University of Guelph

Research Ethics Board (REB)

Application to Involve Human Participants in Research

# DIRECTIONS

## How to submit:

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

## How to answer questions:

* 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/))
* Students **MUST** submit an appropriate certificate of training. See Resources for links to the Core Tutorial **OR** CITI training. Training is highly recommended for the entire research team.
* 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.
* Full functionality of the form will not be available if you edit in Word Online (browser editing on Office 365). Instead, download a copy to your computer and edit in Word.
* Information buttons  will provide information about the question, where the topic can be found in the TCPS2, and sometimes suggested responses. Information can be accessed using CTRL + 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 or go to ‘View’ and choose “Show Navigation Pane”. Please do not delete questions you think do not apply – just choose n/a.
* To enlarge tables, simply tab forward – you will be able to expand the table by adding a new row.

# SECTION A: OVERVIEW Section A Guidelines from the REB Human Participants Application Guidelines page

## A.1 Title of Research Project Section A.1 Guidelines from the REB Human Participants Application Guidelines page

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## A.2 Summary of Research Section A.2 Guidelines from the REB Human Participants Application Guidelines page

Provide a summary of your research project. Be brief and use lay language. Describe the methodology. Discuss any obvious ethical issues.

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## A.3 Background and Justification Section A.3 Guidelines from the REB Human Participants Application Guidelines page

Describe the purpose and background rationale for the proposed project. Include your objectives and hypotheses, if applicable.

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## A.4 Research Steps Section A.4 Guidelines from the REB Human Participants Application Guidelines page

Describe in clear and concise detail and sequentially, each of the research steps in which the research participants will be involved. Please use flow charts, diagrams, and/or point form.

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## A.5 Methods/Procedures Section A.5 Guidelines from the REB Human Participants Application Guidelines page

List, in point form and without description, the methods you will undertake. This list will inform how you fill out subsequent sections which require information for each method/procedure being used. For example, the consent process for your focus groups might be quite different than the consent process for your eSurvey, and you must deal with both in the consent section.

Examples are: - focus groups - interviews - eSurvey - anthropometric measures - blood draws – exercise.

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## A.6 Documents Attached Section A.6 Guidelines from the REB Human Participants Application Guidelines page

Please list all file names for the documents attached to this submission. Multiple files can be uploaded in each category.

**Published Scale/Survey**

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**Researcher Generated Survey**

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**Focus Group Probing Questions**

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**Screening Questionnaire**

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**Interview Questions**

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**Health Questionnaire**

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**Recruitment Document**

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**Consent Document**

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**Training Certificates such as CORE or CITI**

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**Other**

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## A.7 Optional Information Section A.7 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION B: COLLABORATORS Section B Guidelines from the REB Human Participants Application Guidelines page

## B.1 Principal Investigator Section B.1 Guidelines from the REB Human Participants Application Guidelines page

* The Principal Investigator (PI) must be a University of Guelph faculty member which can include Adjunct or Emeritus Professors, or senior staff members.
* Graduate students, undergraduate students, and Post-Doctoral Fellows must list their advisor as the PI.

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| --- | --- | --- | --- | --- |
| Name | Position | Department | Extension/Phone | Email |
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## B.2 University of Guelph Faculty Coinvestigators Section B.2 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

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| --- | --- | --- | --- | --- |
| Name | Position | Department | Extension/Phone | Email |
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## B.3 University of Guelph Student and Other (Non-Faculty) Coinvestigators Section B.3 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

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| --- | --- | --- | --- | --- | --- |
| Name | Degree Program | Department | Extension/Phone | Email | Training certificate included [y/n] If no, provide rationale in Text box below. |
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## B.4 External Coinvestigators Section B.4 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

*Researchers are required to submit a current CV for any external research personnel who will be performing any physical interventions on human participants.*

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| Name | Institution | Contact information | Will seek REB approval from their home institution [y/n] If no, provide rationale in **B.7** **Optional Information**. |
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## B.5 Level of Project Section B.5 Guidelines from the REB Human Participants Application Guidelines page

It is assumed that the PI will have access to the findings of the project for their use. Please check all other applications for the findings.

