

ONTARIO COMMUNITY COLLEGE MULTI-SITE FORM

APPLICATION TO INVOLVE HUMAN PARTICIPANTS IN RESEARCH

This form is for researchers who are planning to conduct research involving human participants at multiple colleges in Ontario.

If your study will take place at two or more colleges, please use this form.*

** Almost all colleges have agreed to accept the Ontario Community College Common REB application form; however, it is the researcher's responsibility to contact the Research Ethics Board Co-ordinator at each college to check site-specific requirements and to determine where and how this form is submitted.*

If you are only conducting research at one site, please use the individual college form.

SECTION A: GENERAL INFORMATION

1. Title of the Research Project

Click here to enter text.

2. Investigator Information

Principal Investigator

Name:	Click here to enter text.
Position:	Click here to enter text.
School/Department:	Click here to enter text.
Mailing Address:	Click here to enter text.
Telephone:	Click here to enter text.
E-mail:	Click here to enter text.

Co-Investigators

Name:	Click here to enter text.
Position:	Click here to enter text.
School/Department:	Click here to enter text.
Mailing Address:	Click here to enter text.

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Telephone:

E-mail:

Student Investigators

Name:

Position:

School/Department:

Mailing Address:

Telephone:

E-mail:

Other Investigator(s):

Name:

Position:

School/Department:

Mailing Address:

Telephone:

E-mail:

3. Project Dates:

Estimated Start Date

Estimated End Date

4. Project Location (Specify Institutional sites):

College/University

City

5. Other Research Ethics Board Approval

Has any other institutional Ethics Board approved this project?

Yes No

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If “Yes”, **please attach a copy of the clearance certificate/approval** and provide the following information:

Title of the Research Project:

Click here to enter text.

Name of Ethics Board:

Click here to enter text.

Date of the Decision:

Click here to enter a date.

6. Project Funding

Is this project currently funded?

Yes No

If there is a sponsoring organization(s), please identify the period of funding, the organization(s) and the contact person(s).

Period of Funding **From:** Click here to enter a date.

To: Click here to enter a date.

Sponsoring Organization: Click here to enter text.

Contact person(s): Click here to enter text.

Mailing Address: Click here to enter text.

Telephone: Click here to enter text.

Fax: Click here to enter text.

E-mail: Click here to enter text.

If yes, describe the sponsorship by value and type (grant, gifts in kind, resources, cash contribution, staff, equipment, etc):

Value	Type of Contribution
Value	Type of Contribution
Value	Type of Contribution
Value	Type of Contribution

If the funding source changes, or if a previously unfunded project receives funding, **you must submit a change/amendment form** to each Research Ethics Board that has approved your project.

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7. Conflict of Interest

Will the researcher(s), members of the research team, and/or their partners or immediate family members:

- a) Receive any personal benefits (for example a financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.) as a result of or connected to this study?

Yes No N/A

If **Yes**, please describe the personal benefits below. (Do not include conference and travel expense coverage, possible academic promotion)

[Click here to enter text.](#)

- b) Are there any real, perceived or potential conflicts of interest of which you are aware (for example, researchers who will benefit financially from the research, research which may be in conflict with institutional roles and responsibilities, faculty members who may be responsible for awarding participant grades)?

Yes No

If **Yes**, please explain those conflicts of interest and how you will address them:

[Please Explain:](#)

- c) Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that the sponsor or institution has placed on the investigator(s)?

Yes No

If **Yes**, please explain:

[Please Explain:](#)

- d) Is there the possibility of commercialization of the research findings?

Yes No

If **Yes**, please explain:

[Please Explain:](#)

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SECTION B SUMMARY OF THE PROPOSED RESEARCH

8. Rationale

Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined:

[Click here to enter text.](#)

9. Methodology

Attach copies of all documents used for the purpose of collecting data including questionnaires, interview guides, intervention protocol or other test instruments.

a) Explain the methodology:

[Please Explain:](#)

b) Describe data collection sequentially and in detail. Outline all procedures in which the research participants will be involved (e.g., paper and pencil tasks, interviews, surveys, questionnaires, physical assessments, physiological tests, time requirements, etc.)

