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1. Introduction

Durham College is committed to advancing and safeguarding high-quality academic and ethical standards in all its activities. It is understood that research often entails risks that can be trivial or profound, physical or psychological, individual or social. Establishing research ethical standards involves identifying, promoting and adopting a clearly understood set of principles and procedures that will guide the actions of researchers, and which the Research Ethics Board (REB) can use to judge the ethical merit of a given research study involving humans. Attention to the ethical and legal implications of research is an accepted and inherent part of good research practice. Research will be conducted at Durham College in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 2014 (TCPS2 (2014)).

2. Purpose

Durham College supports research that consistently meets the highest ethical standards. Research, at times, requires collaboration between human participants and researchers and may require active involvement of participants. Therefore, the interests of both researchers and participants are central to the research and there is an overriding premise that participants must not be treated simply as objects or a means to an end. It also requires that researchers conduct their research studies with accuracy, candour, objectivity and sensitivity.

The purpose of this policy and procedure is to articulate the principles and framework underlying the establishment of the REB as well as the methodology for reviewing the ethical acceptability of research proposals. This document ensures the preservation of human dignity and respect when humans are involved in research activities. Research conducted under the auspices of the College will be in accordance with the policy and procedures developed to ensure proper ethical review and accountability.

3. Definitions

Refer to [Durham College's Standard Definitions](#).

4. Policy statements

4.1. Respect for human dignity

Respect for human dignity is an underlying value in research ethics and as such, research is conducted in a manner that is sensitive to the inherent worth of all human beings and safeguards their interests. Research that benefits society and advances knowledge will be guided by the following three complementary and interdependent core principles of conduct as set out in the TCPS2 (2014):

4.1.1. Respect for Persons

Respect for Persons recognizes the intrinsic value of human beings and respects their ability to deliberate about a decision and to give due deference to a person's judgment.

- a) Respect free, informed and ongoing consent – complete disclosure of the nature of the research so the individual can provide a free and informed consent with respect to their participation.
- b) Respect vulnerable persons – high ethical obligations and special protection against abuse, exploitation or discrimination towards vulnerable persons whose capacity to make informed decisions is diminished.

4.1.2. Concern for Welfare

Concern for Welfare is caring about the quality of a person's experience of life in all aspects.

- a) Respect privacy and confidentiality – protecting access, control and dissemination of personal information to ensure confidentiality and anonymity unless there is consent to disclose.
- b) Protection from harm – there is a duty to ensure participants are not exposed to unnecessary risks and to avoid, prevent or minimize harm to research participants.

4.1.3. Justice

Justice is the obligation to treat people fairly and equitably.

- a) Fairness entails treating all people with equal respect and concern. That the ethics review process ensures no segment of the population will be unfairly burdened with the harm of research. Nor will there be any neglect or discrimination against individuals or a group that may benefit from the research.

- b) Vulnerable or marginalized people may need to be afforded special attention in order to be treated justly in research.

Researchers must strive to achieve an appropriate balance between potential harms and benefits. Harm should not outweigh the anticipated benefits. Researchers must also strive to maximize benefits to the participants and society as a whole by providing access to the research findings.

4.2. Freedom of inquiry

To maximize the benefits of research, researchers will have the freedom of inquiry and the right to disseminate the results of that inquiry, freedom to challenge conventional thought, and freedom from institutional censorship.

4.3. Research Ethics Board

- 4.3.1. Durham College will establish and maintain one REB to provide ethical review and approval of research involving humans, prior to the start of the research. Policies specific to the REB are identified below.
- 4.3.2. While it is not necessary for the REB to review a research proposal before it is submitted to a funding agency, REB approval must be obtained prior to commencing the research.
- 4.3.3. The REB shall function impartially, provide a fair hearing to those involved, and provide reasoned and appropriately documented opinions and decisions of its review of the research.
- 4.3.4. The REB shall use a proportionate approach to ethics assessment. As a preliminary step, the REB determines the level of review based on the level of risk presented by the research. The lower the level of risk, the lower the level of scrutiny (Delegated Review); the higher the level of risk, the higher the level of scrutiny (Full Board Review) which is also the default review. The REB will review the application by assessing the character, magnitude and probability of potential harms of the research from the view of the human participant.

4.4. Aboriginal research

Aboriginal research will respect the distinct world views of the First Nations, Inuit and Métis peoples and ensure they are represented in planning and decision-making from the earliest stages of project design through to analysis and dissemination of results.

4.5. Safeguards

There will be appropriate safeguards on research information that respects the privacy of participants and supports researchers in fulfilling their confidentiality obligations.

4.6. Appeals

Durham College will maintain an appeal mechanism in cases where the principal investigator and REB cannot reach agreement through discussion and reconsideration.

4.7. Research Ethics Board

4.7.1. Purpose

The REB is accountable to the President of Durham College and is vested with the authority to review and make a decision as to whether to approve, reject or recommend modifications to any proposed and ongoing research involving human participants that is conducted at Durham College. The REB will also monitor all research involving human participants through notices of change to research protocol, annual renewal of research projects and notices of research completion. It will suspend or terminate ongoing research that does not comply with this policy and with the TCPS2 (2014).

4.7.2. Independence

The REB shall make decisions independently and be accountable for the process of ethics review as identified in the Durham College Ethical Conduct for Research Involving Humans Policy and Procedure. In order to maintain its decision-making independence and operate at arm's length from administrative and programmatic research structures, the REB shall be provided with appropriate administrative and financial resources and will be supported by the Office of Research Services, Innovation and Entrepreneurship (ORSIE). Senior administrators may not attend REB meetings as they may be perceived as unduly influencing REB deliberations and decisions. The REB must have independence to conduct ethics reviews, free of inappropriate influence, including situations of real, potential or perceived conflict of interests.

