University of Guelph

Research Ethics Board (REB)

Application to Involve Human Participants in Research Guidelines

# DIRECTIONS

## How to submit:

* Email the completed form with all accompanying documentation
* Submit **each document** as **an individual file** – do not merge
* Word documents are preferred
* Email to [reb@uoguelph.ca](mailto:reb@uoguelph.ca)

## How to answer questions:

* T The questions asked are drawn from the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, 2nd Edition ([TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/))
* There is an online tutorial – [the CORE tutorial](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) - discussing the TCPS2 which anyone can take. Create a new account using your University email address. This tutorial is highly recommended for everyone and MANDATORY for University of Guelph students
* Not all questions will apply to your research. Feel free to choose the n/a option, or explain in the text box. Do not leave questions unanswered.
* Information buttons [This hyperlink will bring you to the REB Human Application Guidelines](https://www.uoguelph.ca/research/reb-human-participants-application-guidelines) will provide information about the question, where the topic can be found in the TCPS2, and sometimes suggested responses. Information can be accessed using CNTRL Click OR you can consult the information guide, and find the entry using the section letter and question number.
* This form is ‘unlocked’ to allow the ‘cut and paste’ function and the ‘track changes’ function to be used. You can use Ctrl F to navigate the form. Please do not delete questions you think do not apply – just choose n/a.
* For ease of navigation, no to ‘View’ and choose “Show Navigation Pane”. Doing so will enable you to move back and forth between sections.
* SECTION A: OVERVIEW

## A.1 Title of Research Project

Choose a short, unique title. You do not have to duplicate your grant or thesis title. Consider choosing a title which can be used on consent and recruitment documents and will be accessible to, and provide information for your research participants.

## A.2 Summary of Research

Provide a one paragraph summary in lay language of your research project.

## A.3 Background and Justification

Provide references, disciplinary background which frames your clearly stated research question/hypothesis, include a discussion of justification (i.e. the work has not been done before, or done as being proposed).

## A.4 Research Steps

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 6; [Article 6.11](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.11): "Researchers shall submit their research proposals, including proposals for pilot studies, for REB review and approval of its ethical acceptability prior to the start of recruitment of participants, access to data, or collection of human biological materials. REB review is not required for the initial exploratory phase, which may involve contact with individuals or communities intended to establish research partnerships or to inform the design of a research proposal”.

Use a flow diagram, point form, simple language, to explain what your participant will experience in a step by step manner from beginning to the end of the project.

**Example 1**

Participants will be recruited with flyers and invited to contact the research team. (see Appendix A for recruitment poster)

Focus groups will be run to determine general viewpoints about the particular topic area. (see Appendix B for consent documents and Appendix C for consent scripts)

Information from focus groups will inform an online survey. This will be submitted to the REB once final questions are determined.

Information from the online survey will be presented to the community in the form of workshops. (see Appendix I for invitation poster)

**Example 2**

Interested participants will respond to posters (Appendix A) by contacting the graduate student (name) by email.

First meeting:

1. Screening using health questionnaire (Appendix B)
2. Consent process (Appendix C)
3. Both screening and consent will be undertaken by the student under the direct supervision of the PI. Exclusionary questions will be monitored by the PI.
4. Anthropometric measures
5. Initial blood draw
6. Distribution of test substances (see Appendix D for details)
7. Distribution of 3-day food record with instruction on use (see Appendix E)

Second meeting:

1. Arrive fasted
2. Provide blood sample followed by light snack (see Appendix F for details on snack contents)
3. Bicycle to exhaustion (See Appendix G - SOP on VO2 max)
4. Take muscle biopsy
5. Hand in 3-day food record
6. 24 hours later: follow up with participants to monitor outcome (See Appendix G)
7. Provide results to individuals (see appendix H)

## A.5 Methods/Procedures

List the methods you will undertake. This list will inform how you fill out the rest of this application – you must discuss each section from the perspective of each method you plan to use.

Examples of methods are:

* focus groups;
* interviews;
* eSurveys;
* anthropometric measures;
* blood draws;
* exercise;
* talking circles; and
* participant observation, etc…

Risks, benefits, expertise of the researcher, the need for privacy – all of these things vary depending on what kind of activity the participant is going to engage in. Make sure you think through each of the ‘methods’ you plan to use when answering each question.

## A.6 Documents Attached

Please list all the documents attached to this submission – expand table as necessary by tabbing.

## A.7 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION B: COLLABORATORS

The research team should consist of the Principal Investigator (PI) - the individual who has ultimate responsibility for the conduct of the study, and everyone who will have access to identified data or direct contact with participants.

## B.1 Principal Investigator

The PI will receive all communications throughout the review process and is responsible for forwarding communications, as appropriate, to other team members.

