**Application to Involve Human Participants in Research**

If you have questions about this form, please contact the Research Ethics Coordinator at 519-748-5220, ext. 7108 or by email at rebcoordinator@conestogac.on.ca

Note**: Ethics approval does not constitute institutional approval by CCITAL to conduct research.**

Note**: If you are an external researcher (i.e. not a CCITAL faculty member, student, administrator or other employee), you will be required to have a locally responsible investigator who can provide support on-site for your research. Contact** **rebcoordinator@conestogac.on.ca** **for more information.**

Note**: Researchers must complete the free, on-line TCPS 2 training available** **here****. Researchers will be required to submit a Certificate of Completion of the TCPS 2 training in conjunction with their applications to the REB.**

Send this form and all accompanying supporting material as attachments by email to the Research Ethics Coordinator at rebcoordinator@conestogac.on.ca.

**Date:** Click here to enter a date. **(For Applied Research use only)**

**Protocol#:** Click here to enter text.

# SECTION A – GENERAL INFORMATION

1. Title of the Research Project: Click here to enter text.

For student applications:

Course title and number: Click here to enter text.

School and department: Click here to enter text.

2. Investigator Information

| Applicant | Name & Position | Department/Address | Phone. No. | E-Mail |
| --- | --- | --- | --- | --- |
| Principal Investigator (PI)\*: |  |  |  |  |
| Faculty:Co-Investigator(s) |  |  |  |  |
| Professor:Investigator(s) on student applications |  |  |  |  |
| Student:Investigator(s) |  |  |  |  |
| Other:Investigator(s) |  |  |  |  |

\* must be advisor of any student investigators**.**

3. Proposed Date

a) of commencement:

b) of completion:

**Note: The commencement date should be the date the principal investigator (PI) expects to actually begin interacting with human participants (including recruitment). The completion date should be the date that the PI expects that interaction with human participants, including any feedback or follow-up, will be complete.**

4. Indicate the location(s) where the research will be conducted:

 Conestoga College: [ ]  Brantford [ ]  Cambridge [ ]  Doon [ ]  Guelph [ ]  Waterloo

Other Organization (Please specify site):

5. Other Research Ethics Board Approval

* + 1. Is this a multi-centered study (i.e. does it involve more [ ] Yes [ ]  No [ ]  N/A

than one organization)?

Has any other institutional Ethics Board approved this project? [ ] Yes [ ]  No [ ]  N/A

* 1. If **Yes**, please provide the following information:

Title of the project approved elsewhere: Click here to enter text.

 Name of the Other Institution: Click here to enter text.

Name of the Other Ethics Board: Click here to enter text.

Date of the Decision: Click here to enter text.

 A contact name and phone number for the other Board: Click here to enter text.

**OR**

A copy of the clearance certificate/approval **AND**

final copies of all supporting documentation already approved

* + 1. Will any other Research Ethics Board be asked for approval? [ ] Yes [ ]  No [ ] N/A

1. If **Yes**, please specify which Boards:

6. Level of the Project

Faculty Research [ ]

Student Research [ ]

 Other (please specify):

7. Funding of the Project

* + 1. Is this project currently funded? [ ] Yes [ ]  No [ ] N/A
1. If **YES,** please indicate:

Period of Funding: From:       To:

Agency or Sponsor (funded or applied for)

 [ ]  CIHR:

 [ ]  NSERC:

 [ ]  SSHRC:

Other (please specify the complete title of the funding source)

**Note: If the funding source changes, or if a previously unfunded project receives funding, you must submit a** **change form** **to the Research Ethics Coordinator.**

8. Conflict of Interest

1. Will the researcher(s), members of the research team, and/or their partners or immediate family members:
2. 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

1. If **YES**, **please describe** the personal benefits below. (Do not include conference and travel expense coverage, possible academic promotion, or other benefits which are integral to the general conduct of research.)
	* 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 [ ]  N/A

If **yes, please explain.**

* + 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 [ ] N/A

If **yes, please explain.**

* + 1. Is there the possibility of commercialization of the research findings? [ ] Yes [ ] No [ ]  N/A

If **yes, please explain.**

**SECTION B – SUMMARY OF THE PROPOSED RESEARCH**

9. Rationale

* + 1. Describe the purpose and background rationale for the proposed project, as well as the hypothesis(es)/research question(s) to be examined.