[ ]  PhD Thesis

[ ]  Master’s Thesis

[ ]  Masters Major Research Paper

[ ]  M.Sc by Coursework

[ ]  Undergraduate

[ ]  Honour’s Thesis

[ ]  Class Project – please specify course and submit Supplement VI

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[ ]  Internship

[ ]  Practicum

[ ]  Independent Study

[ ]  Administration

[ ]  Contract – for profit sponsor

[ ]  Other – please specify

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## B.6 Experience and Licensed Qualifications Section B.6 Guidelines from the REB Human Participants Application Guidelines page

### B.6.1 PI Experience Section B.6.1 Guidelines from the REB Human Participants Application Guidelines page

What experience does the principal investigator have with the kind of research undertaken in this project and in this context, including experience with the participant community, methods of data collection, etc.

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### B.6.2 Researcher Expertise or Qualifications Section B.6.2 Guidelines from the REB Human Participants Application Guidelines page

Does any specific procedure require professional expertise/recognized qualifications (e.g. performance of a controlled act)?

[ ]  No

[ ]  Yes

If **YES**, describe, and specify which team members have this expertise (examples are clinical psychologist, phlebotomist, physician, dentist, chiropractor):

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## B.7 Optional Information Section B.7 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION C: APPROVALS Section C Guidelines from the REB Human Participants Application Guidelines page

## C.1 International Research Section C.1 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

### C.1.1 Centre for International Programs Section C.1.1 Guidelines from the REB Human Participants Application Guidelines page

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

[ ]  No

[ ]  Yes

[ ]  Not Applicable

### C.1.2 Ethics Approval in Foreign Countries Section C.1.2 Guidelines from the REB Human Participants Application Guidelines page

If you are undertaking research in a country other than Canada, have you submitted a copy of the clearance certificate/approval from the Research Ethics Board in that country?

[ ]  No

[ ]  Yes

[ ]  Not Applicable

If not, discuss what alternative measures are being taken to ensure the research is culturally appropriate.

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## C.2 Internal University of Guelph Approvals Section C.2 Guidelines from the REB Human Participants Application Guidelines page

### C.2.1 Animal Care Services Section C.2.1 Guidelines from the REB Human Participants Application Guidelines page

Does this project involve live animals in any way?

[ ]  No

[ ]  Yes

If yes, please contact [Animal Care Services](http://www.uoguelph.ca/research/services-divisions/animal-care-services)

### C.2.2 Biosafety Section C.2.2 Guidelines from the REB Human Participants Application Guidelines page

Does this project involve biohazards?

[ ]  No

[ ]  Yes

If yes, please contact [Biosafety](https://www.uoguelph.ca/hr/hr-services-environmental-health-safety-programs/biosafety)

## C.3 External Approvals Section C.3 Guidelines from the REB Human Participants Application Guidelines page

### C.3.1 External Ethics Review Section C.3.1 Guidelines from the REB Human Participants Application Guidelines page

Has the project been approved by other Ethics Boards?

[ ]  No

[ ]  Yes [Submit certificate of approval]

[ ]  Not Applicable

[ ]  Pending [Submit certificate of approval when it is received]

### C.3.2 External Permissions/Approvals Section C.3.2 Guidelines from the REB Human Participants Application Guidelines page

Does this project need approval/clearance from another organization? Examples might be the community with which the participants are affiliated, a business, property owner, etc.

[ ]  No

[ ]  Yes [Submit evidence of approval such as letter or email]

[ ]  Not Applicable

[ ]  Pending [Submit evidence of approval such as letter or email when it is received]

## C.4 Peer Review Section C.4 Guidelines from the REB Human Participants Application Guidelines page

### C.4.1 Funding Section C.4.1 Guidelines from the REB Human Participants Application Guidelines page

Has this project undergone peer review for scholarly merit during the course of funding approval?

[ ]  No

[ ]  Yes

[ ]  Not Applicable

### C.4.2 Graduate Advisory Committees Section C.4.2 Guidelines from the REB Human Participants Application Guidelines page

Has this project undergone peer review for scholarly merit by a graduate advisory committee?

[ ]  No

[ ]  Yes

[ ]  Not Applicable

## C.5 Optional Information Section C.5 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION D: SPONSORS AND CONFLICT OF INTEREST Section D Guidelines from the REB Human Participants Application Guidelines page

## D.1 Sponsor Section D.1 Guidelines from the REB Human Participants Application Guidelines page

Is this project currently funded?

[ ]  No

[ ]  Yes

Provide name of sponsor/granting agency/funding source. Include the Program Name.

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[ ]  Pending [Submit AMENDMENT FORM to update approved submission when funding received]

## D.2 Contract or Research Agreement Section D.2 Guidelines from the REB Human Participants Application Guidelines page

Will there be an agreement with a research partner/funder (i.e. data sharing agreements, research funding agreements, confidentiality agreements etc.)?