4.7.3. Composition of the board

4.7.3.1 The membership requirements are designed to ensure the board has the necessary basic background, expertise, perspectives and independence to conduct an informed independent reflection and a competent research ethics review. The REB shall consist of at least five members of whom:

- a) At least two have broad expertise in the methods or areas of scientific methodology and research;
- b) At least one is knowledgeable in ethics to assist with ethical issues and options;
- c) At least one is from the community and has no affiliation to Durham College. This will broaden the perspective and value base of the board; and
- d) At least one knowledgeable in relevant law so the member can alert the board to possible legal issues and their implications. The member must not be the College's legal counsel.

4.7.3.2 Although an REB member may be qualified to fulfill more than one of the above roles, the individual may fulfill only one designated role during the term of appointment.

4.7.3.3 In addition to the above, the REB will have adequate gender representation and may be expanded to include a representative with legal expertise in biomedicine, if required, to specifically provide insight into biomedical research issues. Should additional representation be added to the board for the purpose of an adequate and thorough review, the community representation will also be increased to maintain a 20 per cent representation on the board, based on the TCPS2 (2014). Where possible, former research participants will be appointed to the REB to provide an experiential perspective.

4.7.3.4 Ad hoc appointments by the REB chair may be made to provide specific expertise and knowledge not present on the REB. However these appointees do not have voting privilege nor can they be counted to establish quorum.

- 4.7.3.5 Members for the REB will be selected based on the following criteria:
- a) Main responsibility is in teaching or research (with the exception of the community member);
 - b) Commitment to ethics and willingness to expand knowledge;
 - c) Regular attendance at meetings and able to contribute to sound decisions;
 - d) Adherence to ethical practice in research;
 - e) Desire to foster ethical research practice within the College; and
 - f) Adherence to College policies and procedures.
- 4.7.3.6 Records related to REB membership, qualifications, and research ethics training will be maintained by ORSIE for a period of seven years.

4.7.4. Terms

Members of the REB will be nominated by the vice-president, Academic and appointed by the president for a period of up to three (3) years, renewable with staggered appointments of no more than one-third being replaced each year to maintain continuity. New members will receive orientation and training on ethics review including the principles, policies, legal and regulatory requirements to understand their role and responsibility on the REB.

4.7.5. Meetings

- 4.7.5.1 Meetings will normally be held monthly from September to June, and at least three times per academic year as required to review research applications. The REB shall normally meet face-to-face to review proposed research that is not assigned to delegated review, for adequate discussion and decision-making. In the event that an REB member cannot attend in person, the member may attend by teleconference or video conference, if the REB chair agrees and if the appropriate technology exists in the meeting room. A meeting schedule will be publicly available.
- 4.7.5.2 A quorum for a full board review shall consist of at least five (5) members who reflect the range of backgrounds and expertise required for the specific protocols under review at the meeting. The community member and the legal member must be present at each meeting at which full board reviews will take place.

4.7.5.3 Protocols will only be approved if sufficient and appropriate expertise is available at the meeting.

4.7.5.4 At least two meetings per year will include administrative matters, with the dean, Research Services attending the administrative portion of the agenda.

4.7.6. Conflict of Interest

Members of the REB must disclose any real or apparent conflict of interest regarding a proposal under review. They may explain the conflict of interest and offer evidence to the REB and the proposer of the research who has the right to hear the evidence and offer a rebuttal. The REB member may not be present for the discussion where there is the perception the member has a vested interest and the member may not participate in the decision process.

4.7.7. Decision-making

Each REB member will make a decision based only on the ethical acceptability of the research, as defined by the TCPS2 (2014). For full board reviews, REB members will normally make decisions on each application by consensus. In cases where one or more members have concerns, the REB will work together to identify needed revisions that will make a project ethically acceptable. The REB chair may consult with the dean, Research Services, other REB chairs, or the Secretariat on Responsible Conduct of Research. If disagreement persists, the majority position will stand.

4.7.8. Professional Development

REB members will have regular opportunities to participate in professional development, including events hosted by the national association, that address identified needs of the REB. In addition, ORSIE will periodically arrange for guest speakers, training, TCPS2 (2014) case studies or interpretations, or other similar opportunities that enhance the effectiveness of the REB.

4.8. Scope

4.8.1. All research conducted under the auspices of Durham College that involves human participants must be approved in writing by the REB, prior to beginning such research. The College does not currently engage in any research involving human biological materials from living and deceased individuals, nor fetal tissue, embryos, fetuses, reproductive materials or stem cells. In the event that research of this nature is undertaken, written approval of the REB will be obtained.

4.8.2. All College employees involved in research involving humans must ensure that they are familiar with the principles in this policy and

incorporate these principles into the research design and implementation of the project.

- 4.8.3. Research on public policy issues, modern history, or creative practice activities does not require an REB review unless the participant is to be approached directly for interviews or private papers are to be accessed.

5. Procedure

5.1. Research requiring a review

5.1.1. All research projects under the auspices of the College involving human participants, regardless of where the research is conducted or funding source, requires a review by and approval from the REB prior to the start of the research. It can include a range of research activities such as:

- Information collected through intervention or interaction e.g. individual interviews or focus groups, surveys and questionnaires;
- Information collected through naturalistic observation of humans;
- Data formally collected from any person in the College community or from any database containing their information;
- Physiological or educational testing derived from individually identifiable human participants.