10. Methodology

1. Describe sequentially, and in detail, 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.)

**Note: Attach a copy of all questionnaire(s), interview guides or other test instruments. These**

**should be on Conestoga College letterhead if they are intended for public dispersal.**

**Please explain the methodology.**

1. Does the nature of the research create vulnerability for any

 of the groups listed below? [ ]  Yes [ ]  No [ ]  N/A

* 1. If **YES**, check all that apply:

[ ]  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):

 If **YES in 10b) above**, **please explain** your screening process (maximum 5 lines):

**Note**: **Researchers must destroy all information collected during screening in a secure**

**manner as soon as screening is complete.**

Please explain how you will destroy your screening data securely.

# Recruitment

1. 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

[ ]  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)

[ ]  Educational records (e.g. academic performance information, Student Information System)

[ ]  Other (please specify):

1. Do you screen personal health information to identify [ ]  Yes [ ]  No [ ] N/A

potential participants?

1. Does your recruitment plan require you to contact potential participants by:
	* 1. Telephone [ ]  Yes [ ]  No [ ]  N/A
		2. Personal E-mail [ ]  Yes [ ]  No [ ]  N/A
		3. Anonymous Email [ ]  Yes [ ]  No [ ]  N/A
		4. Letter [ ]  Yes [ ]  No [ ]  N/A

**Note: If you answered YES to any category above, please attach a copy of all telephone**

**scripts and recruitment correspondence.**

# Informed Consent

**Note:**

* **Participants should *actively* choose whether or not to participate. A lack of response (i.e. a statement such as “you will be assumed to want to participate unless you indicate otherwise to the researchers”) should not be construed to imply consent.**
* **Written consent is not required in all circumstances. For example, you could require participants to click a box in an online survey or provide verbal consent.**
	+ 1. Will you be seeking *written* consent from participants? [ ]  Yes [ ]  No [ ]  N/A

If **YES**, please attach a copy of the Information Letter and Consent form for Participants and move to Question c).

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

 **Please explain:**

Will any participants be minors (i.e. age 0-15)? [ ]  Yes [ ]  No [ ] N/A

Will all participants have capacity to provide consent? [ ]  Yes [ ]  No [ ] N/A

If the participants lack the capacity to provide meaningful consent (see TCPS 2 Article 3), describe the proposed alternate source of consent. Please include any permission/information letter to be provided to the person(s) providing the alternate consent.

**Please explain:**

Who will provide consent to participate for those who lack the capacity to provide meaningful consent?

Please explain:

(Insert text box)

How will capacity to provide consent be determined?

**Please explain:**

When and where will this be done?

**Please explain:**

1. Do you need to request a waiver of consent? [ ]  Yes [ ] No [ ] N/A

If **YES**, **please explain**:

1. Will any of the investigators have a position of power or authority

over the participants? [ ]  Yes [ ] No [ ] N/A

**Note:**

**Undue influence and manipulation may arise when prospective participants are recruited by**

**individuals in a position of authority. The influence of power relationships (e.g., employers and**

**employees, teachers and students) on the ability to provide voluntary consent should be**

**judged from the perspective of prospective participants. Researchers should also pay**

**particular attention to elements of trust and dependency in relationships (e.g., between**

**physician and patient or between professor and student). These relationships can impose**

**undue influence on the individual in the position of dependence to participate in research**

**projects.**

If **YES**, how will you manage and minimize any undue influence? **Please explain**.

1. Will continuing consent (for example, research which may continue beyond

an academic year) be required during the study? [ ]  Yes [ ] No [ ] N/A

If **YES, please explain**:

1. Will participants have the option to withdraw from this study? [ ]  Yes [ ] No [ ] N/A

If **YES**, what do they have to do to withdraw? **Please explain.**

Indicate what will be done with the participant’s data and any consequences for the participant withdrawing from the study. **Please explain.**

1. If the participants will not have the right to withdraw from the project, **please explain** the rationale.
2. Will you be using deception in your research? [ ]  Yes [ ] No [ ] N/A

If **YES, please explain**:

# Collection of Personal Information

1. Please check all types of data which you intend to collect:

[ ] Identifying information which identifies a participant through direct identifiers

 (e.g. full name, medical record number)

[ ] Identifiable information which could identify a participant through a combination of indirect identifiers

 (e.g. DOB plus address)

[ ] De-identified/coded information in which identifiers are removed and replaced with a code;

the code can be used to re-identify participants

[ ] Anonymized information in which all identifiers are removed and no code is kept

[ ] Anonymous information in which no identifiers are collected

1. Will all data be treated as confidential? [ ]  Yes [ ] No [ ] N/A
2. If **NO, please explain**:
3. Will you collect any Personal Health Information (PHI)? [ ]  Yes [ ] No [ ] N/A

