DURHAM COLLEGE
SUCCESS MATTERS

Application for Ethical Review of Research Involving Human Participants

Research Ethics Board (REB)

Please contact reb@durhamcollege.ca if you require assistance to complete this form.

For office use only:	Date Received:	REB#:
	Type of Review:	

Section 1.0 Purpose

This form must be filled out if you are conducting research involving live human participants as it requires ethics review and approval by the Durham College Research Ethics Board (REB) (Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) Article 2.1).

The Durham College REB complies with the TCPS 2 (2022) and the Durham College Policy and Procedure on Ethical Conduct for Research Involving Humans.

Section 2.0 Instructions

For all users of this form, fill out all appropriate sections and then submit **One Signed Softcopy** of this form along with all attachments to reb@durhamcollege.ca. Hand written forms will **not** be accepted. **Under no circumstances shall any research with human participants commence prior to receiving approval from the REB at Durham College.**

The Durham College REB meets monthly in accordance with the published meeting schedule to review research requests. Applications received no less than two weeks before a scheduled meeting will be reviewed. If the research has received approval from another REB, please include the REB's approval letter.

Label all supporting documents that are referenced in the application.

An approved Researcher Institutional Permission form must also accompany the application.

For more assistance with completing your application, please refer to the "Checklist for Researchers" document. Free version of Adobe Acrobat Reader required to complete application.

Section 3.0 Project Information

Title of Research Project:

Proposed Start Date*:

Proposed End Date:

*** Note:** Start date must be after REB approval is expected.

Section 3.1 Principal Investigator (PI) Information

Name:

Position:

Institution:

Email:

All Principal Investigators, Co-Investigators and Research Assistants must complete the TCPS 2 Tutorial Course on Research Ethics (CORE) online at the TCPS 2 Tutorial website. Please attach all Certificates of Completion to this application. This REB Application form will not be approved without it.

☐ TCPS 2 Tutorial Certificates Attached

Definition of a PI: It is acknowledged that the PI is the head researcher/investigator of the project. If the PI is not employed by the institution ultimately responsible for the project (i.e. a student), then the PI must identify the faculty supervisor of the responsible institution in section 3.2, and the faculty supervisor must commit to fulfilling the role as co-investigator.

Section 3.2 Team Information

Co-Investigator(s):

Name:

Position:

Institution:

Email:

Name:	
Position:	
Institution:	
Email:	
Name:	
Position:	
Institution:	
Email:	

*** Note:** If you require additional entries, please attach a document to your submission with all necessary information.

Co-investigator/Faculty Supervisor:

All Student PI's **must** have a Faculty Supervisor listed as a Co-investigator

Name:	
Position:	
Institution:	
Email:	

Section 3.3 Funding Information

a) Is this REB Application associated with a funded research project?

Please select:

If no, please continue onto Section 3.4

b) Funding Status: Please select:

Source/Agency Name:	
Program:	
Award Term Start Date:	
Award Term End Date:	

c) Please indicate the Name of the PI on the funding application. If external to Durham College, please indicate the Institution as well.

Name:

Institution (if applicable):

d) Are there Multiple Funding Sources? Please select:

(If Yes, please provide an attached document with all the information requested above for each funding source

e) Has this application received peer/scientific review? Please select:

If Yes, by whom:

Section 3.4 Location of Research

a) Please indicate the location(s) where the research will be conducted (i.e. hospital, community centre, college, etc.)

b) Is this a multi-centered study?

Please select:

Section 3.5 Approvals & Permissions

a) Has any University/College/Hospital/School Board/etc. approved this research? Select:

i. If No, will approval be sought? Select:

Yes; please fill out section ii below.

No; please justify:

ii. If Yes or Pending, please fill out the following (if more than one, only use the board of record)

Name of Institution:

Name of Board:

Decision Date:

Contact Name and Number of Board Administrator:

b) Has any organization/community/etc. granted permission for this research to occur (e.g. Durham College, hospitals, etc.)? Select:

i. If No, will approval be sought? Select:

Yes; please fill out section ii below.

No; please justify.

ii. If Yes or Pending, please fill out the following (if multiple, please state them all below and attach all permission letters along with this form)

Name of organization(s)/community(s)/etc.:

c) Are you signing an external agreement with an institution governing the use of data? Select:

If yes, please submit it with your application.