[ ]  No, **proceed to D.4 Conflict of Interest (COI)**

[ ]  Yes

If yes, provide a copy of the agreement with your ethics submission package.

Provide name of partner/sponsor.

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Has a copy of the contract been submitted to the Research Services Office for review?

[ ]  No

[ ]  Yes

Has the contract received final signatures?

[ ]  No

[ ]  Yes

## D.3 Optional Information Section D.3 Guidelines from the REB Human Participants Application Guidelines page

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## D.4 Conflict of Interest (COI) Section D.4 Guidelines from the REB Human Participants Application Guidelines page

### D.4.1 Section D.4.1 Guidelines from the REB Human Participants Application Guidelines page

Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits? This might include a financial benefit such as remuneration/income, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options etc.

[ ]  No

[ ]  Yes

If YES, please describe the benefits below. Include details of all fees and/or honoraria directly related to this study, such as those for participant recruitment, advice on study design, presentation of results, or conference expenses.

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### D.4.2 Section D.4.2 Guidelines from the REB Human Participants Application Guidelines page

Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) placed on the investigator(s), including those related to the publication of results. Note the nature of these restrictions and who is applying these restrictions.

[ ]  N/A

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### D.4.3 Section D.4.3 Guidelines from the REB Human Participants Application Guidelines page

Describe the possibility of commercialization of the research findings

[ ]  N/A

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### D.4.4 Section D.4.4 Guidelines from the REB Human Participants Application Guidelines page

Describe any personal or professional relationship between a member of the research team and any participants aside from the researcher/participant relationship.

[ ]  N/A

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### D.4.5 Section D.4.5 Guidelines from the REB Human Participants Application Guidelines page

Describe any consultancy or other contractual agreements, financial, partnership, or business interests within the last two years that might be perceived as a conflict of interest pertaining to this study.

[ ]  N/A

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## D.5 Optional Information Section D.5 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION E: RESEARCH LOCATION Section E Guidelines from the REB Human Participants Application Guidelines page

## E.1 International Research Location Section E.1.1 Guidelines from the REB Human Participants Application Guidelines page

### E.1.1 Section E.1.1 Guidelines from the REB Human Participants Application Guidelines page

Does this research take place outside of Canada?

[ ]  No, **proceed to E.2 Physical Research Location**

[ ]  Yes

If YES, please state what country and region you will be travelling to for the purposes of research and submit Supplement III.

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### E.1.2 Travel Advisories Section E.1.2 Guidelines from the REB Human Participants Application Guidelines page

Determine the [Canadian Travel Advisory](https://travel.gc.ca/travelling/advisories) for the country in which you propose to undertake research or the region through which you plan to travel. Check the box below if either of these travel advisories apply to this country/region.

[ ]  Avoid non-essential travel

[ ]  Avoid all travel

If one of the boxes is checked, please explain below your rationale for continuing to pursue this research, your familiarity with conditions in the proposed research area, and/or your safety plan.

State which member(s) of the research team will be travelling.

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## E.2 Physical Research Locations Section E.2 Guidelines from the REB Human Participants Application Guidelines page

It is important to know where the research will take place, in order to determine risk, need for approvals, etc. Some examples are: health institution, correctional institution, participant’s home or place of business, school, university or college. Provide general description and, where applicable, actual address, such as J. T. Powell Building, University of Guelph, Dr. X’s lab, Room 123.

If you are undertaking online research, simply indicate this.

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## E.3.Optional Information Section E.3 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION F: RESEARCH LANGUAGE Section F Guidelines from the REB Human Participants Application Guidelines page

## F.1 Literacy Section F.1 Guidelines from the REB Human Participants Application Guidelines page

How will you deal with the possibility that your participants may not be sufficiently literate to access the information in a written consent document?

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## F.2 Language Section F.2 Guidelines from the REB Human Participants Application Guidelines page

### F.2.1 Section F.2.1 Guidelines from the REB Human Participants Application Guidelines page

Will the research be conducted in English?

[ ]  No

[ ]  Yes

If no, specify the language in which the research will be conducted?

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### F.2.2 Research Not Conducted in English Section F.2.2 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply, **proceed to Section G.**

#### F.2.2.1 Section F.2.2.1 Guidelines from the REB Human Participants Application Guidelines page

Does the researcher interacting with participants speak the same language as the participants?

[ ]  No

[ ]  Yes

If **NO**, will interpretation be necessary?

[ ]  No

If **NO**, please explain why not.

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[ ]  Yes

If **YES**, a confidentiality agreement must be provided to interpreters. Please submit a copy for review.

