**FORM 1: APPLICATION FOR APPROVAL**

# **Instructions**

If you are planning to conduct research involving human participants, please complete this application form to obtain ethics approval from Seneca College’s Research Ethics Board (REB). This form is to be used by both **internal** and **external** applicants to obtain ethics approval before conducting research involving human participants. This form should be used by all faculty members and/or students conducting a research study, capstone, thesis, or an equivalent research project.

There are four (4) sections in this application form. Please take note of the following sections:

1. Section A: General Information
2. Section B: Project Details
3. Section C: Signatures
4. Section D: Applicant Submission Checklist

# **Submission Instructions**

The Seneca REB will only accept electronic versions of documents in Word or PDF format. Please complete all applicable sections and submit your application with all other appropriate documents to the REB Coordinator. **You are required to submit to the REB all research materials/tools that will be used for this research project**. Electronic signatures are accepted for Section C. You will receive an email acknowledgement of your submission within two (2) business days. The REB Coordinator will notify you if your application is complete and has been assigned for review or if your application requires modification. If a project is determined to be minimal risk, the revisions, requests for clarification, or requests for additional information (if necessary) will be returned in approximately ten (10) business days. Please note that if the project is determined to be greater than minimal risk the reviewing process requires greater scrutiny, which may increase the duration of the reviewing process.

**Additional Resources:** It is encouraged to view and/or use the additional ethics resources available on the Seneca College [REB webpage](http://www.senecacollege.ca/research/ethics-board.html).

# **Section A: General Information**

## **1. Title of Research Project**

(Enter text here)

## **2. Research Project Investigators’ Information**

*Where the PI is a student, the student’s supervisor/instructor must be indicated as the #1 Co-Investigator.*

Principal Investigator

**Name:** (Enter text here)

**Position:** (Enter text here)

**Institution:** (Enter text here)

**School/Department:** (Enter text here)

**Email:** (Enter text here)

**Phone:** (Enter text here)

#1 Co-Investigator

**Name:** (Enter text here)

**Position:** (Enter text here)

**Institution:** (Enter text here)

**School/Department:** (Enter text here)

**Email:** (Enter text here)

**Phone:** (Enter text here)

Other Project Investigators

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** |  | **Role in Project** | **Education/Credentials** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. Please specify if you are internal to Seneca College or an external applicant.

[ ]  Internal [ ]  External

1. Is this project being conducted in partial or complete fulfillment of a course, capstone, thesis, or an equivalent project at Seneca College?

[ ]  Yes [ ]  No

1. Is this project being conducted in partial or complete fulfillment for a Masters/Doctorate graduate program?

[ ]  Yes [ ]  No

1. As part of this research project, do you require access to institutional data related to Seneca faculty, students, administrators, or from any other employees at Seneca College? If “Yes”, institutional approval is required. Please include a completed and approved Seneca College institutional approval form.

[ ]  Yes [ ]  No

**3. Project Dates**

**Approximate Start Date:** (Enter text here)

**Approximate End Date:** (Enter text here)

**4. Project Location(s)& Other Research Ethics Board Approval**

### Project Location(s) & Ethics Approval (please specify institutions and/or organizations):

|  |  |  |
| --- | --- | --- |
| **College/University** | **City** | **REB Approval (Yes/No)** |
| Seneca College | GTA | No |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

\*If you have received REB approval from another institution please attach and submit the **official approval letter** and **all REB documents submitted** to that institution to the REB Coordinator along with this form or submit Form 3.

Please indicate if this is a multi-site project. If this project will only be conducted at Seneca College, please select “No”. (The Ontario Community College Multi-Site Form is also available from Seneca College REB website. Please follow the Multi-Site REB application procedure if conducting research at multiple Ontario Colleges.)

[ ]  Yes [ ]  No

**5. 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:** (Enter text here)

 **To:** (Enter text here)

**Sponsoring Organization:** (Enter text here)

**Contact person(s):** (Enter text here)

**Mailing Address:** (Enter text here)

**Telephone:** (Enter text here)

**Fax:** (Enter text here)

**E-mail:** (Enter text here)

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

|  |  |
| --- | --- |
| **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.

**6. Conflict of Interest**

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

1. 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)

(Enter text here)

1. 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:

(Enter text here)

1. 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:

(Enter text here)

1. Is there the possibility of commercialization of the research findings?

[ ]  Yes [ ]  No

If **Yes**, please explain:

(Enter text here)

# **Section B: Project Details**

## **7. Project Rationale**

##

Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined. Please include citations to relevant related research.