Section 3.6 Professional Expertise & Qualifications

As the PI, do you have the required professional expertise and qualifications for this research? Select:

Yes; provide details:

No; does anybody on your research team (including Supervisor) have the professional expertise and qualifications to carry out this research? Select:

If Yes, provide details:

If No, please explain how you will obtain the necessary qualifications:

Section 3.7 Conflict of Interest

As Researchers, are there any interpersonal relationships (i.e. family), financial partnerships, other economic interests (i.e. spin-off companies in which researchers have stakes or private contract research outside of the academic realm), academic interests or any other incentives that may compromise integrity or respect for the core principles of this Policy?

Select:

If Yes, please identify and describe how you plan to minimize this conflict of interest:

*** Note:** While it may not be possible to eliminate all conflicts of interest, researchers are expected to identify, minimize or otherwise manage their individual conflicts in a manner that is satisfactory to the REB (TCPS 2 Article 7.1)

Section 4.0 Rationale & Research Details

Section 4.1 Purpose & Background

Please describe in lay language the Research Questions, Background Rationale and Hypothesis(es) if applicable:

Section 4.2 Participants

a) Will any participants be individuals or groups whose circumstances may make them vulnerable in the context of research? Select:

If yes, explain the details and demographics of the participants.

Also describe team members knowledge and experience working with these participants.

b) Please describe who the participants will be, demographic details and characteristics (i.e. age, gender, etc.):

c) Please describe and explain what your exclusion criteria will be (if applicable):

d) What is the number of participants required:

e) Explain the rationale for the number of participants required:

f) Where the number of interested participants who meet the inclusion criteria exceeds the number of participants, will all eligible individuals who volunteer be included in the study?

Select:

If No, describe how participants will be selected (e.g., first come/first served) and how they will be informed of this.

Section 4.3 Recruitment

Please attach a copy of all recruitment materials being used (i.e. posters, advertisements, etc.)

a) Please explain and describe in detail (i.e. each step) how participants will be recruited. Include details about who will recruit participants.

b) Please explain and describe from what sources participants will be recruited from.

c) Please explain and describe the relationship between the participants and the researchers and/or sponsors.

Section 4.4 Methods

Please check all the procedures and/or methods that are involved in this study.

- ☐ Questionnaire – snail mail
- ☐ Questionnaire – email and/or web
- ☐ Questionnaire – in person
- ☐ Interview(s) – in person
- ☐ Interview(s) – telephone
- ☐ Interview(s) – Skype/online (video chat)
- ☐ Focus Group(s) – in person
- ☐ Focus Group(s) – Skype/online (video chat)
- ☐ Audio/Video Taping
- ☐ Participant Journals
- ☐ Computer Administered Tasks
- ☐ Unobtrusive Observations
- ☐ Invasive Physiological Measurement (i.e. venipuncture, muscle biopsies)
- ☐ Non-Invasive Physical Measurements (i.e. exercise, heart rate, blood pressure)
- ☐ Analysis of human tissue, body fluids, etc.
- ☐ Other, please specify:

Section 4.5 Data Collection Procedures(s)

Please describe sequentially and in detail, all the procedures in which the research participant(s) will be involved. This also includes the procedures for all stages of the research (pre-tests, etc.) where applicable. Indicate who will be collecting the data and where collection will happen.

Please remember to attach a copy of all data collection materials being used (i.e. questionnaire(s), interview guide(s), etc.)

Section 4.6 Participant Compensation

Will participants receive any compensation for their participation? Select:

If Yes, describe the details of the compensation including the amount:

Section 5.0 Risks & Benefits Assessment

Section 5.1 Risk Assessment to the Participant(s)

Question	Response
a) Are there any possible Physical Risks (bodily contact, physical stress, administration of any substance, etc.)?	
b) Are there any possible Psychological Risks (feeling demeaned, embarrassed, worried, etc.)?	
c) Are there any possible Social and Economic Risks (loss of status, privacy, reputation, etc.)?	
d) Are any possible risks to participants greater than those that they encounter every day?	
e) Is there any deception involved?	
f) Is there potential for participants to feel coerced into participating in the research?	