**Note:**

* **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)**
* **PHI should be collected at the lowest level of identification possible (e.g. initials instead of a name, age instead of DOB)**
1. Limit the amount and type of the information gathered to what is necessary for the identified purposes of the study. Please detail the specific identifiers required for this study:

| Identifier (check all which apply) | Why is this necessary? (Identified research purposes, contact information, other)  |
| --- | --- |
| [ ]  Full name |  |
| [ ]  Initials |  |
| [ ]  Student/Employee number |  |
| [ ]  Social Insurance Number |  |
| [ ]  Health Card Number |  |
| [ ]  Medical Record Number |  |
| [ ]  Address |  |
| [ ]  Full Postal Code |  |
| [ ]  Partial Postal Code |  |
| [ ]  Telephone Number |  |
| [ ]  E-mail |  |
| [ ]  Physician |  |
| [ ]  Date of Birth |  |
| [ ]  Age |  |
| [ ]  Gender Identity |  |
| [ ]  Other: (Specify) |  |

e) How will you record study data?

[ ]  Case report form.

[ ]  Other (please specify):

# Storage and Protection of Information

**Note: 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 they must be encrypted.**
* **Electronic files with identifiable information may be stored on mobile devices (e.g. laptop, CD, USB, PDA), but no alternative method of storage; these files must be encrypted.**
* **Identifying and/or identifiable PHI cannot be transmitted by email unless it is encrypted**

**Note: Coding**

* **Identifying and/or identifiable PHI should be protected by a coding system**
* **The code (study ID and identifiable PHI) must be isolated from study data and**

**stored in a secure manner**

* 1. Will you use a coding system to protect identifiable information? [ ]  Yes [ ]  No [ ]  N/A
		1. If **NO, please explain**
1. How will you store and protect the study code (or other data with identifiers)?

| Type of Record | Required Protection | Location (i.e. building/room) |
| --- | --- | --- |
|  | [ ]  Locked cabinet in locked institutional office |  |
|  | [ ]  Password protected computer on a secure network |  |
|  | [ ]  Encrypted (specify software used): |  |
|  | [ ]  Identifiers and participant data are stored separately |  |

1. How will you store and protect data without identifiers? **Please explain.**
2. Do you plan to anonymize the study data? [ ] Yes [ ]  No [ ]  N/A
	* 1. If **YES**, when? **Please explain.**

**Note: You are required to destroy identifiers or links at the earliest possible time.**

1. How long will you keep the study data?

**Note: If this study requires Health Canada approval, records must be retained for 25 years.**

**For all other studies, the REB recommends 7 years. Sponsors and institutions may set out**

**other requirements.**

1. Do you plan on physically moving the data? [ ]  Yes [ ]  No [ ]  N/A
	* 1. If **YES**, how will the data be secured while in motion? **Please explain.**

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

**Note: 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.**

1. Transmission of Data
2. Will the research data be moved outside its original location of collection (for example, sent for transcription or uploaded to a central data repository? [ ]  Yes [ ]  No [ ]  N/A
3. If **YES**, does this data to be transmitted include identifiers? [ ]  Yes [ ]  No [ ]  N/A
	1. If **YES**, please provide details on the data transfer agreement. **Please explain.**
	2. If **YES**, where will the data be sent?  **Please explain.**

**Note: 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.**

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

**Note: 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.**

| Name | Institutional Affiliation |
| --- | --- |
| Name | Institution |
| Name | Institution |
| Name | Institution |

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):

# Secondary Use of Data

**Note: According to TCPS 2 (2018),** **secondary use of data** **refers to: “the use in research of information originally collected for a purpose other than the current research purpose.” It includes data sets that are collected for specific research or statistical purposes but then re-used to answer other research questions, or incidental findings or discoveries made in the course of research but that are outside the original purpose for which that data was collected.**

**Any secondary use of data must be approved by the REB prior to its use. Consent should be obtained for all anticipated uses of the data collected. For additional guidance on the secondary use of data, please contact the REB Coordinator at** **rebcoordinator@conestogac.on.ca****.**

1. Will you combine research data for this study with another data set? [ ] Yes [ ]  No [ ]  N/A
2. If **YES**, please specify:

Identify the data set:

Explain how the linkage will occur:

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

Can linkage of datasets produce identifiable data?

1. Will your data be entered into another database for future use? [ ]  Yes [ ]  No [ ]  N/A
2. If **YES**, please specify:

Where it will be stored?

Who will be the custodian?

Who will have access to the database?

What security measures will be in place?

1. Will participants be asked to provide consent for secondary use of data? [ ]  Yes [ ]  No [ ]  N/A

 Can consent for secondary use of data be retroactively obtained? [ ]  Yes [ ]  No [ ]  N/A

* + 1. If **NO**, please specify why consent for secondary use cannot be obtained:
1. **Dissemination of Findings**

a) How do you anticipate disseminating your results?