[Please Explain:](#)

c) Describe participants, sampling method and sample size and rationale for sample size:

[Please Explain:](#)

d) Describe inclusion/exclusion criteria:

[Please Explain:](#)

e) Explain the process of data analysis briefly:

[Please Explain:](#)

10. Recruitment

Attach a copy of any advertising, correspondence and/or scripts to be used for the purpose of recruiting participants.

a) How do you plan to recruit participants? (Please check all that apply)

Investigators will approach their own students/patients

Investigators will receive referrals from other faculty

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- Educational records (e.g., academic performance information, Student Information System)
- Indirect advertising (e.g., poster, e-mail, web-based)
- Database of people who consented to future contact
- Direct approach (e.g., random digit dialing, blogs and chat room)
- Other (please specify): [Click here to enter text.](#)

b) Will any of the investigators have a position of power or authority over the participants?

Yes No

If Yes, how will you manage and minimize any undue influence?

[Please Explain:](#)

c) Does your recruitment plan require you to contact potential participants by:

Telephone Yes No N/A

Personal E-mail Yes No N/A

Anonymous Email Yes No N/A

Letter Yes No N/A

If YES, describe permission you have been given or plans to obtain permission to contact the participants.

[Please Explain:](#)

d) Does your study involve any of the groups listed below?

People with relevant health issues

Children

People in medical emergencies

Elderly people

Aboriginal people

People in poverty

People in long-term care

People in prison

People with mental-health issues

People who are unable to consent

Other (please specify): [Click here to enter text.](#)

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- e) Do you screen personal health information to identify potential participants?
 Yes No

SECTION C – DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

11. Possible Risks to Participants

In your best judgment, how much risk does the study involve?

Yes Minimal risk

OR

Yes Greater than minimal risk

- a) Identify who will be collecting the data and where:

Please Explain:

b) Indicate if the participants might experience any of the following risks:

- i) Physical risk (including any bodily contact or administration of any substance)
 Yes No
- ii) Psychological risks (including feeling demeaned, embarrassed worried or upset)
 Yes No
- iii) Social risks (including possible loss of status, privacy and/or reputation)
 Yes No
- iv) Economic risks (including incurring expenses, loss of incentive)
 Yes No
- v) Academic risks (including loss of bonus marks or course standing)
 Yes No
- vi) Potential access to personal data
 Yes No
- vii) Are any possible risks to participants greater than those the participants might encounter in their everyday life?
 Yes No

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If you answered **YES** to any of Points i) through vii) above, please explain the risk:

Please Explain:

- c) Please comment on the magnitude of harm participants are likely to encounter i.e. would you assess it as minimal, substantial, transient or longer lasting?

Please Explain:

- d) Please comment on the probability that participants will encounter harm, i.e. would you assess it as low, medium or high?

Please Explain:

- e) Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used).

Please Explain:

- f) Describe time and any travel demands expected of participants:

Please Explain:

12. Possible Risks to Researchers

Please explain any risks to researchers which you anticipate:

Please Explain:

13. Possible Benefits to Participants

Discuss any potential direct benefits to the participants from their involvement in the project. This may include the (potential) benefits to the scientific community/society that would justify involvement of participants in this study:

Please Explain:

14. Informed Consent

- a) Will you be seeking written consent from participants?

Yes No

If Yes, please **attach a copy of the Information/Invitation Letter** and Consent form for participants.

- b) If consent will not be written, please provide details of how you will obtain consent:

Please Explain:

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c) Will any participants be minors (ie., age 0-15)?

Yes No

d) Will all participants be competent to consent?

Yes No

e) If the participants are minors or are not competent to consent, describe the proposed alternate source of consent and **attach any permission/ information letter** to be provided to the person(s) providing alternate consent.

Please Explain:

f) Who will obtain consent to participate for minors or those not competent to consent?

Please Explain:

g) When and where will this be done?

Please Explain:

h) Will participants have the option to withdraw from this study?

Yes No

If Yes, please explain what they have to do to withdraw:

Please Explain:

If No, please explain why not:

Please Explain:

i) Indicate what will be done with the participant's data and any consequences to the participant withdrawing from the study:

Please Explain:

j) Will you be using deception in your research?

Yes No

If Yes, provide rationale and debriefing plans:

Please Explain:

i. Who will advise the participants of the true nature of the study?

Please Explain:

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ii. When and how will that be done?