Section 5.2 Risk Description(s)

If you answered Yes to any of the above, please explain what the risk is in detail.

Section 5.3 Risk Assessment to the Community and/or Environment

Please describe any risks that may occur to the community and/or environment.

Section 5.4 Risk Management to the Participant, Community, and/or Environment

Describe how the risk(s) identified in **5.1, 5.2 and 5.3** will be managed. If appropriate, include the availability of medical or clinical expertise, etc. Provide justification as to why a less risky alternative will not be used. If research includes deception, provide rationale and debriefing plans.

Section 5.5 Benefits to the Participants, Community and/or Environment

Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the potential benefits to the community and/or environment that would justify involvement of participants in this study.

Section 6.0 The Consent & Withdrawal Process

Section 6.1 Obtaining Consent

Please describe the process that the Researcher(s) will be using to obtain informed consent. Please state clearly what method will be used (written, verbal, etc.).
Please remember to attach a copy of the consent form. For verbal consent processes, provide the consent script.

Section 6.2 Consent Process by Authorized 3rd Party

If the participants are minors or do not have the competency to consent, please describe the proposed alternative sources of assent (agreement to participate in research for minors).
Please remember to attach a copy of the assent form. For verbal assent processes, please provide an assent script.

Section 6.3 Alternatives to Obtaining Consent Prior to Participation

If obtaining individual participant consent prior to commencement of the research project is not appropriate, please explain justification. Please provide details for a proposed alternative consent process.

Section 6.4 Acknowledgement/Feedback to Participants

Please describe what feedback and/or information will be provided to the participants after their participation. This can take the form of debriefing, a thank you letter, or any results that may be available.
Please remember to attach a copy of any papers (i.e. thank you form) that you are planning to give to the participant.

Section 6.5 Participant Withdrawal Process

Please describe how the participants will be informed of their right to withdraw from the project before/during/after data collection. Outline all the procedures that will be followed to allow the participants to exercise this right.
Please remember to capture this information in the consent process (i.e. write it in the consent form).

Please indicate what will be done with the participant's data and any consequences that withdrawal might have on the participant, including any effect that withdrawal may have on participant compensation.

Section 7.0 Data Storage & Confidentiality

Section 7.1 Participant Data Protection

a) Given the definition below, will the data be treated as confidential? Select:

Confidentiality: information revealed by participants that holds the expectation of privacy (this means that all data collected will not be shared with anyone except the researchers listed in this application).

If Yes, please describe the procedure to be used to ensure the confidentiality of data both during the conduct of the research and in the release of its finding.

If No, if participant confidentiality is not appropriate to this research, explain in detail how all participants will be advised that data will not be confidential.

b) Given the definitions below, will the data be anonymous and/or anonymized? Select:

Anonymous Data: the information never had identifiers associated with it and the risk of identification is very low.

Anonymized Data: the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

If Yes, please describe the procedures to be used to ensure anonymity of participants in the release of its findings. If data will be coded, include details of how data will be coded.

If No, if participant anonymity is not appropriate to this research, explain in detail how all participants will be advised that data will not be anonymous and/or anonymized.

Section 7.2 Data Access

Is there anyone who will have access to the data that is not listed as an Investigator on this application? Select:

If Yes, please list them:

(For all personnel listed, they must sign a confidentiality agreement. Please attach a copy of the confidentiality agreement to this application. Please note that we do not need the signed copy(s).)

Section 7.3 Data Storage & Security

a) Please describe in detail where the data will be stored (e.g. encrypted USB key, secure network, cloud storage, filing cabinet, etc.) and housed securely:

b) Please select the option that applies to your storage procedures:

Please select:

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

c) Please describe in detail the duration of storage (with dates), disposal method to be used (e.g. paper copies shredded, USB key destroyed, etc.), and a justification for the procedure you checked off above:

Section 7.4 Secondary Use of Data

I understand that once the research described in this application has ceased, should I desire to use the data for another purpose, this is considered Secondary Use of Data.

☐ **Yes, I agree**

I understand that if I desire to use Secondary Use of Data, re-consent must be sought from the participants.

☐ **Yes, I agree**

The REB recommends that if there is potential for data to become secondary use, please add a line in your current consent form to clearly inform the participants of this possibility; this will satisfy the re-consenting mandate given by the TCPS2.

