SIR SANDFORD FLEMING COLLEGE

POLICY MANUAL

POLICY NO: 9-905 (formerly 2-216) **APPROVED:** June 25, 2008 #4 **Revised:** September 23, 2009 #3 **Revised:** April 25, 2012 #8	**APPROVED BY:** Board of Governors **SUPERCEDES:**
ETHICAL CONDUCT FOR RESEARCH INVOLVING HUMANS	

EFFECTIVE May 2012.

This document constitutes Fleming's policy and procedures for the review of ethical considerations arising from research involving humans.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS or the Policy) 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), or "the Agencies". The people of Canada, through Acts of Parliament, have created and funded the Agencies to promote and assist research within their respective legislative mandates. In discharging their mandates, the Agencies wish to promote research that is conducted according to the highest ethical standards. The Agencies have therefore adopted this Policy as a benchmark for the ethical conduct of research. As a condition of funding, the Agencies require that researchers and their institutions apply the ethical principles and the articles of this Policy and be guided by the application sections of the articles. Indeed, to be eligible to receive and administer research funds from the Agencies, institutions must agree to comply with a number of Agency policies set out as schedules to a Memorandum of Understanding (MOU) between the Agencies and institutions. Institutions must therefore ensure that research conducted under their auspices adhere to this Policy. Researchers are expected, as a condition of funding, to adhere to the TCPS. Institutions should support their efforts to do so.

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, with academic freedom comes responsibility, including the responsibility to ensure that research involving humans meets high scientific and ethical standards that respect and protect the participants. Thus, 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 REBs, 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.

Fleming, the institution and its researchers, adheres to the TCPS; subsequent to the 2010 revisions to the Policy, Fleming College has undertaken to revise its research ethics policy to ensure compliance. This document endeavors to operationalize this compliance.

DEFINITIONS

TCPS2 contains a Glossary intended to assist in the understanding of its revised Policy Statement. The following definitions have been selected from this Glossary to highlight changes in terminology from the original TCPS (1998) to its revision (2010) and for their particular salience to Fleming's research ethics policy. This abbreviated list of definitions does not intend to replace the complete Glossary.

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

Participant – An individual whose data, or 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."

A ***research ethics protocol*** is a document submitted by the applicant for consideration by the Research Ethics Board (REB). 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.

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.

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

Research Ethics Board (REB) – A body of researchers, community members, and others with specific expertise (e.g. 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.

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.

Delegated research ethics board (REB) 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 the ethics review of student course-based research which can be reviewed by delegates from the student's department, faculty, or an equivalent level.

Full research ethics board (REB) 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.

Reciprocal research ethics board (REB) 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.

FLEMING RESEARCH ETHICS REVIEW POLICY

The President of Fleming 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 Research Ethics Board (REB) shall be the sole Research Ethics Board of the College and shall apply the principles and articles set out in the TCPS "*Ethical Conduct for Research Involving Humans*" according to the procedures described in this Fleming document. These procedures may be varied to accommodate future approved amendments to the Tri-Council Policy.

Fleming 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. Fleming's REB is independent in its decision making and is accountable to the President for the process of research ethics review. Fleming College shall respect the authority delegated to the REB. Fleming 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 Fleming College - including all faculty, staff and students, including students carrying out research as part of class assignments - shall fall within the jurisdiction of Fleming College's Research Ethics Review Board (REB), irrespective of the source of financial support (if any) and irrespective of the location of the project, in the latter case, so long as the investigator represents the work as Fleming research. Projects conducted by researchers from outside the Fleming College community who access College resources (either equipment or personnel) will also fall within the jurisdiction of the Fleming College REB.

1. Requirement for Ethics Review

Except for the exemptions that follow, all research projects involving conducted at, in collaboration with or under the auspices of Fleming College require prior ethics review and approval by the Research Ethics Board (REB). This requirement of prior ethics review and approval applies to:

1.1. 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.

1.2. All research carried out on College premises or using College facilities, equipment or human, financial or material resources;

1.3. Research conducted elsewhere under the auspices of the College;

1.4. The research activities of formally affiliated organizations as a condition of affiliation; and

1.5. 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.

1.6. 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.

1.7. In addition, ethics review is required for the following categories of research that may be overlooked or raise questions about the necessity for such a review:
- Pilot studies and feasibility studies, even those involving only one human participant, require the same scrutiny as full-scale research projects involving many human participants.
- Projects that involve the secondary use of data on human participants gathered in earlier projects.
- 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).
- 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: (a) the researcher is hired on his or her own time; (b) the researcher holds no rights in the work; and (c) 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.
- All independent student research projects conducted in partial fulfillment of certificate/diploma/degree requirements. 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.