#### F.2.2.2 Section F.2.2.2 Guidelines from the REB Human Participants Application Guidelines page

How will interpreters be recruited? From what organization? From what region?

Discuss possible relationships between the interpreters and participants, and how these relationships will be managed.

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#### F.2.2.3 Section F.2.2.3 Guidelines from the REB Human Participants Application Guidelines page

The consent information for participants must be translated if the research is conducted in a language other than English.

[ ]  Consent information will be translated into.

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[ ]  Back translations will be submitted for review.

## F.3 Optional Information Section F.3 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION G: RESEARCHER INVOLVEMENT Section G Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify the researcher(s) engaged in that method, and describe their expertise, experience, or qualifications specific to that method.

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| Procedure/Method | Researcher | Expertise/experience |
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## G.1 Optional Information Section G.1 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION H: RISKS Section H Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify the risk which might be experienced by the participant engaged in that method.

Minimal risk research is defined by the TCPS2 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 the aspects of their everyday life that relate to the research.”

Note that "an REB may raise concerns about the safety of student researchers" so these risks should also be addressed here as appropriate.

See TCPS2 Chapter 2 B. Approach to REB Review

Risk types include:

* Physical (including bodily contact or administration of any substance)
* Psychological (including feeling demeaned, embarrassed, worried, or upset)
* Social (possible loss of status or reputation)
* Economic (risk to livelihood or income)
* Privacy (risk to participants physical privacy; privacy of the data provided; privacy with respect to research participation, etc.)

Risk levels include:

* High
* Minimal (as experienced in everyday life)

## H.1 Section H.1 Guidelines from the REB Human Participants Application Guidelines page

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| Procedure/Method | Risk Type | Risk Level | Description |
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## H.2 Mitigation Section H.2 Guidelines from the REB Human Participants Application Guidelines page

For each risk identified above describe how the risk will be managed and include an explanation as to why alternative approaches could not be used.

For privacy risk, you can indicate here that mitigation of the risk to privacy will be discussed in Sections J.5, J.6, L., and M.

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## H.3 Optional Information Section H.3 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION I: BENEFITS Section I Guidelines from the REB Human Participants Application Guidelines page

## I.1 Benefits to Participants Section I.1 Guidelines from the REB Human Participants Application Guidelines page

Describe the benefits which may accrue to the participant AS A RESULT of the research. This does NOT include incentives or compensation.

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## I.2 Benefits to Discipline or Society Section I.2 Guidelines from the REB Human Participants Application Guidelines page

Describe the benefits which will result from the research.

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## I.3 Feedback to Participants Section I.3 Guidelines from the REB Human Participants Application Guidelines page

### I.3.1 Section I.3.1 Guidelines from the REB Human Participants Application Guidelines page

Will aggregate feedback or a summary of results be provided to participants?

[ ]  No

[ ]  Yes If yes, please inform participants in the consent form how they may obtain this feedback.

If **NO**, please be aware that it is strongly encouraged to provide participants with a summary of results of some kind. Please explain why this is not feasible.

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### I.3.2 Section I.3.2 Guidelines from the REB Human Participants Application Guidelines page

Will individual results be provided to participants?

[ ]  No

[ ]  Yes

If **YES**, submit a sample of how the results will be provided.

## I.4 Dissemination Section I.4 Guidelines from the REB Human Participants Application Guidelines page

How do you plan to disseminate your findings?

Check all that apply:

[ ]  Academic journal

[ ]  Thesis

[ ]  Open source journal

[ ]  Workshop

[ ]  Conference presentation

[ ]  Poster presentation

[ ]  Other – please specify:

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## I.5 Optional Information Section I.5 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION J: PARTICIPANTS Section J Guidelines from the REB Human Participants Application Guidelines page

## J.1 Fairness and Equity Section J.1 Guidelines from the REB Human Participants Application Guidelines page

Chapter 4 of the TCPS2 describes the importance of fairness and equity with respect to participants. Fairness in terms of distribution of research benefits and the opportunity to be engaged in research, and equity with respect to the distribution of risk but protection from exploitation.

The following are the criteria under which a participant may be excluded from a research project.

Check all that apply:

[ ]  Language

[ ]  Religion

[ ]  Race

[ ]  Disability

[ ]  Sexual Orientation

[ ]  Ethnicity

[ ]  Linguistic Proficiency

[ ]  Sex

[ ]  Gender

[ ]  Age

[ ]  Capacity to Consent

[ ]  Vulnerability

[ ]  Other – please specify:

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For each criterion checked above, provide a justification based on your research question/methodology, etc.