I understand that should the opportunity arise to use secondary data, I will need to submit a Secondary Use of Data Application Form to obtain REB approval before commencing.

☐ **Yes, I agree**

Section 8.0 Summary of Research Tools/Materials

Please check off all appropriate research tools and materials below that you will be using for your research.

Please remember to attach each item along with this application when you submit electronically.

Recruitment Materials

- ☐ Letter of Invitation
- ☐ Verbal Script (include copy of script)
- ☐ Telephone Script (include copy of script)
- ☐ Advertisement (posters, etc.)
- ☐ Online Correspondence
- ☐ Social Media (include script, links, etc.)
- ☐ Other – Please specify:

Letter of Approval/Permission (if applicable)

(please note, these are not letters of support)

- ☐ School Board(s)
- ☐ Co-operating Organization(s)
- ☐ Hospital(s)
- ☐ Community Agencies
- ☐ Universities/College(s)
- ☐ Other – Please specify:

Consent Materials

- ☐ Consent Form
- ☐ Assent Form
- ☐ Parental 3rd Party Permission Form
- ☐ Transcriber Confidentiality Agreement

☐ Other – Please specify:

Data Gathering Instruments

☐ Questionnaires
☐ Interview Guides
☐ Focus Group Guides
☐ Tests
☐ Other – Please specify:

Plans for Dissemination/Communication to Participants

☐ Thank you Letter
☐ Feedback Letter
☐ Debrief Workshops
☐ Verbal Thank you Script
☐ Debriefing Letter
☐ Other – Please specify:

Plans for Dissemination/Communication to Others

☐ Class presentation
☐ Publication
☐ Conference presentation
☐ Other – please specify:

Section 8.1

This section has been created for the purpose of informing the REB of anything that you feel is pertinent to its review of your application that you were unable to convey anywhere else.

Section 9.0 Signatures

Section 9.1 Principal Investigator Signature

- ☐ I certify the information provided in this Application is complete and accurate. I have complied with the TCPS 2 (2022) and Durham College's policies and procedures governing the protection of human participants in research.
- ☐ I will report any adverse or unanticipated events (unanticipated negative consequences or results affecting participants) to the Durham College REB as soon as possible.
- ☐ Any additions or changes in the research protocol approved will be submitted to the Durham College REB prior to implementing them.
- ☐ If my research remains for more than the original expiry date of one year, I will renew annually in accordance with the Tri-Council Policy Statement.
- ☐ I will complete and submit a Study Completion Form to the Durham College REB once the research has completed.
- ☐ I take full responsibility in ensuring that all other researchers involved in this research follow the protocol as outlined in the application.
- ☐ I am submitting my approved Researcher Institutional Permission Request form with this application.

Principal Investigator	
First Name:	Last Name:
Signature:	

Section 9.2 Co-investigator Signatures

☐ I certify the information provided in this Application is complete and accurate. I have complied with the TCPS 2 (2022) and Durham College's policies and procedures governing the protection of human participants in research.

☐ I will report any adverse or unanticipated events (unanticipated negative consequences or results affecting participants) to the Durham College REB as soon as possible.

☐ Any additions or changes in the research protocol approved will be submitted to the Durham College REB prior to implementing them.

Co-investigator #1	
First Name:	Last Name:
Signature:	
Co-investigator #2	
First Name:	Last Name:
Signature:	
Co-investigator #3	
First Name:	Last Name:
Signature:	

*(for additional Co-investigators, submit extra copies).

Notice of Collection: In accordance with Section 39(2) of the Freedom of Information and Protection of Privacy Act, 1990, the personal information collected on this form is collected under the legal authority of the Ontario Colleges of Applied Arts and Technology Act, 2002 and may be used and/or disclosed for processing applications for the Research Ethics Board. Your personal information may also be used for various administrative, statistical and/or research purposes of the College and/or ministries and agencies of the Government of Ontario and the Government of Canada. If you have any questions about the collection, use and disclosure of your personal information by the College, please contact the Freedom of Information and Protection of Privacy Coordinator, 2000 Simcoe Street North, Oshawa, ON, L1G 0C5, 905.721.2000 ext. 3292.