- 5.1.2. Research under the auspices of Durham College includes the following:
- Research conducted by a Durham College employee, full-time or part-time, where the employee is a principal investigator, co-investigator, or collaborator, and the employee's affiliation with Durham College is explicit in the research plan, regardless of where the research is conducted;
 - Research conducted by a researcher not affiliated with Durham College that involves Durham College students or employees as human participants, where the students' or employees' affiliation with Durham College is explicit in the research plan, regardless of where the research is conducted;
 - Research conducted by a researcher not affiliated with Durham College that involves the use of Durham College resources, including but not limited to space, class time, email distribution lists, controlled bulletin boards, internet services, computers, assistance or collaboration from staff, and the like; and
 - Research conducted by Durham College students to fulfill course requirements.
- 5.1.3. A Durham College employee who is undertaking graduate studies at the Masters or PhD level and who plans to utilize Durham College resources (eg, for recruitment or data collection) may submit an application as a principal investigator when the research is conducted to fulfill the degree requirements, and the faculty supervisor will be listed as co- investigator. In these cases, the Durham College employee must obtain REB approval from the university at which he or she is studying prior to seeking approval from the Durham College REB. In cases where this procedure is in conflict with the university's procedure, the REB will work with the researcher to establish a mutually agreeable solution for both REBs.
- 5.1.4. Whether the researcher is internal or external, the REB reserves the right to request information that demonstrates that the researcher or another member of the research team possesses the qualifications necessary to execute the research plan.
- 5.1.5. Research conducted by an external researcher who uses publicly available information or resources to recruit Durham College employees or students is not considered under the auspices of Durham College.

- 5.1.6. Research involving Durham College employees or students that is not connected in any way to their affiliation with the College and does not involve College resources is not considered under the auspices of Durham College.
- 5.1.7. Research conducted under the auspices of the College performed in whole or in part outside of Canada shall undergo a research ethics review by the REB and by a responsible review body at the research site. Information on permissions and ethics review requirements/approvals or efforts to identify suitable review mechanisms shall be provided to the REB.
- 5.2. Research exempt or not normally requiring a review by the REB
- 5.2.1. Research exempt or not normally requiring a review by the REB includes research involving:
- a) Quality assurance studies assessing the performance of the College; staff performance reviews; nationally or provincially mandated studies such as key performance indicators; primary data collection designed and administered by the College to facilitate the management of the institution (e.g. for review and renewal of programs); or testing done within normal education requirements;
 - b) Research based exclusively on secondary use of anonymous information or anonymous biological materials that does not generate identifiable information, including publicly available information, documents, records, works, performances, archival materials or third-party interviews;
 - c) Information that is legally accessible to the public and appropriately protected by law or when the information is publicly accessible and there is no reasonable expectation of privacy.
 - d) Naturalistic observation of participants where:
 - There is no direct interaction or intervention staged by the researcher
 - There is no reasonable expectation of privacy; and
 - Any dissemination of research results does not allow for identification of individuals.
 - e) Practicums, field placements or on-the-job training where students are integrated into an organization for the purposes of learning and development of competencies;

- f) Class projects or student information gathering activities which are either not classified as research or where the research is conducted by students on other members of the class as an exercise on learning how to conduct research. These activities are part of the learning compendium for the purpose of skill development and could include:
- Conducting interviews, administering standard tests or collecting information to provide advice, diagnosis or as the basis for intervention for a client;
 - Development of a competency to learn a professional standard of practice;
 - Conducting projects where students pose questions, gather data and analyze the results; and
 - Information exchange as part of the relationship between students and participants (e.g. student and teacher, health professional and client).

5.2.2. If these activities are used for the purposes of research as defined by the TCPS2 (2014), they may be considered course- based research (see below for further information).

5.2.3. Where there is uncertainty about whether or not the research requires a review, the principal investigator will request a written opinion from the REB Chair as to the need for an ethics review and approval. If the researcher identifies the activity as research, the REB will conduct an ethical review.

5.3. Institutional permission

5.3.1. All researchers, whether internal or external to Durham College, planning to conduct research involving human participants and wishing to access Durham College faculty, staff, students, or resources, must first obtain institutional permission to conduct the research before applying for ethical approval from the REB. Institutional permission is intended to ensure that the research does not unreasonably interfere with Durham College operations. Permission may or may not be granted on the basis of the project's costs, effort, risk, impact on members of the College, and/or impact on institutional resources. Research ethics approval does not constitute institutional permission.

5.3.2. External researchers seeking access to Durham College faculty, staff, students, or resources must seek institutional permission from the vice- president, Academic or other vice-president (VP) or the chief administrative officer (CAO) as appropriate. The *External Researcher's Institutional Permission Request Form* will provide an overview of the intended research and information on the specific resources required.

- 5.3.3. The researcher will submit this form to the REB along with the complete ethics application, and the finance and ethics compliance coordinator will coordinate with the Office of the VPA, or other VP or CAO as appropriate, on behalf of the researcher to facilitate the institutional permission process, prior to the ethical review of the REB application. The Office of the VPA or other VP or CAO will consult with the affected executive dean(s) and/or director(s)/executive directors as necessary.
- 5.3.4. Durham College researchers seeking access to Durham College faculty, staff, students, or resources that are limited to one department or school only, may seek administrative permission from the executive dean or director/executive director responsible for the school or department. The researcher must complete the *Internal Researcher's Institutional Permission Request Form*, providing an overview of the intended research and information on the specific resources required. The form must be approved before the ethical review is conducted.
- 5.3.5. Durham College researchers seeking access to Durham College faculty, staff, students, or resources in multiple departments and/or schools, must seek institutional permission from the executive deans and/or directors/executive directors responsible for the schools and/or departments in addition to the vice-president, Academic or other VP or CAO as appropriate. The researcher must complete the *Internal Researcher's Institutional Permission Request Form*, providing an overview of the intended research and information on the specific resources required. The form must be approved before the ethical review is conducted.
- 5.3.6. If the research involves participation by senior executives of Durham College, permission may be required from the President.
- 5.3.7. If approved, Durham College researchers must include the approved *Internal Researcher's Institutional Permission Request Form* with the REB application.
- 5.4. Application for ethical approval
 - 5.4.1. Research projects involving human participants must be submitted on a completed *Application for Ethical Review Involving Human Participants* form prior to the start of recruitment of participants or access to data.
 - 5.4.2. Researchers may contact the Office of Research Services, Innovation, and Entrepreneurship (ORSIE) or the REB chair for assistance in the process. Meetings between the REB chair and researcher may occur to clarify aspects of the application or to expedite the process but shall not substitute for the formal review process.