In the case of graduate level research, the PI must be the faculty advisor/supervisor of the graduate student.

## B.2 University of Guelph Faculty Coinvestigators

**TBA**

## B.3 University of Guelph Student Coinvestigators

[CORE](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/) provides an applied approach to the guidance provided in TCPS2. This self-paced course is a media-rich learning experience that features interactive exercises and multi-disciplinary examples. CORE consists of eight modules ranging from Core Principles to REB Review. It is designed primarily for the use of researchers and REB members – though anyone may take this course and print their own certificate of completion. This course, while not mandatory, is strongly recommended by the REB.

## B.4 External Coinvestigators

If an external team member will have direct contact with participants or access to identified data, they should seek ethics clearance from their home institution. Please submit a copy of a certificate or discuss why you will not be seeking ethics approval.

## B.5 Level of Project

Data from one project may contribute to a faculty member's research enterprise, as well as contributing to a graduate student's thesis. Each can be indicated separately under that person's name. Knowing the level of research helps the REB reviewers to determine the degree of risk, and how it might be managed.

## B.6 Experience and Licensed Qualifications

### B.6.1 PI Experience

Some research requires the researcher to have specific qualifications (clinical psychologist, chiropractor, phlebotomist). Please outline these here if this applies to your work.

Some higher risk research project should only be undertaken by a researcher experienced in the field. Please outline these here if this applies to your work.

### B.6.2 Researcher Expertise or Qualifications

Some research requires the researcher to have specific qualifications (clinical psychologist, chiropractor, phlebotomist). Please outline these here if this applies to your work.

Some higher risk research project should only be undertaken by a researcher experienced in the field. Please outline these here if this applies to your work.

## B.7 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION C: APPROVALS

## C.1 International Research

### C.1.1 Centre for International Programs

Students travelling to foreign countries must register with the [Centre for International Programs](https://www.uoguelph.ca/cip/) prior to departure.

### C.1.2 Ethics Approval in Foreign Countries

If you are undertaking research outside of Canada, you must do at least one of the following:

* obtain ethics approval from an REB/IRB in that country;
* liaise with an institution (University or NGO, for example) in that country which can review your work to ensure that it is culturally acceptable;
* liaise with individuals from that country who can help to guide your research project;
* explain to the REB what other mechanism you will use to ensure that your research is culturally appropriate. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.4), Chapter 8; [Article 8.4](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.4)
* To help locate REBs/IRBs in foreign countries, you can use the following:
* IRBs registered with the [Office for Human Research Protections (OHRP) of the US Department of Health & Human Services](https://ohrp.cit.nih.gov/search/search.aspx?styp=bsc) can be searched, giving you information about IRBs available in countries around the world.
* You can refer to the [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/sites/default/files/2018-International-Compilation-of-Human-Research-Standards.pdf) compiled by the US Department of Health & Human Services on their website.

## C.2 Internal University of Guelph Approvals

### C.2.1 Animal Care Services

**TBA**

### C.2.2 Biosafety

**TBA**

## C.3 External Approvals

### C.3.1 External Ethics Review

You may need to obtain REB approval from another institution if you are involving their employees, students, or facilities. Approval from the University of Guelph REB will not be withheld, but research should not begin until such approval is in place, and the U of G REB has been provided with a copy of the approval notice. Faculty members from another institution who have access to identified data or direct contact with participants will also need to inquire from their home institution, regarding whether ethics review will also be required there.  
[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 6; [Article 6.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6/#ch6_en_a6.1)

### C.3.2 External Permissions/Approvals

Researchers are responsible for ascertaining and complying with the laws, regulations, or customs of the jurisdiction where the research will take place. In some cultures, community consent is required prior to obtaining individual consent. This question gives the researcher the opportunity to discuss unique requirements for their project, and how these requirements will be addressed. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 1, Chapter 8; [Article 8.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter8-chapitre8/#ch8_en_a8.3) (b) and Chapter 9; [Article 9.11](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#ch9_en_a9.11)

## C.4 Peer Review

### C.4.1 Funding

The REB takes a proportionate approach to the interpretation to Chapter 2; [Article 2.7](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.7) of the [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) which states "As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research".  
If the work under review has been peer reviewed elsewhere (for example during the funding process, or by a graduate committee) then the REB will not usually comment on the methodology.  
If the project poses at most minimal risk to participants, the REB will usually not make methodological comments.  
If the project poses higher than minimal risk to participants, the REB may require external peer review.