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### J.1.1 Section J.1.1 Guidelines from the REB Human Participants Application Guidelines page

Are participants University of Guelph students?

[ ]  No

[ ]  Yes

### J.1.2 Section J.1.2 Guidelines from the REB Human Participants Application Guidelines page

Are participants affiliated with (formally or informally) a particular organization or institution (other than the University of Guelph?

[ ]  No

[ ]  Yes

If **YES**, please name and provide details of the affiliation

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## J.2 Participants Section J.2 Guidelines from the REB Human Participants Application Guidelines page

### J.2.1 Section J.2.1 Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify the number of participants engaged in that method and the size of the pool from which you plan to recruit. For example, you may be recruiting 5 retail managers for an interview from a company which employs 25 retail managers (this is the ‘pool’).

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| Procedure/Method | #Participants | #in Pool | Time required |
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### J.2.2 Section J.2.2 Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, list the inclusion and exclusion criteria for that method.

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| Procedure/Method | Inclusion Criteria | Exclusion Criteria |
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## J.3 Recruitment Section J.3 Guidelines from the REB Human Participants Application Guidelines page

### J.3.1 Section J.3.1 Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to recruit the participants.

* Check all that apply and describe the distribution method for each document
* The REB# should appear on all recruitment documents
* Submit a copy of each document with your application

[ ]  Poster

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[ ]  Advertisement

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[ ]  Email

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[ ]  Web page

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[ ]  Letter of Invitation

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[ ]  Telephone Call

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[ ]  Social Media

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[ ]  Verbal Script

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[ ]  SONA – Psychology

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[ ]  SONA – Marketing & Consumer Studies

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[ ]  [Office of Research Participant Recruitment Site](http://www.uoguelph.ca/research/Research-Participants-Needed)

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[ ]  Other – describe below

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### J.3.2 Section J.3.2 Guidelines from the REB Human Participants Application Guidelines page

Are you accessing non-public contact information?

[ ]  No

[ ]  Yes

If **YES**, describe how permission will be obtained.

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## J.4 Incentives Section J.4 Guidelines from the REB Human Participants Application Guidelines page

[ ]  If you are not providing incentives or compensation of any kind, check here and proceed to J.5

Important information for researchers:

If the research team must collect ‘proof of payment’ to submit to University Financial Services, participants must be told in the consent process what will be required of them (e.g. initialing a receipt, signing a receipt, providing name and address, providing SIN number). Contact departmental administrative staff for directions.

### J.4.1 Financial Incentives Section J.4.1 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to provide financial incentives to participants.

Types of financial incentive include

* Gift cards – indicate what the gift card is for
* Cash
* Etransfers
* Draws
* Other – specify in table.

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| --- | --- | --- | --- |
| Procedure/Method | Type  | Dollar value | Description |
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### J.4.1.1 Draws Section J.4.1.1 Guidelines from the REB Human Participants Application Guidelines page

Describe the prize for the draw you are proposing:

* Value of the prizes:

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* Number of prizes:

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* Probability of winning:

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* How you will manage the draw. For example, how the winner will be chosen, how they will be notified, how many times they will be contacted before moving to a new ‘winner’

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### J.4.2 Incentives – Non-Financial Section J.4.2 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to provide non-financial incentives to participants.

Types of Non-financial incentives include:

* Food or drinks
* Small gifts

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| Procedure/Method | Type  | Dollar value | Description |
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### J.4.3 Course Credits Section J.4.3 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

If you are providing course credit or bonus marks as an incentive, describe how many and the course in which they will be awarded.

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Describe the alternative assignment:

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### J.4.4 Additional Costs to Participants Section J.4.4 Guidelines from the REB Human Participants Application Guidelines page

Participants may incur additional costs due to participation in research, such as travel costs, parking, or child care. Could participants in this project incur costs?

[ ]  No

[ ]  Yes

If **YES**, describe the costs. Will the research team cover the costs?

[ ]  No

[ ]  Yes

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### J.4.5 International Section J.4.5 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

If you are conducting research in an international setting or a distinct community, describe the value of the incentive in the context of the community involved. What is the ‘buying power’ in that community? How long would it take the ‘average’ person to earn that much?

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### J.4.6 Withdrawing Section J.4.6 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

Participants who withdraw are still eligible for incentives. Indicate how you will ensure withdrawing participants will receive incentives.

Researchers can prorate the incentive. If you plan to do this, please describe.