5.4.3. The REB review will be based upon fully detailed submissions that will include:

5.4.4. Application for Ethical Review of Research Involving Human Participants:

- Description of the research;
- Methodology; and
- Individuals/ population required for the investigation.

5.4.5. Risk management:

- Analysis of direct and indirect risks to human participants;
- Plans to eliminate or minimize risk and provisions to remedy any harm;
- Benefits must outweigh the risks inherent in the project; and
- All foreseeable risk factors are presented to the participant prior to consent.

5.4.6. Collection and confidentiality of data:

- The type of data to be collected and the purpose for which it will be used;
- Methods of data collection and observation e.g. cameras, tape recorders that may only be used after consent has been obtained;
- Modes of observation or access to information that allows for identification of particular participants within the strict limits of the terms of consent;
- Preservation of the participant's anonymity unless otherwise expressly consented;
- Consequences of the proposed use of institutional records and potential invasion of privacy without individual's consent of their record;
- Appropriate safeguards for security and confidentiality of data for the full life cycle of the research; from its collection, use, dissemination, retention and/or disposal ;
- Anticipated linkage of data gathered in the research with other data about participants;

- Secondary uses of data which will not normally include access to personal identifiers; and
- Limits on the use, disclosure and retention of the data.

5.4.7. Conflict of interest disclosure:

- The likelihood or perception that the researcher may be influenced by private or personal interests; and
- Whether the trust relationship between researcher and participants could reasonably be maintained if they had accurate information on the potential sources of conflict of interest;
- Correspondence including any comments from the public;
- Relevant documents, including survey instruments, focus group questions, recruitment materials, information letters, and consent forms;
- Ethical certificates, such as a Certificate of Completion for the Tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 (2014)) for all members of the research team;
- Letter confirming institutional permission to conduct the research;
- Revised materials, if requested by the REB or other REBs that have approved the research;
- If required, a separate peer review of the research on the scholarly merit of the project from a subject matter expert or ad hoc committee that is arm's-length from the project under review. In evaluating the scholarly merit, it should not be rejected on the basis of controversy or that it challenges mainstream thought. Research in the humanities and social sciences that pose minimal risk at most is not normally required by the REB to be peer reviewed; and
- If required, the necessity and justification of withholding or misrepresenting significant facts (deception) when informing the participant about the research, must include an explanation:
 - Of reasons for the deception or concealment and the effectiveness to the project;

- That no other alternative investigative methods will produce the same results;
- That the deception must extend to all the elements as proposed;
- That the deception will not invalidate any aspects of informed consent that would influence the participant's willingness to participate and will not risk their dignity or self-esteem;
- The waived or altered consent does not adversely affect the rights and welfare of the participant and does not involve a therapeutic intervention; and
- That full disclosure will be provided upon completion of the project.
- Durham College recognizes there is a range of risk to human participants associated with research and the proportionate approach to research ethics assessment is categorized into two levels of review:
 - Full board review (default);
 - Delegated review by the REB chair or subgroup of the REB.

5.4.8. At either level of review, consideration is given to the foreseeable risks, the potential benefits and the ethical implications of the research.

5.5. Full board review

- 5.5.1. When a completed application with a detailed protocol has been submitted, or where applicable, a progress report has been brought forward, the REB chair will convene a meeting of the REB to review the submitted documentation. Research proposals will be sent to the members of the REB at least 10 business days in advance of the meeting.
- 5.5.2. The REB may invite researchers to be available to participate in the discussion about their proposals during the REB meeting. However, if a researcher participates in the discussion, the REB will function impartially and hold a full discussion, without the researcher present when reaching a decision. In addition, if there are follow-up questions or concerns raised by the REB, the principal investigator will address them, either in person or in writing, at the discretion of the REB.

5.5.3. Under most circumstances, applications will be reviewed within 30 business days from receipt of the application, with the exception of the summer months in which the REB does not normally meet. The REB will deliver its decision and reasons on the research application in one of the following categories:

- Approval as submitted;
- Approval pending modifications and/or clarifications;
- Deferral;
- Disapproval.

5.5.4. Applicants will receive a response, which may be in the form of questions, from the REB within 10 business days of the meeting. Requests for modifications will be explained and once the application is revised, it will be reviewed by the REB chair. If REB requirements have been met, approval will be granted. Decisions will be provided in writing, including the reason for the decision if required. When considering a negative decision, the REB will provide the principal investigator with reasons and give the researcher an opportunity to reply before making a final decision

5.6. Delegated review

5.6.1. The REB chair will review all applications to assess the level of risk of harm to the human participant. If the proposed research is deemed to pose no greater than “minimal risk” to the research participants (i.e. where the probable level of risk is reasonably anticipated to be no greater than what the participants may encounter in everyday life), doesn’t involve vulnerable populations, sensitive information (e.g. legal, social or employability risk) or physical or psychological invasive procedures and raises no other substantive ethical concerns, then the proposal may be referred to delegated REB review. If it does not meet the criteria for a delegated review then it is referred to the REB for a full board review.