(Enter text here)

## **8. Methodology & Procedure**

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

1. 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.). What specifically will the research participants be doing from start to finish when participating in this research study?

(Enter text here)

1. Approximately how long will it take for participants to complete your research study?

Time: 00**hrs** 00**min**

1. Will participants be asked to repeat the current or any other research study at a future date because of their participation in this study? If ‘Yes’, please explain in the space below.

[ ]  Yes [ ]  No

(Enter text here)

1. Please specify who will be collecting the data from the participants. Provide your response in the space below.

(Enter text here)

1. Does this study involve administering a questionnaire/survey in a classroom? If ‘Yes’, please specify whether the researcher will be present during the administration of the research tool and justify why the chosen method is appropriate.

[ ]  Yes [ ]  No

(Enter text here)

1. Will any treatments, interventions, or manipulations be used in this study. If ‘Yes’, please describe in the space provided below.

[ ]  Yes [ ]  No

(Enter text here)

1. How will the data be collected and recorded (e.g. handwritten notes, video, recording, survey, etc.)? Provide your response in the space below.

(Enter text here)

1. Does this study involve the use or administration of any health products? If ‘Yes’, please provide more detail on the product that will be used/administered.

[ ]  Yes [ ]  No

(Enter text here)

1. Does this project involve the use of equipment/procedures that requires sterilization? If ‘Yes’, please indicate what specifically will be sterilized and the method of sterilization.

[ ]  Yes [ ]  No

(Enter text here)

1. Explain the process of data analysis briefly:

(Enter text here)

## **9. Participant Recruitment Method**

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

1. Please indicate the planned number of participants that will complete this study?

**#**000

1. Describe the demographics of the population that will be recruited for this study. Indicate location, gender (e.g. trans, gender non-conforming, male, female), and age range. If applicable, include specific participant inclusion/exclusion criteria.

(Enter text here)

1. How will participants be recruited? (Please attach to this form when submitting all recruitment material(s) including: posters, advertisements, letters, social media postings, etc.)

(Enter text here)

1. Does your recruitment plan require you to contact potential participants by:

|  |  |
| --- | --- |
| In-person *(Private location apart from Seneca)*  | [ ] Yes [ ] No [ ] N/A |
| 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. (Include copies of correspondence indicating those permissions if applicable.) *\*Please note that permission to recruit is different from obtaining consent for the study.*

(Enter text here)

1. Is there potential for participant(s) to feel coerced to participate in this study? Will any of the investigators have a position of power or authority over the participants (real or perceived)? If ‘Yes’, please provide a detailed explanation below of how you plan to mitigate coercion.

[ ]  Yes [ ]  No

(Enter text here)

**10. Research Involving Vulnerable Persons and/or Children**

1. Does this study target participants considered to be vulnerable, or dependent? If ‘Yes”, please explain below.

[ ]  Yes [ ]  No

(Enter text here)

Please specify if any of the following groups may or will be participating in your study.

[ ]  Persons with health problems

[ ]  Persons in long-term healthcare

[ ]  Persons with mental health issues

[ ]  Persons in a medical emergency

[ ]  Elderly population

[ ]  Children under the age of 16

[ ]  Persons unable to provide formal informed written consent

[ ]  Persons in prison

[ ]  Persons living in poverty

[ ]  Indigenous persons or communities

[ ]  Other: (Enter text here)

1. If applicable, explain what procedures have been implemented to ensure children participating in this study will be able to comprehend and understand the research being conducted and their voluntary participation in it. (Attach a Verbal Assent Script if applicable.)

(Enter text here)

1. Does this study involve students, teachers, or employees from local school boards in the York Region, Greater Toronto Area, or other school boards? If ‘Yes’, please specify and attach the official school board approval letter. (Please note that all school boards have their own REB approval process and you must obtain school board approval **before** applying for Seneca REB approval.)

[ ]  Yes [ ]  No

(Enter text here)

## **11 Possible Risks to Participants & Mitigation**

In your own judgment, what is the level of risk to participants in this study? Minimal risk research is defined as “research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research”.