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## J.5 Participant Privacy Section J.5 Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to protect the privacy of the participant’s identity.

### J.5.1 Section J.5.1 Guidelines from the REB Human Participants Application Guidelines page

Will you collect identifiable personal information for any purpose (e.g. recruitment, arranging interviews, providing incentives?

[ ]  No

[ ]  Yes

If **YES**, describe the nature of the information, and:

* Who will have access to identifiable personal information?

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|  |

* How will identifiable personal information will be secured?

|  |
| --- |
|  |

* How long will identifiable personal information will be kept?

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* How will identifiable personal information will be destroyed?

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### J.5.2 Section J.5.2 Guidelines from the REB Human Participants Application Guidelines page

Will a master list be created linking identifiable personal information through a participant ID#, to the data?

[ ]  No

[ ]  Yes

If **YES**, describe

* Who will have access to the master list?

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|  |

* How will the master list be secured?

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* How long master list will be kept?

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* How will the master list be destroyed?

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### J.5.3 Section J.5.3 Guidelines from the REB Human Participants Application Guidelines page

Will this data set be linked at any time with another data set?

[ ]  No

[ ]  Yes

If yes, provide a complete description of the other data set and whether linkage will increase the likelihood that the participant’s identity will become known.

If you are proposing to use *Mass Testing* (Psychology only) as part of this project, provide the REB number under which the mass testing item was approved.

Provide a copy of the *Mass Testing* questions.

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## J.6 Limits to Privacy Section J.6 Guidelines from the REB Human Participants Application Guidelines page

Occasions may arise which make it difficult or impossible to protect a participant's identity as promised in the consent process. Does this apply to your project?

[ ]  No

[ ]  Yes

If yes, discuss for the overall project or for each procedure/method, as appropriate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Procedure/Method | Limit by Subpoena | Limit by Duty to report | Limit by Report to Authorities | Likelihood |
|  |  |  |  |  |
|  |  |  |  |  |

Discuss:

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## J.7 Incidental Findings Section J.7 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

There are sometimes unanticipated discoveries made in the course of research that are outside the scope of the research, but which may have significant welfare implications for the participant. Consider each method you propose to undertake and discuss possible incidental findings which might arise. Indicate how you will disclose these incidental findings and to whom you will disclose them.

Discuss if the possibility of incidental findings will be communicated to the participant during the process of consent.

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| --- | --- | --- |
| Procedure/Method | Incidental Finding | Discussion |
|  |  |  |
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## J.8 Optional Information Section J.8 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION K: CONSENT Section K Guidelines from the REB Human Participants Application Guidelines page

## K.1 Consent – General Section K.1 Guidelines from the REB Human Participants Application Guidelines page

### K.1.1 Section K.1.1 Guidelines from the REB Human Participants Application Guidelines page

Are you applying for a waiver of prior informed consent?

[ ]  No

[ ]  Yes

If **YES**, discuss Article 3.7 (a) to (e) TCPS2 and its correlation to your work.

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### K.1.2 Section K.1.2 Guidelines from the REB Human Participants Application Guidelines page

Will the participant be free to give or withhold consent without any undue influence or coercion (for example through power over relationships)?

[ ]  No

[ ]  Yes

If **NO**, Describe the potential for a perception of undue influence or coercion?

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### K.1.3 Section K.1.3 Guidelines from the REB Human Participants Application Guidelines page

How will you ensure that consent is ongoing throughout the project? How will you ensure that necessary information is provided to participants on an ongoing basis?

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### K.1.4 Section K.1.4 Guidelines from the REB Human Participants Application Guidelines page

Are your participants capable of deciding for themselves whether to participate or not?

[ ]  No

[ ]  Yes

If **NO**, be sure to fill out the **K.4 Proxy Consent section**

### K.1.5 Section K.1.5 Guidelines from the REB Human Participants Application Guidelines page

\*Will the information provided during the consent process be accurate?

[ ]  No

[ ]  Yes

If **NO**, be sure to fill out the **K.5 Deception section**

### K.1.6 Section K.1.6 Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to obtain consent from participants.

Who will interact with participant during the consent process?

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What training in the consent process has this person had?

*Individuals inexperienced in administering consent should submit a script on how consent will be managed.*

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Describe how the participants will be informed of their right to withdraw and outline the procedures that will be followed to allow participants to exercise this right.

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Participants must have the right to withdraw their data from the project. Exceptions include anonymous data and focus group data. Indicate what will be done with participants' data if they withdraw from the study.

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How long will participant be able to withdraw data? Provide a date - here and in the consent form beyond which data withdrawal will not be possible.