Please Explain:

15. Collection and Protection of Personal Information

- The collection, use and disclosure of Personal Health Information (PHI) are regulated by the Personal Health Information Protection Act (PHIPA). Researchers must comply with this legislation
- Collection of participant SIN (social insurance number) is prohibited, unless payments to participant exceed \$500/year (required for tax purposes)
- Personal data should be collected at the lowest level of identifiability possible (e.g. initials instead of a name, age instead of DOB)

Note: Coding

- Identifying and/or identifiable data should be protected by a coding system
- The code (study ID and identifiable data) must be isolated from study data and stored in a secure manner
- You are required to destroy identifiers or links at the earliest possible time.

a) Will all data be treated as confidential?

Yes No N/A

If **No**, please explain:

Please Explain:

b) Will you use a coding system to protect identifiable information?

Yes No N/A

If **NO**, please explain:

Please Explain:

c) Please check all types of data which you intend to collect:

Anonymous information in which no identifiers are collected

Anonymized information in which all identifiers are removed and no code is kept. **Describe when study data will be anonymized:**

Please Explain:

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- De-identified/coded information in which identifiers are removed and replaced with a code; the code can be used to re-identify participants
- Identifiable information which could identify a participant through a combination of indirect identifiers (e.g. DOB plus address)
- Identifiable information which identifies a participant through direct identifiers (e.g. full name, medical record number)

Please detail the specific identifiers required for this study:

Check all that apply and explain why it is necessary:

- Full name Please Explain:
- Initials Please Explain:
- Student/Employee number Please Explain:
- Social Insurance Number Please Explain:
- Health Card Number Please Explain:
- Medical Record Number Please Explain:
- Address Please Explain:
- Full Postal Code Please Explain:
- Partial Postal Code Please Explain:
- Telephone Number Please Explain:
- Email Please Explain:
- Physician Please Explain:
- Date of Birth Please Explain:
- Age Please Explain:
- Other: (Specify) Please Explain:

16. Storage of Information

PHIPA Requirements

- **Paper files with identifiable information must be kept in a locked cabinet within a locked office (but not at home)**
- **Electronic files with identifiable information may be stored on a password-protected computer on a secure network (i.e., virus protection, file backup, firewall) or encrypted.**
- **Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA) with no alternative method of storage; these files must be encrypted.**

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- **Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted**

Secondary Use of Data

- **Use of data for purposes other than those for which the data was originally collected is considered to be secondary use of data and requires participant's permission.**

Duration of Storage

- **Individual funding and research organizations have different requirements. This review defers to these external requirements and it is the responsibility of the researcher to identify and comply with those requirements.**

a) How will you store and protect data without identifiers?

Please Explain:

b) How will you store and protect the study code (or other data with identifiers)?

Please Explain:

c) How long will you keep the study data?

Please Explain:

d) Who will take responsibility for data destruction after that time period?

Please Explain:

e) What will you do with the study data after this period?

Please Explain:

17. Moving and Transmission of Data

- **Data sent to the United States, or uploaded to American servers (e.g. Survey Monkey), is open to access by American regulatory bodies. Researchers must inform study participants of this possibility.**
- **If you require outside sources to have access to participant data, you need to ensure that mechanisms are in place to ensure data security, confidentiality and anonymity.**

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a) Do you plan on physically moving the data?

Yes No N/A

If YES, how will the data be secured while in motion?

Please Explain:

b) Will the research data be physically or electronically moved outside its original location of collection (for example, data on a laptop is brought to the office, sent for transcription or uploaded to a central data repository)?

Yes No N/A

c) If YES, does this data include identifiers?

Yes No N/A

If YES, please provide details on steps taken to ensure data security and privacy:

Please Explain:

d) If data are being transmitted, where will the data be sent?

Please Explain:

e) Please list the names and affiliations of persons outside of your research team who will have access to the identifiable data.

Name	Affiliation
Name	Affiliation
Name	Affiliation
Name	Affiliation

f) How will the data be transmitted?

Fax

Email **(Note: Encryption protocol must be attached)**

Private Courier **(Note: Delivery must be traceable)**

Canada Xpresspost **(Note: Regular mail may not be used)**

Other: Please Explain:

18. Secondary Use of Data

- Any secondary use of data must be approved by the REB prior to its use.

a) Will you combine your research data with any other data sets?