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:

2.1 Research that relies exclusively on publicly available information does not require REB review when:
(a) 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
(b) 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. In addition, research that is non-intrusive and does not involve direct interaction between the researcher and individuals through the Internet, also does not require REB review e.g. 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.

2.2. Archival analysis of records by College departments normally engaged in the collection, maintenance, and analysis of such records. Nevertheless, it is incumbent on such units to ensure that the anonymity of individuals and confidentiality of their records are maintained. (If individuals to whom the information refers have reasonable expectations of privacy then REB review is required.)

2.3 REB review is not required for research involving the observation of people in public places where:
(a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups;
(b) individuals or groups targeted for observation have no reasonable expectation of privacy; and
(c) any dissemination of research results does not allow identification of specific individuals

2.4. Class research projects which involve human subjects and which are conducted by students on other members of the class as exercises to learn how to conduct research.

2.5 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.

2.6. Preliminary, informal interviews or casual conversations that are carried out to help clarify the design of a research project.

2.7. 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 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.

2.8 Research undertaken as a teaching exercise and entailing minimal risk shall be reviewed by school or department level committee on behalf of the REB.

2.9 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.

3. Uncertainty About the Need for REB Review

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.

4. Academic Freedom

Academic freedom is "The collective freedom of faculty and students to conduct research, and to disseminate ideas or facts without religious, political, or institutional restrictions. It includes freedom of inquiry, freedom to challenge conventional thought, freedom to express one's opinion about the institution, its administration or the system in which one works, and the freedom from institutional censorship" (TCPS2, p. 189). Thus, all REBs and all persons involved in the ethics review process shall act in such a manner as to ensure that there is no infringement of the academic freedom of researchers.

5. 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 in 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.

6. Responsibilities of Researchers

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

6.1 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 be prepared to provide the REB with the full documentation of scholarly reviews already completed.

6.2. Reading and becoming thoroughly familiar with applicable ethical guidelines.

6.3. 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.

6.4. 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.

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

6.6. 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.

6.7. Obtaining free and informed consent from all prospective participants as outlined in section 7 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.

6.8 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.

6.9. 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.

6.10 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.

6.11 Researchers should be inclusive in selecting participants. 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.

6.12 Researchers should consider ways to ensure the equitable distribution of any benefits of participation in research.

6.13 Promptly 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.

6.14 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.

6.15 <u>Qualitative Research Proposals</u>

- 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.

7. Free and Informed Consent of Subjects

7.1. Consent shall be voluntary. The researcher is responsible for obtaining free and informed consent 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 TCPS2. 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.

7.1.1 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.

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

7.3. The REB may approve a consent procedure that differs from that outlined in 7.1 and 7.2 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.

7.4 Researchers shall provide prospective participants or authorized third parties with full disclosure of all information necessary for making an informed decision to participate in a research 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; and
- 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.

- 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.

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.

7.5 Capacity–refers to 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. This ability 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.

7.5.1 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.

7.5.2 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 is not 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;

- 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.

7.6 Research Ethics during Emergencies

7.6.1 *Publicly Declared Emergencies* – This section addresses research ethics review within the context of the official declaration of public emergencies. Fleming, 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.

7.6.2 *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.

8. Governance of Research Ethics Review

8.1 Responsibilities

The Fleming College Research Ethics Review Board is responsible to the President of the College for:

8.1.1 Developing policies regarding ethical issues relating to the use of humans in research and experimental teaching protocols;

8.1.2 Conducting research ethics review of all research involving humans;

8.1.3 Ensuring adherence of Fleming's research ethics policy with the most current version of the TCPS;

8.1.4 Dealing with matters concerned with research involving humans referred to the REB by the President of the College;

8.1.5 Preparing an annual report for submission to the President, as outlined in Section 12 of this policy;

8.1.6 Ensuring REB members participate in initial and ongoing training relevant to their responsibilities and duties to the REB.

8.1.7 Annually reviewing REB membership and overseeing nominations process and appointments and renewals of REB members.

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."*

8.2 Composition of the Board

Basic REB Membership Requirements – Fleming 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.

Selection of REB Members – The selection of REB members, including the Chair, should be fair and impartial in accordance with Fleming'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.