### C.4.2 Graduate Advisory Committees

The REB takes a proportionate approach to the interpretation to Chapter 2; [Article 2.7](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.7) of the [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) which states "As part of research ethics review, the REB shall review the ethical implications of the methods and design of the research"  
If the work under review has been peer reviewed elsewhere (for example during the funding process, or by a graduate committee) then the REB will not usually comment on the methodology.  
If the project poses at most minimal risk to participants, the REB will usually not make methodological comments.  
If the project poses higher than minimal risk to participants, the REB may require external peer review.

## C.5 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION D: SPONSORS AND CONFLICT OF INTEREST

## D.1 Sponsor

The name of the sponsor is required to establish any conflict of interest issues. The University of Guelph, through the Memorandum of Understanding with the Tri-Agencies, has agreed not to release funds to researchers until all compliance permissions are in place. This section allows the Office of Research to link the human ethics clearance with the funding source, so that Research Finance can release funds as appropriate. If funds are required before it is possible to submit an ethics application, contact the Ethics Office ([reb@uoguelph.ca](mailto:reb@uoguelph.ca)) for assistance. The identity of the sponsor must be disclosed as part of the informed consent process. See [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) Chapter 3; [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2)

**Note:** Scholarships need not be reported

Is this project currently funded?

If **NO**, this indicates that you are receiving no support for this project, including in-kind or anticipated support.

If **YES**, indicate the name of your sponsor (whether financial or in-kind) in the box below.

**Note:** Scholarships need not be reported

If **PENDING**, when funding is received, please update through an amendment submission. You will also need to amend consent forms, listing the amended funding source.

## D.2 Contract or Research Agreement

The REB needs to review your contract or research agreement in order to ensure that there are no inconsistencies between the agreement/contract and the REB application. Ethics Office personnel will work with Research Services Office personnel and the research team to finalize the agreement.

Question: Has a copy of the agreement been submitted to the Research Services Office for review?

All agreements must be reviewed by the Research Services Office.

## D.3 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

## D.4 Conflict of Interest (COI)

Is there a conflict of interest management plan?

**Info:** If you have already filed a conflict of interest management plan with your Dean/Director, then you should not have to repeat that information in this form. Choose 'yes' and upload a copy with your application form. If you have not filed a conflict of interest management plan, then choose 'no' and complete the series of conflict of interest questions on the application form.

If **YES**, please submit the COI management plan with your ethics application.

### D.4.1

The REB is charged with dealing with conflict of interest (COI) at the institutional level, within the REB itself, and at the level of the research team. Chapter 7 [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) The PI should answer these questions, taking into consideration all of his or her team members. Of particular importance for Human Ethics, is the last question "Describe any personal or professional relationship between a member of the research team and any participants aside from the researcher/participant relationship." Consider dual roles for yourself, and for your research team members such as researcher/instructor; researcher/TA; researcher/employee or colleague. Provide a discussion of how conflicts of interest (COI) due to dual roles in particular can be managed. COI is usually most effectively dealt with through disclosure - usually during the consent process. Consider the potential for conflict between the interests of the sponsor, and of members of the research team (such as the balance between protection of sponsor’s IP and the need for graduate students to publish) Consider the potential for conflict between the interests of the sponsor and the interests of the research or the participants themselves. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) Chapter 3; [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2); Application (e). Consider the potential for conflict between a member of the research team and the participants. This can also be discussed as a potential for ‘undue influence’ or ‘coercion’ by the research team. Note that any employment on the part of a member of the research team may place them in a position of COI (power over) the participant. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) Chapter 3; [Article 3.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.1); Application (a)

### D.4.2

Such restrictions usually occur within a contract or research agreement. Ensure that in such agreements, there is the right to disseminate research results both to enhance the benefits of the research project, and to support any graduate student involved in the project.

### D.4.3

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2) indicates "information concerning the possibility of commercialization of research findings" must be included in the consent form. See also Chapter 9; [Article 9.13](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#ch9_en_a9.13); [Article 9.18](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#ch9_en_a9.18), Chapter 12; [Article 12.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.2); [Article 12.6](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.6); [Article 12.13](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter12-chapitre12/#ch12_en_a12.13) and Chapter 13; [Article 13.7](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter13-chapitre13/#ch13_en_a13.7)

### D.4.4

This may include dual role relationships or power-over relationships such as: - advisor/student - instructor/student - clinician/client - physician/patient [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 7, Dual Roles Dual roles of researchers and their associated obligations (e.g., acting as both a researcher and a therapist, health care provider, caregiver, teacher, advisor, consultant, supervisor, student or employer) may create conflicts, undue influences, power imbalances or coercion that could affect relationships with others and affect decision-making procedures (e.g., consent of participants). Chapter 3; [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2)(e) reminds researchers of relevant ethical duties that govern real, potential or perceived conflicts of interest as they relate to the consent of participants. To preserve and not abuse the trust on which many professional relationships rest, researchers should be fully cognizant of conflicts of interest that may arise from their dual or multiple roles, their rights and responsibilities, and how they can manage the conflict. When a..." patient should be withdrawn). It is important REBs appreciate the potential conflicts between these roles and the possible impact on the welfare of prospective participants.