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## K.2 Information to Participant Section K.2 Guidelines from the REB Human Participants Application Guidelines page

The two aspects of consent are documentation that consent has occurred, and provision of information to the participant.

A copy of the document used to convey consent information must be submitted with your ethics application.

Consent information must be provided to the participant.

Consent information must display a University of Guelph logo or be printed on University of Guelph letterhead. *You may state on the consent form at the top that this will be done.*

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to provide consent information to the participant.

|  |  |
| --- | --- |
| Method/procedure |  |
| Hard copy information letter | [ ]  No[ ]  Yes  |
| Electronic information letter | [ ]  No[ ]  Yes  |
| Information at beginning of survey of invitation to print | [ ]  No[ ]  Yes  |
| Other – please describe |  |
| How will information be delivered to participants? |  |

## K.3 Documentation of Consent Section K.3 Guidelines from the REB Human Participants Application Guidelines page

The two aspects of consent are documentation that consent has occurred, and provision of information to the participant.

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you plan to document that consent has occurred.

|  |  |
| --- | --- |
| Method/procedure |  |
| Signature on Paper | [ ]  No[ ]  Yes  |
| Electronic or Email | [ ]  No[ ]  Yes  |
| Through an action (such as submission of a survey) | [ ]  No[ ]  Yes  |
| Other (e.g. field notes, recording) | [ ]  No[ ]  Yes |
| If Signature on Paper was not chosen, please justify why not. |  |

## K.4 Proxy Consent Section K.4 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

### K.4.1 Section K.4.1 Guidelines from the REB Human Participants Application Guidelines page

How are you determining that proxy consent is necessary? In what way is your participant population non-competent to give consent?

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### K.4.2 Section K.4.2 Guidelines from the REB Human Participants Application Guidelines page

How will you deliver assent information to the participant? Be sure to submit a copy of the written assent information.

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### K.4.3 Section K.4.3 Guidelines from the REB Human Participants Application Guidelines page

How will you record assent from the participant?

*Standard practice is for participants under 18 is*

* *12 to 18 - written assent*
* *7 to 12 - written assent*
* *below 7 - oral assent*.

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### K.4.4 Optional Information Section K.4.4 Guidelines from the REB Human Participants Application Guidelines page

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## K.5 Deception Section K.5 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

### K.5.1 Section K.5.1 Guidelines from the REB Human Participants Application Guidelines page

Is deception by

[ ]  Omission (Partial Disclosure) – usually minimal risk

[ ]  Commission (Lying) – usually higher than minimal risk

Describe deception:

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### K.5.2 Section K.5.2 Guidelines from the REB Human Participants Application Guidelines page

Describe how, and where and when the deception/partial disclosure will be revealed.

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### K.5.3 Section K.5.3 Guidelines from the REB Human Participants Application Guidelines page

State who will reveal the partial disclosure/deception.

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### K.5.4 Section K.5.4 Guidelines from the REB Human Participants Application Guidelines page

State what training and/or experience this person has in the disclosure of deception/partial disclosure.

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### K.5.5 Section K.5.5 Guidelines from the REB Human Participants Application Guidelines page

Will second consent be obtained?

[ ]  No, Justify why this will not be done in **K.6 Optional Information**

[ ]  Yes

If **YES**, identify what type of written documentation will be provided?

[ ]  Hard copy

[ ]  eCopy

[ ]  Other

|  |
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|  |

Second Consent will be documented by:

[ ]  Signature on paper

[ ]  Electronic or email signature

[ ]  Submission of a response (e.g. survey completion)

[ ]  Audio recording the consent conversation

## K.6 Optional Information Section K.6 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION L: INFORMATION SECURITY Section L Guidelines from the REB Human Participants Application Guidelines page

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 Section L.1 Guidelines from the REB Human Participants Application Guidelines page

Describe the data you are collecting in each category:

**Directly Identifying Information**

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|  |

**Indirectly Identifying Information**

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|  |

**Coded Information**

|  |
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**Anonymized Information**

|  |
| --- |
|  |

**Anonymous**

|  |
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## L.2 Optional Information Section L.2 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION M: DATA PROTECTION Section M Guidelines from the REB Human Participants Application Guidelines page

Consider the list of methods/procedures you made in A.5 and, for each method/procedure, identify how you will protect the data you plan to collect. Note that even anonymous data must be secured.