[ ]  Directly to participants

[ ]  Class presentation/course assignment

[ ]  Published article

[ ]  Conference presentation

[ ]  Internet (e.g. blogpost, podcast)

[ ]  Other (please specify:

# Experience

1. What is your experience with this kind of research? **Please explain.**

**Note: Researchers must complete the free, on-line TCPS 2 training available** **here****. Researchers will be required to submit a Certificate of Completion of the TCPS 2 training in conjunction with their applications to the REB.**

#  Compensation

1. Will participants receive compensation for participation?
	* 1. Financial[ ] Yes [ ] No [ ]  N/A
		2. Non-financial [ ] Yes [ ] No [ ]  N/A

1. If **Yes** to **either** i) or ii) above, **please provide details**.
2. If participants choose to withdraw, how will you deal with compensation? **Please explain.**

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

# Possible Risks to Participants

1. Indicate if the participants might experience any of the following risks: Yes No N/A
	* 1. Physical risk (including any bodily contact or administration of any

substance)? [ ]  [ ]  [ ]

* + 1. Psychological risks (including feeling demeaned, embarrassed worried

or upset)? [ ]  [ ]  [ ]

* + 1. Social risks (including possible loss of status, privacy and/or reputation)? [ ]  [ ]  [ ]
		2. Economic risks (including incurring expenses, loss of incentive)? [ ]  [ ]  [ ]
		3. Academic risks (including loss of bonus marks or course standing)? [ ]  [ ]  [ ]
		4. Potential access to personal data [ ]  [ ]  [ ]
		5. Are any possible risks to participants greater than those the participants

might encounter in their everyday life? [ ]  [ ]  [ ]

1. If you answered **YES** to any of Points i) through vii) above, **please explain the risk**.
2. 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?

**Note: Conestoga has developed a** **level of risk to participants’ assessment tool** **which may be useful to help you determine the magnitude and probability of risk**

1. Please comment on the **probability** that participants will encounter harm, i.e. would you assess it as low, medium or high? **Please explain.**
2. Describe how the risks will be managed (including an explanation as to why alternative approaches could not be used). **Please explain.**

# Possible Risks to Researchers

**Please explain any risks to researchers which you anticipate and how you plan to mitigate or address these risks.**

# Possible Benefits to Participants

1. Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific community/society that would justify involvement of participants in this study. **Please explain.**

**SECTION D – PARTICIPANT FEEDBACK**

1. 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 and, if they will be made available on the internet, the URL to be used to access the results:

**Note: 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.**

**Please explain.**

**SECTION E – MONITORING ONGOING RESEARCH**

# Annual Review and Adverse Events

1. Protocol review requires the completion of a “Renewal/Completed Status Report” at least annually. Indicate whether any additional monitoring or review would be appropriate for this project. **Please explain.**

**Note: It is the principal investigator’s responsibility to notify the REB using the “Renewal/Completed Status Report” when the project is completed, or if it is cancelled.** **The form is available** **here****.**

1. **Adverse events** (i.e. unanticipated negative consequences or results affecting participants) must be reported to the Research Ethics Board and the Research Ethics Coordinators soon as possible using the form available **here****.**

# Additional Information

**Please explain.**

(Use an additional page if more space is required to complete any sections of the form, or if there is any other information relevant to the project that you wish to provide to the Research Ethics Board.)

# List of Attachments

Below, please indicate the files or attachments being submitted in support of this application.

|  |  |
| --- | --- |
| [ ]  | TCPS 2 certificate |
| [ ]  | Information letter |
| [ ]  | Consent form |
| [ ]  | Scripts (web/email/telephone/focus/interview guide) |
| [ ]  | Script of oral explanation given to participants |
| [ ]  | Questionnaires/test instruments |
| [ ]  | Debriefing script/written feedback |
| [ ]  | Any tools/posters/web announcements used to recruit participants |
| [ ]  | Clearance from other REBs |

**SECTION F – 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, 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, Conestoga College ITAL Policies and Procedures for Ethical Conduct of Research, and the conditions of approval indicated by the Conestoga College 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 the 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 Research Ethics Coordinator immediately. I further understand that I may not start any research at CCITAL without receiving a Certificate 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 REB 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.**

**Name of Principal Investigator:** Click here to enter text.

**Signature of Principal Investigator:**

**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 Coordinator and should clearly indicate that this electronic copy is to be treated as your official digital signature.**

Acknowledgement: This form has been adopted from the University of Guelph and McMaster University with permission and adapted for Conestoga College. Conestoga College gratefully acknowledges the contribution of the Universities in this regard.