### D.4.4

**TBA**

## D.5 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION E: RESEARCH LOCATION

The physical location (building, room, laboratory) can have an impact on the risks to both participant and to researchers, as can the geographic location (country, city, neighbourhood) in which research is taking place. There may also be the need for permission from owners or other authorities. When entering locations (physical or geographic), provide only the data which is pertinent to your project. For e-surveys, for example, you might only want to indicate the country(ies) targeted by your recruitment, even though it is possible that the research might be 'done' in any country.

## E.1 International Research Location

### E.1.1

**TBA**

### E.1.2 Travel Advisories

Look up the [Canadian Travel Advisory](https://travel.gc.ca/travelling/advisories) for the country in which you propose to undertake research. The only travel advisories of import are 'avoid non-essential travel' or 'avoid all travel'. If one of these two advisories is listed for the country in question or for the region through which you plan to travel or in which you plan undertake research indicate which researcher will be travelling to this area, and justify the risk being taken.

## E.2 Physical Research Location

This refers to where the researcher and/or the participant will physically be when the research takes place(building, room, laboratory). - web based research, please choose 'other' and indicate your project is web-based.

## E.3.Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION F: Research Language

## F.1 Literacy

Best practice is to go over the consent information verbally with participants to ensure that they have been provided with all the pertinent information. Then give them an opportunity to read the consent information document. This way all participants, regardless of the level of literacy, will have read or heard the important consent information.

## F.2 Language

### F.2.1

**TBA**

### F.2.2 Research Not Conducted in English

#### F.2.2.1

If the language the research is conducted in differs from the language which the participant is fluent in an interpreter must be provided.

#### F.2.2.2

**TBA**

#### F.2.2.3

## If the language the research is conducted in differs from the language which the participant is fluent in all research documents provide to the participant must be translated into the appropriate language.

Back translations are not currently required for minimal risk studies, but may be required for higher risk or more complex studies.

## F.3.Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION G: RESEARCHER INVOLVEMENT

For each method you plan to undertake, list the collaborator(s) who will be involved and the expertise each one has.

Methods might include - Focus groups - Interviews (Key informant; Skype; phone, for example) - Questionnaires or surveys (face to face; paper; Qualtircs; other online, MTurk, for example) - Observation (naturalistic; participant, for example) - Invasive physiological measurements (venipuncture; GVS; finger prick; muscle biopsies; TMS, etc - Ingestion/sensory testing - Non-Invasive physiological measurements (Collection of personal health information; heart rate; blood pressure, anthropometrics, force plate/balance; Optitrak, for example) - Exercise - Psychological tests/assessments (Researcher generated; published scale, for example) - Cognitive or perceptual experiments (computer administered tasks, for example) - Data linkage (medical records; student records, for example) - Data collection (journals; video recording; audio recording; photography, for example) - Collection of biological materials (human tissue; body fluids for example) - Genetic analysis.

## G.1 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION H: RISKS

List each method you propose to undertake, and answer the questions about that particular method. If the same information pertains to multiple methods, then they can be grouped. If the same information pertains to all methods, simply state 'all'

Risk Type:

* **Examples Economic** - an employee risks a job by expressing unpopular views; a farmer risks access to services by criticizing an NGO
* **Physical** - bruising from a blood draw; sore muscles from an exercise routine Privacy - an interview recording is made public
* **Social** - a participant expresses unpopular views in a focus group; a person is seen by peers taking part in a critical study
* **None** - there are very few studies (with the possible exception of anonymous surveys on innocuous topics) which pose no risk at all to participant. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) Chapter 2; [Part B](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1b)

Risk Level:

* **Minimal** - "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." [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) Chapter 2; [Part B](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#toc02-1b)
* **Medium** - poses more risk than the participant would face in everyday life
* **High** - requires a high level of care due to risk posed to participant

## H.1

**TBA**

## H.2 Mitigation

**TBA**

## H.3 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION I: BENEFITS

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter; [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2) (f) There may be no direct benefit to participants

- if this is the case, this should be stated. Vulnerable participants must either benefit directly, or that vulnerable population in general must benefit.

Clear statements of the benefits which may accrue to society and/or the discipline must be outlined.

The REB will examine the risk of harm, and balance this with the benefits as outlined in this section. In order for the project to go ahead, the benefits must outweigh the risks of harm to the participants.