* Discuss all that apply for each method and for the life of the research project
* Discuss security measures for identifiers
* Discuss security measures for deidentified data
* Refer to [University of Guelph Research Data Classification Document](https://www.uoguelph.ca/ccs/infosec/rdc)
* Refer to [University of Guelph Encryption Service](https://www.uoguelph.ca/cio/content/encryption-service)

## M.1 Recording Data or Observations Section M.1 Guidelines from the REB Human Participants Application Guidelines page

How are you recording your data or observations? Some examples are Qualtrics eSurvey, eNotes, paper notes, video recording, audio recording:

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## M.2 Protection of Data Section M.2 Guidelines from the REB Human Participants Application Guidelines page

How will you protect the data you are holding (identified, deidentified, coded, or anonoymous) during the following:

**Collection**

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|  |

**Transit**

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**Processing/analysis**

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**After project completion/dissemination**

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## M.3 Transcription of Data Section M.3 Guidelines from the REB Human Participants Application Guidelines page

Will data be transcribed?

[ ]  No

[ ]  Yes

If **YES**, who will transcribe?

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If the transcriptionist is not part of the research team described in Section B, a confidentiality agreement must be signed. A draft copy of this agreement must be submitted with your application.

## M.4 Electronic Transfer of Data Section M.4 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

If data will be transferred electronically, indicate how this will be done securely:

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## M.5 Pre-screening Data Section M.5 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

If you are pre-screening participants, describe what will happen to pre-screening information already collected if the participant is deemed not eligible to take part in the project.

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## M.6 Long Term Storage and Open Access Section M.6 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

If data will be made available through Open Access, please describe here. Include a statement of how this should be addressed in the consent form/communicated to participants.

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Describe long term stewardship. Include who is responsible for the data, how it will be stored, and if there are costs involved.

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## M.7 Data Destruction Section M.7 Guidelines from the REB Human Participants Application Guidelines page

[ ]  This is section does not apply.

Indicate the date the data will be destroyed:

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|  |

Describe the method of destruction. Be sure to cover all data types discussed in M.1

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## M.8 Optional Information Section M.8 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION N: POST APPROVAL Section N Guidelines from the REB Human Participants Application Guidelines page

## N.1 Continuing Ethics Review Section N.1 Guidelines from the REB Human Participants Application Guidelines page

Minimum requirement for Continuing Ethics Review is the submission of an Annual Renewal at least annually. It is the responsibility of the Principal Investigator to notify the REB using the Annual Renewal when the project is completed, or if it is cancelled.

Indicate whether any additional monitoring or review would be appropriate for this project. Additional monitoring may be required by the REB.

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## N.2 Adverse Events Section N.2 Guidelines from the REB Human Participants Application Guidelines page

Unanticipated consequences or results affecting participants must be reported to the Research Ethics Board and the Ethics Office as soon as possible using the Event report.

## N.3 Optional information Section N.3 Guidelines from the REB Human Participants Application Guidelines page

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# SECTION O: ATTESTATION AND SIGNATURE Section O Guidelines from the REB Human Participants Application Guidelines page

The Principal Investigator must attest and sign the REB application upon submission of the package.

## PRINCIPAL INVESTIGATOR SIGNATURE:

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ [PLEASE PRINT] *acknowledge that, as required by TCPS2, I am responsible for ensuring that the consent process as described in this application is followed and I am responsible for the actions of any member of the research team involved in the consent process. I have read and am responsible for the content of this application. If any changes are made in the above arrangements or procedures, or adverse events are observed, I will bring these to the attention of the ETHICS OFFICE.*

There are three ways to do this:

## O.1 Email Attestation Section O.1 Guidelines from the REB Human Participants Application Guidelines page

Send an email to reb@uoguelph.ca from your @uoguelph.ca account stating:

*I acknowledge that, as required by TCPS2, I am responsible for ensuring that the consent process as described in this application is followed and I am responsible for the actions of any member of the research team involved in the consent process. I have read and am responsible for the content of this application. If any changes are made in the above arrangements or procedures, or adverse events are observed, I will bring these to the attention of the ETHICS OFFICE.*

In the subject line, quote the project title to which this email will be attached

## O.2 E-Signature Section O.2 Guidelines from the REB Human Participants Application Guidelines page

Create a jpeg of your signature and insert it on the signature line

## O.3 Hard Copy Signature Section O.3 Guidelines from the REB Human Participants Application Guidelines page

Print the REB application and sign the last page. Scan the whole document and submit as a .pdf

|  |  |
| --- | --- |
|  |  |
| Signature | Date |

|  |  |
| --- | --- |
|  |  |
| Graduate Student Signature (optional) | Date |