5.6.2. The REB can delegate the review of the submission to two individuals who have appropriate expertise, one of whom is normally the REB chair. After completing the review, they will provide a written assessment on whether or not there are additional risk factors in the research that constitute greater than minimal risk. If one or both reviewers determine the risk is greater than minimal, the ethics submission will be referred to the REB for a full board review. Submissions that meet the minimal risk criterion and comply with ethical standards, or which require only minor modifications and are subsequently revised, the REB chair may approve on behalf of the REB.

5.6.3. Any delegated reviews and the results are reported by the REB chair to other members of the REB at the subsequent full board meeting. This permits REB members to continue their responsibility and maintain surveillance over decisions made on their behalf.

5.7. Ethical review for research with prior REB approval

If a researcher has obtained prior research ethics approval at another institution and the study is considered minimal risk, the REB chair has the option of conducting a delegated review. In this case, the researcher may submit the research ethics application form along with all supporting documents that were sent to the principal REB, as well as the approval certificate. However, the REB may require additional information that is not included in the original package before approving the study.

5.8. Reconsideration

Principal investigators have the right to request reconsideration of decisions affecting a research protocol. If the REB does not approve the submission based on ethical reasons of the research activity or if the REB imposes conditions that compromise the research, the principal investigator will be given an opportunity to refute the reasons in writing or in person and the REB has an obligation to reconsider its decision.

5.9. Appeals

5.9.1. If the principal investigator and REB cannot reach agreement through discussion and reconsideration, the principal investigator may request an appeal in writing to the REB chair within 30 business days. The appeal process is not a substitute for the REB, nor is it a forum to merely seek a second opinion.

5.9.2. Grounds for an appeal include any alleged breaches to the established research ethics review process or any element of the REB decision that is not supported by the TCPS2 (2014). The onus is on the researcher to justify the grounds on which he or she requests an appeal and to indicate any breaches of review process.

5.9.3. Upon granting an appeal, the REB chair, with assistance from the dean, Research Services as necessary, will make arrangements with another REB that possesses sufficient experience and expertise to deal with the issues involved in the specific protocol under appeal. Once the appeal REB accepts this role, the finance and ethics compliance coordinator will forward the application and related documentation to the appeal REB within 20 business days of receiving the request for an appeal. Both the researcher and a representative of the REB will be granted the opportunity to address the appeal REB but shall not be present when the appeal REB deliberates. The appeal REB shall review the submission in a fair and impartial manner and render a final, binding decision by:

- Confirming the original REB decision;
- Modifying the decision;
- Imposing specific conditions for approval; or
- Reversing the decision.

5.9.4. The principal investigator and REB will be notified in writing, with reasons, in accordance with the appeal REB's normal operating procedures.

5.10. Multi-jurisdictional research

5.10.1. The globalization of research and increasing number of collaborations among researchers from multiple institutions or countries may result in different arrangements, such as a review by REBs at other institutions or a review by external or independent REBs. There are a range of models for alternate research ethics review. However the ultimate responsibility for ethical acceptability and conduct of research and decision regarding alternate models rests with the principal REB.

5.10.2. To provide flexibility and efficiency and avoid unnecessary duplication of review, without compromising the integrity of ethical conduct for the participants, the TCPS2 (2014) allows for the following models:

- a) Independent ethics review by all participating institutions who then provide their separate decisions either concurrently or sequentially;
- b) Delegation of the research ethics review to a single joint REB or an external REB based on geographical proximity, resources or shared expertise and formalized through an agreement; or
- c) A reciprocal REB review whereby multiple institutions enter into agreement under which they accept the research ethics review of each other's REBs.

5.11. Ontario Community College Multi-site Research – Ethical Review

Durham College is a participant in the Ontario Community College Multi-site Research Ethics Common Application Form process. This form is for researchers who are planning to conduct research at more than one college in Ontario. The researcher completes one common application form rather than a separate form for each College. The researcher submits this common application form to each college where the application undergoes independent ethics review by each REB. It is the researcher's responsibility to contact the research ethics coordinator at each site to determine specific submission requirements. In the case of external researchers applying to the DC REB, the institutional permission procedure (section 4.3) is required, and external researchers must submit a completed *External Researcher's Institutional Permission Request Form*, along with the *Multi-site Research Ethics Common Application Form*.

5.12. Ethics review for student course-based research

5.12.1. Course-based research is defined as minimal risk research that occurs within the context of a specific course offering, and involves an assigned research activity. The research activity must meet the TCPS2 (2014) definition of research: an undertaking to extend knowledge through a disciplined inquiry or systematic investigation. In other words, research must be the intended purpose. However, to qualify as course-based research, the research cannot be an extension of the faculty member's research; it must be minimal risk; and it cannot involve the collection of data which will subsequently be used towards the completion of a Masters or PhD degree. Faculty may consult with the REB chair to confirm whether a specific activity meets the definition of course-based research. If a student research project does not meet the criteria for consideration as course-based research, the research must be reviewed by the REB.

5.12.2. Specific procedures have been established for the review and approval of course-based research:

- a) The REB will delegate research ethics review to a faculty member who is deemed faculty supervisor (FS) for purposes of the course-based research, and who is responsible for supervising students conducting course-based research projects involving humans. If more than one faculty member teaches the same course, one faculty member is identified as FS for all sections of the course.