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 2; [Part B](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/" \l "toc02-1b)

## I.1 Benefits to Participants

**TBA**

## I.2 Benefits to Discipline or Society

**TBA**

## I.3 Feedback to Participants

### I.3.1

While the REB does not absolutely require that researchers provide aggregate feedback to participants, this is strongly advised. Receiving the results from the project they participated in may ensure that participants understand that their contribution is valued by the research community, ensuring their continued support of the research enterprise.

### I.3.2

Providing individual results to participants is not always appropriate. Care must be taken that in providing results, it is made clear that the results are experimental and are not diagnostic in nature (unless member(s) of the research team have the professional capacity to diagnose). Care must be taken that in providing individual results to one participant, you do not thereby reduce the privacy conferred on other participants.

## I.4 Dissemination

Researchers may not know how dissemination will occur, but communicating intention is important, and often should be discussed in consent information, as should any limits to use or disclosure. This question is mandatory ONLY for clinical trials. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 11; [Article 11.12](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter11-chapitre11/#ch11_en_a11.12)

With respect to research findings: Institutions and REBs should take reasonable measures to ensure that sponsors, researchers and institutions publish or otherwise disseminate the analysis of data and interpretation of clinical trial results (i.e., the findings) in a timely manner without undue restriction. Any prohibition or undue limitation on the publication or dissemination of scientific findings from clinical trials is ethically unacceptable. Institutions should develop reasonable written policies regarding acceptable and unacceptable clauses in clinical trial research contracts relating to confidentiality, publication and access to data.

## I.5 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION J: PARTICIPANTS

## J.1 Fairness and Equity

### J.1.1

**TBA**

### J.1.2

**TBA**

## J.2 Participants

### J.2.1

The size of the pool is important to determine the ability to offer anonymity. If you are interviewing 3 people out of a possible 6, it is much more likely that others may 'guess' who took part and try to attribute data to one individual. If you are interview 3 people out of a possible 50, attribution would be highly unlikely. The general rule is that there must be at least 8 people in any one 'pool' or 'data set' in order to promise confidentiality.  
  
If there is a significant amount of time between interactions, then participants should be re-consented. This can take a number of forms, and is dependent on the context of the project. Consider whether it might be appropriate to remind participants of the consent information at subsequent interactions. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.3)

Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

### J.2.2

How will you decide who takes part? Males, females, over 18, diabetic, etc. You do not have to repeat one criteria - in other words if your inclusion criteria is 18 to 40 years of age, you do not have to indicate that exclusion criteria would be less than 18 years of age.

## J.3 Recruitment

### J.3.2

**TBA**

### J.3.2

Privacy legislation says that non-public information cannot be accessed for the purposes of research recruitment unless permission is already in place to share this personal information. Is such permission in place? Who obtained that permission?

## J.4 Incentives

### J.4.1 Financial Incentives

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.1) Incentives are anything offered to participants, monetary or otherwise, for participation in research (incentives differ from reimbursements and compensation for injury, which are discussed in [Article 3.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.2) [j]). Because incentives are used to encourage participation in a research project, they are an important consideration in assessing voluntariness. Where incentives are offered to participants, they should not be so large or attractive as to encourage reckless disregard of risks The onus is on the researcher to justify to the REB the use of a particular model and the level of incentives. In considering the possibility of undue influence in research involving financial or other incentives, researchers and REBs should be sensitive to issues such as the economic circumstances of those in the pool of prospective participants, the age and decision-making capacity of participants, the customs and practices of the community, and the magnitude and probability of harms. Guardians and authorized third parties should not receive incentives for arranging the involvement in research of the individual they represent. However, they may accept reasonable incentives or compensation on behalf of that individual, as long as these are suitable to the circumstances.

Currently, there are two ways that researchers can be reimbursed for incentives paid to participants.

1. Keep track of payments using participant ID numbers or gift card numbers, for example. Researchers often have participants initial for receipt of payment. This evidence is then submitted through a travel expense claim, and coded to the appropriate grant account.
2. Provide the participants name, address, and SIN number to Financial Services, and have Financial Services provide a cheque. Regardless of the option chosen, the participant must be told how payment of incentives will be documented, during the consent process.  
   **NOTE:** Policy on reporting payments to Financial Services is currently under development. Please check with your administrative staff for directions."

#### J.4.1.1 Draws

If you wish to use a draw as an incentive, you must communicate to the participant what they may win, the dollar value of the prize, and the likelihood that they will win this prize. You can state the chances of winning (e.g. 1/100, 1/50), or you can state how many people are eligible. (e.g. We estimate that there will be 500 people taking part, and there will be two prize draws of $250). Please establish in this section of your application, who will draw the prize, how the winner will be notified, the number of times contact will be attempted, what will happen if the winner cannot be reached, and how personal information will be managed (how long kept and where stored).

