceptions to consents, and initial exploratory phases (though not pilot studies).

d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on organizations. Such research should not be blocked using harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse and, in extremis, through action in the courts for libel.

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

3.7 Principle of Proportionate Review: The REB will tailor its level of scrutiny to the level of risk presented by the research, and assesses the ethical acceptability of the research through consideration of:

- the foreseeable risks;
- the potential benefits; and
- the ethical implications of the research, both at the stage of the initial review and throughout the life of the project (continuing ethics review).

3.8 Delegated Review: Delegated review does not require face-to-face or virtual meetings of the REB members. The researcher must choose to apply for delegated or full review and the REB Chair may reject any application for delegated review and refer it to the REB for full review. The Chair must report requests for delegated review and results of such reviews to other members of the REB at an appropriate time. Delegated review is reviewed by two members (the Chair may be one of these) rather than the full REB. It is available only in cases, which fulfill one of the following criteria:

- Research which obviously involves no more than minimal risk.
- Research projects which have already received approval by the College REB, have complied fully with any requirements, have an up-to-date file, and the applicant is simply renewing the ethical approval without significant changes to the ongoing research process.

3.9 Division/Departmental Level Review: This policy requires that all research involving human subjects must be submitted to the REB. If, however, a study is a teaching exercise (i.e. part of a diploma or undergraduate degree level course) and entailing no more than minimal risk, it must be reviewed by a divisional/departmental level committee on behalf of the REB and in compliance with the TCPS. The Departmental ethics committee must report results of such reviews to the REB at the end of the academic year.

Student research deemed to be beyond minimal risk must be reviewed by the REB. Department level review should not be used to review research undertaken by a student as part of a faculty member’s research program.

3.10 Review of Multi-Centered Research: Contemporary research often involves collaborative partnerships among researchers from multiple institutions or countries. It may

call upon the participation of a number of local populations and involve multiple institutions and/or multiple REBs.

3.11 Review Mechanisms for Research Involving Multiple Institutions and/or Multiple REBs: This refers to ethics review mechanisms for research involving multiple institutions and/or multiple REBs. It is not intended to apply to ethics review mechanisms for research involving multiple REBs within the jurisdiction or under the auspices of a single institution.

The College's REB, with permission from the Executive Vice President, Applied Research, may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with the TCPS. REB review models may include:

a) Independent Ethics Review by Several REBs,

b) Research Ethics Review Delegated to an External, Specialized or Multi-Institutional REB, and

c) Reciprocal REB review.

The institution remains responsible for the ethical acceptability and ethical conduct of research undertaken within its jurisdiction or under its auspices irrespective of where the research is conducted.

3.12 Ethics of Research Conducted Outside the Institution: Where research conducted under the auspices of the College and performed in whole or in part outside of Canada has been approved under the REB review model involving multiple institutions and/or REBs consistent with the TCPS, the terms of that model apply.

The information to be provided to the researcher's home REB will be determined by the provisions of the research ethics review model. When conducting research outside the jurisdiction of their home institution whether at a site abroad, or in Canada, researchers shall provide their home REBs with:

- The relevant information about the rules governing research involving humans and the ethics review requirements at the research site, where any exist;
- The names and contact information for the relevant REBs or comparable ethics bodies, if known, that will review the proposal at the research site; and,
- Relevant information about the target populations and circumstances that might have a bearing on the research ethics review by the researcher' home REB.

3.13 The REB's approval of a research project covers only the procedures outlined by the applicant in his/her original application. Any changes in the procedures affecting interaction with human subjects should be reported to the REB. Significant changes will require the submission of a revised application for REB approval. The rigor of continuing ethics review will be subject to the Policy and the appropriate review process as determined by the principle of proportionate review outlined in Section 2.3 of the Procedure.

a) Ongoing research shall be subject to continuing ethics review throughout the life of the project. The Chair of the REB must be promptly notified of any substantial change to the research plan or research protocol. Researchers will be asked to include monitoring mechanisms by which the public participating in the research may contact the Chair of

the REB. Problems or complaints will be taken seriously by the REB and researchers may be asked to modify their studies in view of such complaints.

b) All protocol approvals are for a maximum of one year and may be renewed by submission of an annual report prior to the anniversary date of the original protocol approval. Such reports should clearly indicate the status of data collection and, if there are changes to the protocol that was approved, specify in detail the nature of any changes that are required. If no substantial change has been made to the research plan or research protocol, the Chair of the REB may issue a one-year renewal. If, in the opinion of the REB Chair, the research plan or research protocol has been substantially changed, re-submission and review by the REB is required. Protocol submissions for data collection for a period less than one year lapse at the end of the time specified.

c) The researcher shall promptly notify the REB when the project concludes.

3.14 Conflict of Interest: If the REB is reviewing research in which a member of the REB has a personal interest in the research under review (e.g. as a researcher or as an entrepreneur), conflict of interest principles require that the member declare their interest and remain neutral or not be present while the REB is discussing or making its decision. In cases of disagreement over conflicts of interest, both the REB member in potential conflict and the researcher may present evidence and offer a rebuttal concerning the nature of the conflict of interest. The other members of the REB will make a final decision regarding the conflict and how to proceed.

3.12 Decisions of the REB: After review by a REB, the protocol submission may be:

- Approved as submitted;
- Approved with suggestions for minor changes;
- Approved with conditions (that must be met before final approval is granted);
- Deferred, pending receipt of additional information or major revisions;
- Not approved.

a) The REB shall notify each researcher in writing of its decision regarding his/her proposed research activity. Normally the researcher will accept the proposed modification or offer a counterproposal to the Chair of the REB. This exchange is concluded normally when an ethically acceptable form for the research is agreed upon. To facilitate the continuing processing 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.

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

c) 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 researcher shall be given an opportunity to respond in writing or in person. The Chair will make himself or herself available to the applicant on a reasonable basis to endeavor to develop a proposal that will meet the ethical standards required by the REB. The REB may, at its discretion, review and reconsider its decision not to approve the research activity.

d) 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 TCPS.

3.13 Appeal: Researchers must apply in writing to the Executive Vice President, Applied Research of the College to appeal a negative REB decision based on substance or process. Appeals must be in writing and a copy of the appeal letter should also be sent to the REB Chair. The College shall use a duly constituted Appeal Committee to review decisions of the REB. The Appeal Committee will be appointed by the Executive Vice President, Applied Research and consist of at least five members, none of whom is a member of the REB. Appeal committees shall have the same constitution as the REB.

Non-compliance with the substance of the TCPS is a reason for refusing to grant an appeal. Appeals may be granted only on procedural grounds or when there is a significant disagreement over an interpretation of the TCPS. The decision of the Appeal Committee shall be binding.

4.0 – 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
- Application to Involve Human Participants in Research
- Ontario Community College Multi-Site REB Application Form
- Annual Research Study Status and End-of-Study Report Form

5.0 – History of Amendments & Reviews

Date	Activity
2008	Originally approved; replaced Policy 2-214 and associated procedures
2009	Reviewed and revised
2012	Reviewed and revised, replaced 2-216
2024	Reviewed and Updated, Procedure separated from Policy