- b) Prior to the REB delegating research ethics review to the FS, the FS must:
- Complete the Tri-Council online tutorial Course on Research Ethics (CORE) and submit the Certificate of Completion to the REB; and
 - Complete and sign a *Request for Ethical Approval of Course Based Student Research Projects – Form A* accompanied by the course outline and submit it to the REB;
- c) The REB must review and approve the course-based research project before the project can proceed;
- d) Upon REB approval, each faculty member involved in the course will have their students complete a *Student Application to Involve Human Participants in Research – Form B* for each separate research project for the course;
- e) In the consent form, the information letter, or the script for oral consent, whichever is used by the students, the following statement is to be inserted: *This project is an opportunity to give students experience in doing research; it is a training and teaching exercise. Please note that if you decide not to participate or decide to withdraw from the study at any time, my grade, as a student researcher in the course will not be affected;*
- f) Copies of all students' forms and accompanying materials must be sent to FS for review once the course is complete. The FS is responsible for submitting these forms to the REB at the conclusion of the course;
- g) It is the responsibility of the FS to submit an *Annual Review Form* to the REB;
- h) If changes are made to a class project, the FS must complete a *Change Request* form and submit it to the REB. All sections of the course, whether on campus or not, must follow the procedures and all faculty members must ensure compliance with these policies.

5.12.3. Individual schools are expected to support and train students so that individual student research projects are ethical and may be efficiently reviewed by the FS.

5.13. Ongoing reporting requirements

5.13.1. In accordance with a proportionate approach to ethics review, the REB will make the final determination as to the nature and frequency of the continuing ethics review. At a minimum, an annual status report with sufficient details to make a judgment about the ethical acceptability of the research will be submitted to the REB chair. However, reports may be requested at shorter intervals and/or additional requirements may be imposed depending on the risks and probability of harm. If research that is expected to be completed within one year continues, the principal investigator must submit a request for an extension prior to the expiration of the current approval. Researchers will fulfill these requirements by completing the *Change Request and/or Study Renewal Form* and submitting it to the REB. Where there has been little or no change to the protocol, a delegated review may be considered.

5.13.2. Any unanticipated issues or adverse effects suffered by the participants are to be reported immediately to the REB by the principal investigator and resolved within seven (7) business days of their occurrence. The researcher will complete the *Unanticipated Issues Reporting Form* and submit it to the REB. This report will enable the REB to better protect research participants in future research projects. Depending on the nature of the event or issue, the REB may require adjustments to the protocol to prevent a reoccurrence.

5.13.3. Contemplated changes to the research protocol must be submitted to the REB through the completion of a *Change Request and/or Study Renewal Form* with an explanation and are subject to an ethics review before the changes are implemented. The only exception is when changes are necessary to eliminate an immediate hazard to the research participants. The rigour of the review will be in accordance with proportionate approach. The REB chair has the discretion to refer the matter for the opinion of the REB if the change is substantial or to approve it on his/her own authority. The REB has the authority to terminate an approved research protocol that deviates and no longer complies with the policy. Upon completion of a project, the researcher is to complete a *Study Completion Form* on or before the expiry date noted on the Approval Letter. For purposes of research ethics, a project is considered completed when there is no further participant involvement at the site, all new data collection is complete, and the sponsor closeout activities, if applicable, have been completed. Once this form has been processed, the research ethics file will be closed and no additional procedures or data collection may take place.

5.14. Records

All documentation submitted for review and minutes of all REB meetings will clearly record the decisions, any dissents and the reasons for them and be kept in a file. Plans for continuing ethics review, timelines and any conditions or limitations attached to the approval will also be documented. A “closed” file will be maintained in a secure location in ORSIE for a period of seven years as a record to demonstrate compliance with the policy. The files will remain the property of Durham College, subject to audit by authorized representatives of the College, members of appeals boards and funding agencies.

5.15. Informed consent procedure

An important mechanism for respecting participants’ autonomy in research is the requirement to seek their free, informed and ongoing consent. This requirement reflects the commitment that participation in research is according to their values, preferences and wishes. Participation through the use of one’s data, or biological materials, should be a matter of choice and that, to be meaningful, the choice must be informed. An informed choice is one that is based on as complete an understanding as is reasonably possible of the purpose of the research, what it entails, its risks and potential benefits, both to the participant and to others.

Therefore, research may only proceed if the following requirements are met:

5.15.1. Requirements for research to proceed

- Potential participants have voluntarily and freely agreed to participate in the research study on the basis of well understood information about the objectives of the research and the nature of their participation; and
- Their consent is maintained throughout the duration of their participation in the research.

5.16. Competent human participants

Once REB approval has been granted for a research protocol, potential participants or authorized third parties must be fully informed about the nature of the research in a clear and transparent manner and become part of a dialogue before being invited to participate in the study. Participants are given the opportunity to discuss and reflect on their participation prior to giving free and informed consent once they understand the following:

- 5.16.1. The purpose of the research, the identity of the principal investigator and research team members, and the contact information for a person in the event there are concerns or complaints;
- 5.16.2. How they will be asked to participate, the duration of the study, how much time will be required, responsibilities and how they will be selected (e.g. if randomized, the probability of participant selection);
- 5.16.3. Full disclosure of any actual or perceived conflicts of interest on the part of the principal investigator or Durham College and any potential for commercialization of the research;
- 5.16.4. Whenever possible and appropriate, additional information such as incidental findings discovered in the course of the research or any changes to the research project that may affect them will be provided; and
- 5.16.5. Information on any costs, payment reimbursement for expenses or compensation.

5.17. Risks and benefits

The potential risks and benefits that may arise from participation in the research include any consequences of non-action, treatment or where there is a potential for physical, psychological or social impacts.

5.18. Voluntariness

- 5.18.1. Participation must be strictly voluntary and no coercion or undue influence such as physical duress, fraudulent misrepresentation, exercise of control, or abuse of power relationships will be used to gain acceptance.
- 5.18.2. Withdrawal of consent is allowed at any time, without explanation or penalty, and none of the data or biological materials previously collected will be included in the research findings. The consent form is to set out any circumstances that do not allow a withdrawal of data or biological materials once collected.