 [ ]  Minimal [ ]  Greater than minimal risk

1. Identify who will be collecting the data and where:
2. **Indicate if the participants might experience any of the following risks:**
3. Physical risk (including any bodily contact or administration of any substance)

[ ]  Yes [ ]  No

1. Psychological risks (including feeling demeaned, embarrassed worried or upset, loss of self-confidence due to poor performance, regret)

[ ]  Yes [ ]  No

1. Social risks (including possible loss of status, privacy and/or reputation)

[ ]  Yes [ ]  No

1. Economic risks (including incurring expenses, loss of incentive)

[ ]  Yes [ ]  No

1. Academic risks (including loss of bonus marks or course standing)

[ ]  Yes [ ]  No

1. Potential access to personal data

[ ]  Yes [ ]  No

1. Legal risk (including apprehension or arrest, exposed identification of a legally-compromised group, revelation of child abuse)

[ ]  Yes [ ]  No

1. Are any possible risks to participants greater than those the participants might encounter in their everyday life?

[ ]  Yes [ ]  No

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

(Enter text here)

1. Please comment on the magnitudeof harm participants are likely to encounter i.e. would you assess it as minimal, substantial, transient or longer lasting?

(Enter text here)

1. Please comment on the probability that participants will encounter harm. I.e. would you assess it as low, medium or high?

(Enter text here)

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

(Enter text here)

1. Describe time and any travel demands expected of participants:

(Enter text here)

## **12 Possible Risks to the Researcher**

Please explain any risks to researchers, which you anticipate:

(Enter text here)

## **13 Possible Benefits of the Research Study**

Please describe what the benefits of this research study are to the participants, researchers, sponsoring organization, research community, and society-at-large. Justify why these benefits outweigh the potential risks involved in this study.

(Enter text here)

## **14 Voluntary & Informed Consent**

1. How will you be obtaining consent?

[ ]  Written [ ]  Verbal

For written consent, please **attach a copy of the Information/Invitation Letter** and **Consent form** for participants; for verbal consent, please attach the **script** for obtaining consent.

1. If consent will not be written, please provide details of how you will obtain consent:

(Enter text here)

1. Will any participants be minors (i.e. age 0-15)?

[ ]  Yes [ ]  No

1. Will all participants be competent to consent?

[ ]  Yes [ ]  No

**If the participants are minors or are not competent to consent:**

* 1. Describe the proposed alternate source of consent and **attach any permission/ information letter** to be provided to the person(s) providing alternate consent.

(Enter text here)

* 1. Who will obtain consent to participate for minors or those not competent to consent?

(Enter text here)

* 1. When and where will this be done?

(Enter text here)

1. Will participants have the option to withdraw from this study?

[ ]  Yes [ ]  No

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

(Enter text here)

If No, please explain why not:

(Enter text here)

1. Indicate what will be done with the participant’s data and any consequences to the participant withdrawing from the study:

(Enter text here)

1. Will you be using deception in your research?

[ ]  Yes [ ]  No

If Yes, provide rationale and debriefing plans:

(Enter text here)

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

(Enter text here)

1. When and how will that be done?

(Enter text here)

**15 Privacy & Confidentiality: Collection & 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.**
1. Will all data be treated as confidential?

[ ] Yes [ ] No [ ] N/A

If **No**, please explain:

(Enter text here)

1. Will you use a coding system to protect identifiable information?

☐Yes ☐No ☐ N/A

If NO, please explain:

 (Enter text here)

1. 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:**

(Enter text here)

☐ 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 and explain)

## Is there a reasonable chance that the researcher(s) may become subject to legal obligations to report participant information to authorities to protect the health, life, or safety of a participant or a third party (e.g. reporting children in need of protection)? (If yes, a statement regarding the obligation to report is required in the project information letter.)

[ ]  Yes [ ]  No

**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.**
* **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.**
1. How will you store and protect data without identifiers?

(Enter text here)

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

(Enter text here)

1. How long will you keep the study data? (Please note that upon publication most journals require the ownership of de-identified data to be transferred to the journal and the data to be stored indefinitely).

(Enter text here)

1. Who will take responsibility for data destruction after that time-period?

(Enter text here)

1. What will you do with the study data after this period?

(Enter text here)

**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.**
1. Do you plan on physically moving the data?

[ ]  Yes [ ]  No [ ]  N/A

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

(Enter text here)

1. If you are collecting data using an electronic device, will auto upload to cloud or auto-backup be turned off?

[ ]  Yes [ ]  No [ ]  N/A

If NO, please provide details on steps taken to ensure data security and privacy:

 (Enter text here)

1. 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

 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:

(Enter text here)

1. If data are being transmitted, where will the data be sent?

(Enter text here)

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

(Enter text here)

1. 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.**
1. Will you combine your research data with any other data sets?