### J.4.2 Incentives – Non-Financial

Dollar Value: What would it cost to buy the item(s) you are providing to participants?

### J.4.4 Course Credits

**TBA**

### J.4.4 Additional Costs to Participants

**TBA**

### J.4.5 International

If you are in a unique community (e.g. prison, school, Northern community) or if you are in country outside of Canada, what would it cost to buy what you are giving the participant? What is the value beyond the financial value?

### J.4.6 Withdrawing

Participants should receive any incentives or reimbursements if they chose to withdraw. These payments can be prorated based on level of participation. "The participant should not suffer any disadvantage or reprisal for withdrawing nor should any payment due prior to the point of withdrawal be withheld. If the research project used a lump-sum incentive for participation, the participant is entitled to the entire amount. If a payment schedule is used, participants shall be paid in proportion to their participation.

## J.5 Participant Privacy

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 5: Privacy

Privacy refers to an individual’s right to be free from intrusion or interference by others. It is a fundamental right in a free and democratic society. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. Research affects these various domains of privacy in different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself. The concept of consent is related to the right to privacy. Privacy is respected if an individual has an opportunity to exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure of information (see Chapter 3 for further discussion of consent).

[Article 5.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#ch5_en_a5.1) Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality. Article 5.2 Researchers shall describe measures for meeting confidentiality obligations and explain any reasonably foreseeable disclosure requirements: - in application materials they submit to the REB; and - during the consent process with prospective participants.

[Article 10.4](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/#ch10_en_a10.4) In some research contexts, the researcher may plan to disclose the identity of participants. In such projects, researchers shall discuss with prospective participants or participants whether they wish to have their identity disclosed in publications or other means of dissemination. Where participants consent to have their identity disclosed, researchers shall record each participant’s consent.

### J.5.1

**TBA**

### J.5.2

Please indicate if you are creating a list of participant identifiers for any purpose, such as: - As a master list - linked to a participant ID# - As a contact list - As a list for payment of incentives

Creation of a master list is considered 'best practice' for securing identified research data.

### J.5.3

**TBA**

## J.6 Limits to Privacy

If a researcher makes a promise to a participant to keep their identity and/or the information they provide private, it is important for the integrity of the research enterprise that they then do so. There may be occasions when this promise is very difficult or impossible for the researcher to uphold. Consider the three possibilities below in the context of your research project and indicate how likely it is that they occur. Feel free to add more discussion in the box at the bottom of the page.

A third party (such as a court) may seek access to information obtained and/or created in confidence in a research context "through either “voluntary disclosure” or “force of law".

A researcher may have a legal obligation to “report information to authorities to protect the health, life or safety of a participant or third party”. The average person (including a researcher) has a duty under law to report ongoing child abuse, or past abuse when the abuser is still in a position of authority over minors. Some researchers may have extended obligations based on professional designations.

Under some circumstances, identified data must be made available to authorities. This may occur at the request of auditors (e.g. Health Canada, Tri-Council).

## J.7 Incidental Findings

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3 “Incidental findings” is a term that describes unanticipated discoveries made in the course of research but that are outside the scope of the research. Incidental findings are considered to be material incidental findings if they have been interpreted as having significant welfare implications for the participant. Material incidental findings may appear at any stage of the research. This may include, for example, while screening for eligibility for inclusion in a study or while collecting baseline information, both of which may involve the prospective participants’ consent.

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.4](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.4) Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.

## J.8 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION K: Consent

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 10; [Article 10.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/#ch10_en_a10.2) Researchers shall explain in their research design the proposed procedures for seeking consent and the strategies they plan to use for documenting consent.

### K.1.1

**TBA**

### K.1.2

Undue influence can involve the perception that services might be withheld; job opportunities might be withheld; social acceptance is altered, etc. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.1](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.1): Undue Influence Power over relationships are characterized by "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. Any relationship of dependency, even a nurturing one, may give rise to undue influence even if it is not applied overtly. There may be a greater risk of undue influence in situations of ongoing or significant dependency." "This control may be physical, psychological, financial or professional, for example, and may involve offering some form of inducement or threatening some form of deprivation."

### K.1.3

In the Participants tab, you are asked to describe how you will ensure that consent is ongoing over several distinct interactions. Here you are asked to describe how you will ensure that the participant has not changed his/her mind about participation during the course of the research. This may involve only one interaction, or more than one. How will you ensure that the participant receives all the information they need to sustain the decision to take part? [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.3): Consent shall be maintained throughout the research project. Researchers have an ongoing duty to provide participants with all information relevant to their ongoing consent to participate in the research.

### K.1.4

**TBA**

### K.1.5

**TBA**

### K.1.6

Which member of the research team will be charged with obtaining consent?