5.19. Confidentiality

- 5.19.1. Confidentiality must be strictly maintained and no identifiers are to be disseminated in any of the findings.
- 5.19.2. All research findings will be kept secure, accessible only to the research team, and will be destroyed within a reasonable time frame.
- 5.19.3. The researcher is expected to inform research participants on the ways in which the outcomes of the research will be published, how participants will be informed of the results, and what opportunities will be provided for their feedback at the end of their participation.

5.20. Documentation of consent

- 5.20.1. Documentation of consent will be in written form, but where not appropriate, the REB may accept verbal consents that are witnessed and confirmed by a neutral third party. Alternately they may indicate their consent by participating directly in the data collection (e.g. surveys).
- 5.20.2. The REB has developed a sample *Information/Consent Form* that may be used as a guide by researchers. Researchers are advised that additional information may be required depending on the research being conducted.

5.21. Naturalistic observation

Free and informed consent must be obtained for all prospective participants with the exception of minimal risk naturalistic observation studies that examine behaviour in a natural (not staged) environment and where there is no expectation of privacy. However, the research records must still protect the identity and dignity of the participants in these cases so REB review is required, and where possible and appropriate, participants will be debriefed and provided with relevant information after the observation. Where the research plans to disclose the identity of participants, it shall be discussed with the participant and their consent recorded.

5.22. Aboriginal Research

Researchers should be informed about rules or customs that may apply to a First Nations, Inuit or Métis people and shall seek and advise the REB on the plan of engagement with the relevant community as well as communities of interest and service organizations. If the research project is to be conducted on First Nations, Inuit or Métis lands then researchers will secure the agreement of the formal leaders who are charged with protecting the welfare of the community and/or customary authority.

5.23. Critical Inquiry

Research that adopts a critical perspective with respect to an institution or organization policies and practices such that the object of the research may not endorse the project, should not prevent the research from receiving ethics approval. Individuals of these organizations who are approached to participate should be fully informed about the views of the organization regarding the research. Researchers need to be attentive to the risks and secure research materials.

5.24. Clinical trials

5.24.1. Ethics

- A clinical trial is any investigation involving participants that evaluates the effects of one or more health related interventions on health outcomes. Any foreseeable risk to the participants is justified by potential benefits and appropriately minimized. Researchers should clearly indicate which risks are attributable to the research (including cumulative risks) and which risks would occur during the course of their clinical care.
- In all clinical trials, researchers and REBs should be aware of ethical issues including the type and phase of the trial (e.g. pharmaceutical, natural health product, medical device, psychotherapy), registration, safety, selection and recruitment of participants, undue inducement, consent, dissemination of findings and real, potential or perceived conflicts of interest.

5.24.2. Placebo controlled trials

Placebo controlled trials will only be used where a new therapy or intervention is generally tested against an established effective therapy. A randomized controlled clinical trial is only acceptable if its use is scientifically and methodologically sound and has been justified to the REB and where it does not compromise the safety or the health of participants. General principles of consent are respected and the participants informed about any therapy that will be withdrawn or withheld for purposes of the research and the anticipated consequences of such action.

5.24.3. Registration

Registration of the clinical trial on a web-accessible public registry before recruitment will avoid unnecessary duplication and improve the ability of researchers to identify potential collaborators or gaps in research which may be pursued.

5.24.4. Safety

Safety of the participants will be ensured through the submission of a plan for the monitoring, tabulation, analysis and reporting of safety data and the sharing of other new information that permits the REB to interpret and respond accordingly. Any new information that may affect the welfare or consent of the participants will be reported to the REB and to the participants to whom the information applies. The REB shall develop procedures to review safety reports and other new information arising from clinical trials and to take appropriate steps.

5.24.5. Procedures for recruitment

Procedures for recruitment and consent should clearly articulate the differences between the goals of health care and the goals of research. The benefits of research participation should not be exaggerated by the clinician who has a dual role and where there is the likelihood of therapeutic misconception.

5.24.6. Conflicts of interest

Conflicts of interest should be considered and must not affect the core principles or the scientific validity and transparency of trial procedures. Clinical budgets are reviewed to ensure conflicts of interest are identified and minimized, or otherwise managed.

5.24.7. Dissemination of information

Dissemination of information occurs in a timely manner without undue restriction.

5.25. Vulnerable human participants

- 5.25.1. Some individuals may be competent but certain factors could diminish the person's ability to exercise their autonomy and effectively render them vulnerable. The determination of capacity to participate in research is not a static determination but is a process that may change over time. Diminished capacity could be the result of inadequate information or understanding for deliberation, or a lack of freedom to act due to controlling influences or coercion. Sectors influenced by the nature of their relationship include students, employees, patients dependent on caregivers or long-term care residents therefore caution must be exercised and the best interests of the participant protected.
- 5.25.2. A person is legally incompetent when they cannot be legally bound by their actions. Such would be the case for someone with limited mental capacity. Research involving vulnerable persons will be conducted if the research questions can only be addressed with the participation of that identified group. It must not expose them to more than minimal risk without the potential for direct benefits and consent must be granted from a neutral authorized representative who is not connected to the research project.
- 5.25.3. For research involving individuals who lack capacity, the REB shall ensure that, as a minimum, the following conditions are met:
 - The researcher involves participants to the greatest extent possible in the decision-making process;
 - The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the participant's best interests will be protected;
 - The authorized third party may not be the researcher or any other member of the research team;
 - The free and informed consent of the third party is required for continued participation of the legally incompetent participant, so long as they remain incompetent;
 - If the legally incompetent participant who has entered into a research project through third-party authorization understands the nature and consequences of the research, the researcher must fulfill the same requirements for a competent participant and determine the wishes of the individual;
 - Research must terminate if the participant does not agree. Dissent is considered a refusal to participate even if a third party has provided consent on behalf of the participant.