[ ] Yes [ ]  No [ ]  N/A

If **YES -**

Identify the data set:

(Enter text here)

Explain how the linkage will occur:

(Enter text here)

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

(Enter text here)

1. Will your data be entered into another database for future use?

[ ]  Yes [ ]  No [ ]  N/A

If **YES**, please specify:

Where it will be stored:

(Enter text here)

Who will be the custodian?

(Enter text here)

Who will have access to the database?

(Enter text here)

What security measures will be in place?

(Enter text here)

## **19 Research Ethics Training & Experience**

1. Please confirm that the PI and all other investigators for this study have completed the [TCPS CORE Tutorial](https://tcps2core.ca/welcome) certification. (You are required to submit all TCPS 2 CORE certificates with this form.)

[ ]  Yes, both myself as the PI and all other investigators have completed the TCPS 2 CORE tutorial certification

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

(Enter text here)

## **20 Participant Compensation**

1. Will participants receive a form of compensation for their participation? If ‘Yes’, please specify (e.g. financial, gift card, non-financial, etc.).

[ ]  Yes [ ]  No

(Enter text here)

1. If applicable, please explain if and how the participants’ compensation for their participation will be affected if they choose to withdraw from the study.

(Enter text here)

## **21 Dissemination of Study Findings & Participant Feedback**

1. Do you anticipate publishing and/or presenting the study findings (e.g. academic journal, conference, research/academic forum, workshop, thesis, class presentation)? If ‘Yes’, please describe the planned dissemination of your study findings. (A statement regarding the dissemination of the project findings is required in the project information letter.)

[ ]  Yes [ ]  No

(Enter text here)

1. Will feedback on the research study findings be made available to participants? If ‘Yes’, please explain how and when the findings will be made accessible and how you will determine and follow through on the method of communication back to the participants.

[ ]  Yes [ ]  No

(Enter text here)

## **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.**
1. Will this project require any additional monitoring or review?

[ ]  Yes [ ]  No [ ]  N/A

If Yes, please explain:

(Enter text here)

##  **23 Additional Information**

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

(Enter text here)

#  **Section C: Signatures**

1. **Principal Investigator’s Signature**

I certify that the information in this document is true and correct to the best of my knowledge.

Principal Investigator’s Signature Job Title Date

1. **Instructor/Course Supervisor’s Signature (Student applicants)**

I am aware of and have approved this research project to be conducted as outlined in this document.

Instructor/Supervisor’s Signature Job Title Date

1. **Supervisor’s Signature (Chair/Director/Dean) (Seneca Faculty/Staff)**

I am aware of and have approved this research project to be conducted as outlined in this document.

Chair/Director/Dean’s Signature Job Title Date

# **Section D: Applicant Submission Checklist**

## **REB Submission Checklist**

1. I have read all the questions in this form and completed those applicable

to this research study. [ ]

1. I have signed this form acknowledging all information provided is true

and accurate. [ ]

1. I have obtained the signature of my respective instructor/supervisor/ Chair/Director/Dean (Internal applicants only). [ ]
2. I have obtained administrative approval to conduct the study at Seneca [ ]

(External applicant only)

1. I have attached the consent form that will be used for this research study. [ ]
2. I have attached my TCPS 2 CORE Certificate. [ ]
3. I have attached **all** research materials/ tools that will be used in this

research study including: recruitment documents, surveys, questionnaires, invitation to participate, verbal recruitment script, confidentiality

agreements, etc. [ ]

1. I have obtained permission for data collection at a non-Seneca site [ ]

(if applicable)

1. I will complete and submit a [Request Form for Amendment or Extension](http://www.senecacollege.ca/research/ethics-board.html)

if any changes are made to the study design/protocol or if the project will

not be completed on time as specified in this form. [ ]

1. I will complete and submit an [Adverse Event/Unanticipated Issue Form](http://www.senecacollege.ca/research/ethics-board.html)

in the event that one occurs. [ ]

1. When this study is complete I will submit a [Study Completion Form](http://www.senecacollege.ca/research/ethics-board.html). [ ]

Acknowledgement:

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