The right to withdraw must be detailed in the consent information. Ensure that participants can skip any question they would prefer not to answer. Make sure your eSurvey software will allow this.

Data from withdrawing participants should be destroyed unless they have given permission to retain the data.

Consider when data will be de-identified and/or when it will be aggregated when you consider your answer. Once a publication has been drafted it is no longer reasonable to allow a participant to withdraw.

## K.2 Information to Participant

The two aspects of consent are documentation that consent has occurred, and provision of information to the participant. In this section indicate how you plan to provide consent information to the participant. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.12](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.12): Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

Article 10.3 In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection is afforded the participant.

## K.3 Documentation of Consent

The two aspects of consent are documentation that consent has occurred, and provision of information to the participant. In this section indicate how you plan to document that consent has occurred. See help text for examples. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.12](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.12): Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent.

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 10; [Article 10.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter10-chapitre10/#ch10_en_a10.3): In research involving observation in natural environments or virtual settings where people have a reasonable or limited expectation of privacy, the researcher shall explain the need for an exception to the general requirement for consent. The REB may approve research without requiring that the researcher obtain consent from individuals being observed on the basis of the justification provided by the researcher and appropriate privacy protection is afforded the participant.

Note that a hard copy signature on paper is the default mechanism for documenting consent. But for many types of research it is not appropriate. Justify why you are not obtaining written consent (if you have chosen another method) [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.12](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.12): Evidence of consent shall be contained either in a signed consent form or in documentation by the researcher of another appropriate means of consent. Written consent in a signed statement from the participant is a common means of demonstrating consent, and in some instances, is mandatory (e.g., Health Canada regulations under the Food and Drugs Act, the Civil Code of Québec).

## K.4 Proxy Consent

Explain who will make the decision that the participant is not capable of providing consent. What is their relationship to the participant? Normally this person must be a parent, legal guardian, or have Power of Attorney. In some cases, a member of the 'circle of care' can provide this information. For lower risk studies others may aid in this decision. See FAQ on the use of the Mini Mental State Exam on the Human Ethics website.

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.9](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.9): For research involving individuals who lack the capacity, either permanently or temporarily, to decide for themselves whether to participate, the REB shall ensure that, as a minimum, the following conditions are met: a. the researcher involves participants who lack the capacity to decide on their own behalf to the greatest extent possible in the decision-making process; b. the researcher seeks and maintains consent from authorized third parties in accordance with the best interests of the persons concerned; c. the authorized third party is not the researcher or any other member of the research team; d. the researcher demonstrates that the research is being carried out for the participant’s direct benefit, or for the benefit of other persons in the same category. If the research does not have the potential for direct benefit to the participant but only for the benefit of the other persons in the same category, the researcher shall demonstrate that the research will expose the participant to only a minimal risk and minimal burden, and demonstrate how the participant’s welfare will be protected throughout the participation in research; and e. when authorization for participation was granted by an authorized third party, and a participant acquires or regains decision-making capacity during the course of the research, the researcher shall promptly seek the participant’s consent as a condition of continuing participation.

K.4.2

**TBA**

K.4.2

You can use the same options for proxy consent as for regular consent - hard copy information letter; electronic information letter; information at the beginning of a survey; or other. They method chosen will depend on the nature of the individual giving assent, and their capacity. See the guideline on the Human Ethics website on obtaining Assent.

### K.4.3

You can use the same options for proxy consent as for regular consent - hard copy information letter; electronic information letter; information at the beginning of a survey; or other. They method chosen will depend on the nature of the individual giving assent, and their capacity. See the guideline on the Human Ethics website on obtaining Assent.

### K.4.4 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

## K.5 Deception

### K.5.1

Deception by Omission occurs when the research team simply does not tell the participant everything about the research project.

Deception by Commission occurs when the research team actually lies to the participant about the research project. Refer to the Guidelines on Deception on the Human Ethics webpage [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 3; [Article 3.7A](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter3-chapitre3/#ch3_en_a3.7a): The REB may approve research that involves an alteration to the requirements for consent set out in Articles 3.1 to 3.5 if the REB is satisfied, and documents, that all of the following apply: a. the research involves no more than minimal risk to the participants; b. the alteration to consent requirements is unlikely to adversely affect the welfare of participants; c. it is impossible or impracticable (see Glossary) to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required; d. in the case of a proposed alteration, the precise nature and extent of any proposed alteration is defined; and e. the plan to provide a debriefing (if any) which may also offer participants the possibility of refusing consent and/or withdrawing data and/or human biological materials, shall be in accordance with Article 3.7B.

### K.5.2

Best practice is to reveal the deception before the participant leaves the research site.