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Yes No N/A

If **YES** -

Identify the data set:

Please Explain:

Explain how the linkage will occur:

Please Explain:

Provide a list of data items contained in the data set:

Please Explain:

b) Will your data be entered into another database for future use?

Yes No N/A

If **YES**, please specify:

Where it will be stored:

Please Explain:

Who will be the custodian?

Please Explain:

Who will have access to the database?

Please Explain:

What security measures will be in place?

Please Explain:

19. Experience

- It is strongly recommended that researchers complete the free online TCPS CORE (Course on Research Ethics) training, available at: [The TCPS2 Tutorial Course on Research Ethics \(CORE\)](#)
- Some REBs require that researchers complete this training.

a) What is your experience and what qualifications do you have for doing this kind of research?

Please Explain:

20. Compensation

a) Will participants receive compensation or an incentive for participation?

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Financial Yes No

Non-financial Yes No

If Yes, to either, please provide details:

Please Explain:

b) If participants choose to withdraw, how will you deal with compensation?

Please Explain:

21. Participant Feedback

- **Feedback should be provided in a way which is accessible to participants. For example, some participants may not have access to a computer so uploading results to a website may not be sufficient.**

a) Explain what feedback/ information will be provided to the participants after participation in the project. (For example, a more complete description of the purpose of the research, or access to the results of the research). Indicate when results will be available.

Please Explain:

22. Annual Review and Adverse Effects

- **It is the Principal Investigator's responsibility to notify the REB the project is completed, or if it is cancelled, using the appropriate form.**
- **Adverse events (i.e. unanticipated negative consequences or results affecting participants) must be reported to each Research Ethics Board and the Research Ethics Coordinator as soon as possible using the form available on individual college websites. This must be reported to EACH institution directly.**
- **Protocol review requires the completion of a "Renewal/Completed Status Report" at least annually.**

a) Will this project require any additional monitoring or review?

Yes No N/A

If Yes, Please Explain:

23. Additional Information

a) Is there any other information relevant to the project that you wish to provide the Research Ethics Board?

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Please Explain:

SECTION D - SIGNATURES

Principal Investigator (PI) Assurance:

I, _____ [PLEASE PRINT] have the ultimate responsibility for the conduct of the study described in this application including my responsibilities as an advisor to any students involved in this project. I have read and am responsible for the content of this application. The information provided is complete and accurate. I understand that, as Principal Investigator, I will be the primary link with the REB at each institution, other researchers involved with this project, and the research participants. I agree to conduct the research in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, this individual college's policies and procedures for ethical Conduct of Research, and the conditions of approval indicated by the - _____ Research Ethics Board.

I also understand that if I make any changes whatsoever to the sample documents provided with this application (including, but not limited to, the recruitment scripts, information and consent letters, survey questions, interview or focus group questions), I need to complete a change request form and submit this to each REB for review. I further understand that these changes, if determined to be substantive by the REB, may require a new application if they constitute new research. If any changes are made in the above arrangements or procedures, or if adverse events are observed, I will bring these to the attention of the all institutional Research Ethics Coordinators immediately. I further understand that I may not start any research without receiving a Certificate/Letter of Ethical Acceptability. I further understand that ethical approval does not constitute institutional approval of this research.

I understand that if I fail to advise the participating REBs of any changes or adverse events, or fail to comply with research protocols outlined in this application, or make any unauthorized changes to any document submitted with this application, the Certificate of Ethical Acceptability may be rescinded by the REB.

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Name of Principal Investigator:

Signature of Principal Investigator:

Signature Date: [Click here to enter a date.](#)

Please contact each college to find out how and where to submit this form.

Note: If you send an electronic copy, this must be sent from your specific ISP. This electronic communication should be sent from a secure socket and sent from a secure address. If a fax is sent, this should be a scanned copy of the actual signature. Following this fax and/or electronic submission, the applicant should follow up with a verbal confirmation to be made to the REB Co-ordinator and should clearly indicate that this electronic copy is to be treated as your official digital signature.

Acknowledgement:

This form has been adapted with permission from a form developed by Conestoga College, which in turn was adapted from forms from the University of Guelph and McMaster University with their permission.