5.25.4. Beyond the legal requirements for obtaining free and informed consent from authorized third parties, family members and friends may provide information about the interests and previous wishes of prospective subjects. In some cases, the REB will have to determine from whom the free and informed consent should be sought.

5.25.5. Individuals who have signed a research directive indicating their preferences about future participation in research in the event they lose capacity or upon death will provide guidance to researchers and authorized third parties.

5.26. Specific circumstances to obtaining consent

5.26.1. An REB may approve a consent procedure that does not have all the elements or may waive the informed consent requirement in the following circumstances:

- a) The research is no more than minimal risk to the participants;
- b) The waiver or alteration is unlikely to adversely affect the rights and welfare of the participants;
- c) The research could not practicably be carried out without the waiver or alteration;
- d) Whenever possible and appropriate, the participants will be provided with additional pertinent information after participation; and
- e) The waived or altered consent does not involve a therapeutic intervention.

5.26.2. For qualitative research where consent is dynamic or must be negotiated and the approach cannot be determined in advance of the research, the researcher will explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

5.27. Emergency health situations

5.27.1. Research involving emergency health situations will only be conducted without free and informed consent if it addresses the immediate health needs of the individuals involved, and only by pre-established criteria approved by the REB. An emergency health situation must apply to all of the following:

- a) A serious threat to the participant that requires immediate intervention;

- b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the participant in comparison with standard care;
- c) 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 participant;
- d) The prospective participant is unconscious or lacks capacity to understand risks, methods and purposes of the research;
- e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
- f) No relevant prior directive by the participant is known to exist.

5.27.2. Once 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.

5.28. Public emergencies

Extraordinary events such as natural disasters or communicable disease outbreaks that arise unexpectedly and require a quick response to minimize damage create certain challenges for research ethics review. REBs need to consider how official emergencies may affect research and anticipate the pressures and challenges that may arise to ensure quality, timely, proportionate research ethics review. The REB in collaboration with researchers should develop a preparedness plan for emergency research ethics review to allow for modified procedures and practices for the duration of the emergency only. During these extraordinary circumstances, the REB will exercise due diligence in respecting the core principles of respect for persons, concern for welfare and justice when reviewing the ethics of research.

6. Roles and responsibilities

- 6.1. As required by the TCPS2 (2014), it is the responsibility of the president, as the highest authority for establishing an REB, to ensure that the Ethical Conduct for Research Involving Humans procedure is fully implemented.
- 6.2. The Vice-President, Academic, is responsible for overseeing the College's research ethics processes, as well as nominating REB members and appointing the REB Chair.
- 6.3. The Academic Leadership Team will approve the REB's protocols manual and periodic revisions.

- 6.4. The Dean, Research Services, will ensure the provision of administrative support to the REB, address REB training needs, and recommend revisions to the policy and procedure every three years, or earlier if necessitated by any changes to the TCPS2 (2014).
- 6.5. The Finance and Ethics Compliance Coordinator will provide administrative support to the REB, attend REB meetings as a non-voting member to take minutes, draft agendas, maintain the REB portal, receive and screen applications, and respond to inquiries from internal and external researchers.
- 6.6. All individuals associated with Durham College in any capacity and conducting research involving humans must comply with this policy and procedure. This includes individuals not associated with Durham College who approach faculty, staff or students or seek approval or endorsement from the College, or use College facilities for research involving humans.
- 6.7. Responsibility for ethical review and for consideration of ethical research is vested in the REB, which ensures that ethical procedures are implemented and regularly reviewed in the College.
- 6.8. All members of the REB, including the REB chair and REB vice-chair if there is one, must complete the Tri-Council online tutorial Course on Research Ethics (CORE) and submit the Certificate of Completion to ORSIE, and sign a confidentiality agreement before commencing responsibilities with the REB.
- 6.9. All members are responsible for impartially assessing each applicant's project for compliance with TCPS2 (2014) standards and ethical acceptability.
- 6.10. Specifically, members will review applications before each meeting, attend meetings prepared, participate in the delegated review process as requested by the REB Chair, offer feedback during meetings and delegated reviews as appropriate, request revisions as required, and approve or deny approval of protocols.
- 6.11. Members are expected to attend all scheduled meetings. In the case of illness or emergency, members will notify the finance and ethics compliance coordinator and the REB chair as soon as possible before the meeting.
- 6.12. Members may be replaced if they are absent for two scheduled full board review meetings in an academic year.

7. Accessibility for Ontarians with Disabilities Act considerations

Accessibility for Ontarians with Disabilities Act (AODA) standards have been considered in the development of this policy and procedure and it adheres to the principles outlined in the College's commitment to accessibility as demonstrated by the Accessibility Plan (ADMIN-203).

8. Non-compliance implications

- 8.1. Failure to comply with this policy and procedure may result in damage to internal and external relationships, financial loss, property damage, reputational harm, legal action and/or a diminished ability to achieve the mission of Durham College.
- 8.2. Failure to comply with this policy and procedure may also affect the College's status as an institution eligible to receive funding from the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada.

9. Communications plan

- A message will be posted on ICE alerting employees when new or revised policies and procedures are added to ICE.
- A message will be posted on MyCampus alerting students when new or revised policies and procedures are added.

10. Related forms, legislation or external resources

- Tri-Agency Framework: Responsible Conduct of Research
- Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, 2014.
- Freedom of Information and Protection of Privacy Act, R.S.O. 1990, c. F.31
- Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Schedule. A