### K.5.3

The individual who carries this out must be trained appropriately.

### K.5.4

The individual who carries this out must be trained appropriately.

### K.5.5

Since the participant did not give informed consent, consent must be obtained once the project is complete, during the debriefing. Written information explaining the deception and the need for deception, apologizing for the deception, indicating that the participant is free to withdraw without penalty and their data will be destroyed, must be provided to the participant.

## K.6 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION L: Information Security

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 5: Privacy Confidentiality: The ethical duty of confidentiality refers to the obligation of an individual or organization to safeguard entrusted information. The ethical duty of confidentiality includes obligations to protect information from unauthorized access, use, disclosure, modification, loss or theft. Fulfilling the ethical duty of confidentiality is essential to the trust relationship between researcher and participant, and to the integrity of the research project.

Security refers to measures used to protect information. It includes physical, administrative and technical safeguards. An individual or organization fulfils its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include the use of locked filing cabinets, and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about participants. Technical safeguards include use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss or modification. Article 5.1 Researchers shall safeguard information entrusted to them and not misuse or wrongfully disclose it. Institutions shall support their researchers in maintaining promises of confidentiality. [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 5; [Article 5.3](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#ch5_en_a5.3): Researchers shall provide details to the REB regarding their proposed measures for safeguarding information, for the full life cycle of information: its collection, use, dissemination, retention and/or disposal.

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify the **type of data you plan to collect**. Discuss all that apply for each method and during the course of the research project.

## L.1 Proposed Data to be collected

**Directly Identifying Information**

The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

**Indirectly Identifying Information**

The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

**Coded Information**

Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).

**Anonymized Information**

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.

**Anonymous**

The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

## L.2 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION M: Data Protection

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 5: Security refers to measures used to protect information. It includes physical, administrative and technical safeguards. An individual or organization fulfills its confidentiality duties, in part, by adopting and enforcing appropriate security measures. Physical safeguards include the use of locked filing cabinets, and the location of computers containing research data away from public areas. Administrative safeguards include the development and enforcement of organizational rules about who has access to personal information about participants. Technical safeguards include use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss or modification.

## M.1 Recording Data or Observations

You may be recording data on paper during collection and then transferring to eformat. You can choose paper here, and then discuss the transition to eformat below.

## M.2 Protection of Data

* **Collection**   
  For example: Notes will be taken on paper during collection. There is a separate paper for each participant to avoid on participant seeing another's data. Once data collection is complete for a participant, the paper will be stored in a file. At the end of the data collection session, the file will be stored in a locked cabinet in the PI's office.
* **Transit**  
  For example: Notes will be taken on paper during collection. There is a separate paper for each participant to avoid on participant seeing another's data. Once data collection is complete for a participant, the paper will be stored in a file. At the end of the data collection session, the file will be stored in a locked cabinet in the PI's office.
* **Processing/analysis**  
  For example: Data on paper files will be transferred to spreadsheets on the student's encrypted (U of G full disc encryption) laptop computer. All analysis will be done on this computer. Back-up copies of the data files will be made daily on encrypted USB keys and stored in a locked cabinet in the student's home.
* **After project completion**For example: A complete data copy will be stored in the University of Guelph's secure storage site in the Library OR A complete data set will be stored on an encrypted USB key in a locked cabinet accessible only by the PI.

## M.3 Transcription of Data

If a member of the research team will transcribe data, an agreement is not necessary. If transcription is done outside the team, an agreement is required to ensure that the transcriptionist will provide confidentiality and data security.

## M.4 Electronic Transfer of Data

For help in determining how to transfer electronic data securely, contact your CCS representative.

## M.5

**TBA**

## M.6 Open Access

[TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 5; [Article 5.7](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter5-chapitre5/#ch5_en_a5.7): Researchers who propose to engage in data linkage shall obtain REB approval prior to carrying out the data linkage, unless the research relies exclusively on publicly available information as discussed in [TCPS2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/), Chapter 2; [Article 2.2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/#ch2_en_a2.2). The application for approval shall describe the data that will be linked and the likelihood that identifiable information will be created through the data linkage. Where data linkage involves or is likely to produce identifiable information, researchers shall satisfy the REB that: the data linkage is essential to the research; and appropriate security measures will be implemented to safeguard information.

## M.7 Data Destruction

**TBA**

## M.8 Optional Information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION N: Post Approval

## N.1 Continuing Ethics Review

**TBA**

## N.2 Adverse Events

**TBA**

## N.3 Optional information

These text boxes are available for the applicant to provide further information, as appropriate.

# SECTION O: Attestation and Signature

## O.1 Email Attestation

**TBA**

## O.2 E-Signature

**TBA**

## O.3 Hard Copy Signature

**TBA**