REB Size – Fleming may determine the size of its REB which will vary in accordance to institutional needs. In accordance with the TCPS, Fleming'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 non-voting 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.

To ensure the independence of REB decision making, Fleming senior administrators 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, Fleming may appoint them as non-voting members.

Substitute membership – Fleming 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.

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.

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).

REB Chair – is responsible for ensuring that the REB review process conforms to the requirements of the TCPS2. The Chair provides overall leadership for the REB and to facilitate 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 his or her designate. Fleming shall provide the necessary resources and adequate administrative support to enable the REB chair to fulfill his or her responsibilities.

8.3 Quorum

Quorum rules must meet the minimum requirements of membership. As long as Fleming'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.

8.4 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 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.

8.5 On-going Training

Fleming 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, Fleming'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.

PROCEDURAL GUIDELINES FOR THE REVIEW OF A RESEARCH PROPOSAL

1. Submission

While it is not essential for the REB to review a research proposal before it is submitted to a funding agency, it is expected that the review process will be in-process at the time of funding application. REB approval however must be obtained before the research begins. Visiting researchers should contact the chair of the Fleming College Research Ethics Board well in advance of the anticipated start date of research. Submissions for review should be submitted to the REB using the appropriate forms and by following the instructions on that form. Prospective applicants may approach the REB chair or any REB member for assistance in selecting the appropriate forms for submission.

2. Scholarly Review

2.1 In case of research proposals that present more than minimal risk, the design of the project must be peer reviewed to assure that it is capable of addressing the question(s) being asked in the research. Sufficient peer review may be considered to 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.

2.2 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.

2.3 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 TCPS2; 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).

2.4 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 through the use of 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.

2.5 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. 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).

4. Normal Review Process

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

4.2 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.

4.3 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.

4.4 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.

4.5 It is the responsibility of the researcher to address all the recommendations made by the REB and keep the file complete and up-to-date at all times. When the research project is finished, and the researcher(s) notifies the REB, these files shall be "closed" and 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 Fleming College and cannot be removed from their secure location by the researchers. These files shall be subject to audit by authorized representatives of Fleming College (research administrators), members of Appeal Boards, and funding agencies. The REB file on applications for ethical review should contain the following documents:

- Application 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 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.

5. Delegated Review

Delegated review does not require face-to-face 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 review 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 Fleming 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.

6. 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.

7. 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 research ethics boards (REBs).

7.1 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.

Fleming's REB, with permission from the President, may approve alternative review models for research involving multiple REBs and/or institutions, in accordance with the TCPS2. REB review models may include 1) Independent Ethics Review by Several REBs, 2) Research Ethics Review Delegated to an External, Specialized or Multi-Institutional REB, and 3) 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.

7.2 Ethics of Research Conducted Outside the Institution
Where research conducted under the auspices of Fleming 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.

8. Continuing Ethics Review

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 Ethics approval. The rigor of continuing ethics review will be subject to

the appropriate review process as determined by the principle of proportionate review outlined in Section 3 of the Procedural Guidelines for the Review of a Research Proposal.

8.1 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.

8.2 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 will be 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.

8.3 The researcher shall promptly notify the REB when the project concludes.

9. 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.

10. 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.

10.1 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 counter-proposal 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.

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

10.3 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 to not approve the research activity.

10.4 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.

11. Appeal

Researchers must apply in writing to the President of Fleming 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. Fleming College shall use a duly constituted Appeal Committee to review decisions of the REB. The Appeal Committee will be appointed by the President 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.

12. Reports of Research Ethic Board Committee Decisions

An annual activity report from the REB will be submitted to the President of Fleming College, the Executive Leaders Team, and the Academic Leaders Team.

13. 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.

14. Administration

14.1 Administrative Support

The work involved in the ethical review process should be distributed appropriately among faculty members, staff, researchers, and administrators. Fleming 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.

Deans will 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.

Individual departments are expected to 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.

14.2 College Support

Fleming College supports the administrative processes and educational activities required by the REB so that the College as a whole remains in compliance with TCPS.

14.3 Reporting of Non-Compliance

The REB role is limited to reporting cases of failure to comply with the provisions of the TCPS and Fleming College research policies to the President.

14.4 Interpretation

Questions of interpretation or application of this policy or its procedures shall be referred to the President or designate whose decision shall be final.

15. Forms

Ethical Guidelines and the required forms for submission to the REB will be made available from the administrative assistant to the REB.