



**Not for actual use. This is what the online submission form will look like. You can use this to help in preparing your submission. All asterisk questions are mandatory. Note that the general information portion uses a student PI only as an example. Questions without text boxes will have Y/N options in the online form. Also note that text boxes in the online form accept plain text only. Where questions have sub-sections e.g. question 1 in the Funding section also has a question 1a, question 1a appears in the online form only if the response to question 1 was 'Yes'.**

### GENERAL INFORMATION

\*Protocol #:

\*Principal Investigator:

\*Study Title:

\*Is the Principal Investigator's primary affiliation with the Faculty of Medicine or Dentistry?

\*If one of the following statements is true, answer "YES" below.

a) Does the research involve invasive medical procedures or interventions, genetic testing, medical imaging, or use of tissues (prospective or secondary use)?

OR

b) Is the research being directly funded by any U.S. federal agency (e.g., DHHS, DOD, NIH, NSF, FDA, etc.)?

*{Answering 'yes' to the above two sections would direct your application to a different form (the REB Medicine form), not included in this sample.}*

\*Is the Principal Investigator of this study a graduate student or postdoctoral fellow?

Note that undergraduates cannot apply as Principal Investigator.

\*Please specify the Principal Investigator's current status:

- Master's Student
- Doctoral Student
- Postdoctoral Fellow

\*Completion of the online CORE ([TCPS2](#)) Tutorial is mandatory before submitting an application. Has the Principal Investigator, and the faculty supervisor if the PI is a student, completed the [TCPS Tutorial](#)?

## FACULTY SUPERVISOR AND STUDENT PI ACCESS

\* Please add your McGill Faculty Supervisor by clicking on the "Add" link at the top of this section.

Your supervisor will have access to edit this application.

## RESEARCH PERSONNEL

List all co-investigators, collaborators, student researchers. For each, indicate their name, affiliation and their role in this project.

### *Example*

Last Name: Doe

First Name: John

Affiliation: McGill University

Role on Project: Post-Doctoral Student - Co-Investigator - responsible for recruitment, interviews and analysis of data.

## FUNDING AND OTHER REVIEWS

### **Funding**

\*Q1. Does this study have approved or pending financial support?

\*Q1a. Sources of funding.

### **Scholarly Review**

\*Please indicate if the research has undergone scholarly review prior to this submission. The REB is required to ensure appropriate scholarly review has been undertaken for all research considered greater than minimal risk.

Please select one of the options below.

- Student Research: This project has undergone scholarly review by thesis committee, departmental committee, or equivalent.
- Faculty Research: This project has undergone scholarly review by a peer-review committee or other equivalent.
- The research has not undergone scholarly review.

### **Multi-jurisdictional Research and Other Ethics Reviews**

**\*Q1.** Are there non-McGill researchers involved in this study?

**\*Q1a.** Indicate if ethics approval has or will be obtained from another ethics board. NOTE: All researchers must normally obtain ethics approval from their own institution, in addition to the approval obtained by the lead investigator. In some cases, when Quebec collaborators are involved, only the lead PI needs ethics review. Please contact the REB Office to verify applicability.

**Q1b.** Attach any approvals already received. If more than one document, upload as separate documents, identifying by title and version date in file name and on each document.

**\*Q2.** Depending on the population to be recruited and/or the location of the study (e.g., students at another university, patients at a hospital) ethics review may be needed by another ethics board. The researcher is responsible for obtaining all necessary ethics approvals before the research begins.

Will any such external ethics reviews be required for this study?

**\*Q2a.** Please describe:

**Q2b.** Attach any approvals already obtained. If more than one document, upload as separate documents, identifying by title and version date in file name and on each document.

## STUDY INFORMATION

### Purpose of the Research

**\*Q1.** Using lay language, describe the purpose and rationale for the proposed study. State the hypotheses and/or research questions and objectives. Provide the background information and cite relevant literature to contextualize the study.

**\*Q2.** Describe the anticipated value and potential benefits of the study and explain how the results will be disseminated (e.g., thesis, academic presentations/publications, websites, community organization, etc.).

### Location

**\*Q3.** Describe the locations (e.g., country, city) and settings (e.g., campus lab, private home, youth centre) where the data collection will take place.

Indicate any organization approvals, local legislation, regulations, permissions or customs that need to be addressed to conduct this research (e.g., research visa; school boards).

Attach support letters if already obtained. If more than one document, upload as separate documents, identifying by title and version date in file name and on each document.

The researcher is responsible for determining and obtaining all necessary approvals prior to starting the study.

Upload all relevant documents:

### Participant Description

**\*Q4.** Describe in detail the characteristics of the participant population(s). List and provide justification for all inclusion/exclusion criteria.

**\*Q5.** In what language(s) will the research be conducted?

English

French

Other

**\*Q6.** Given the participant population, is it likely that participants may have communication difficulties (e.g., who may need translation, who are illiterate/have low literacy, who may have trouble understanding or producing speech) and who may require special support?

**\*Q6a.** Please describe the issue and how it will be addressed.

**\*Q7.** Does the research involve Aboriginal peoples (Inuit, Métis, First Nations) where research is conducted on their territory; or Aboriginal identity is used as a variable for the purpose of analysis; or interpretation of results will refer to Aboriginal communities, peoples, language, history or culture? Please see the [TCPS2, Chapter 9](#) for detailed guidance.

**\*Q7a.** Describe the plan for community engagement. Attach supporting letters and other relevant documents, if available. If community engagement will not be sought, explain why not, referencing [TCPS2, Article 9.2](#).

**\*Q7b.** Describe the organizational structure and community process to obtain approval to conduct research on the territory/in an organization or with a particular community.

**\*Q7c.** Will there be a research agreement between the researcher and the community/organization?

**Q7d.** Upload all relevant documents (e.g., support letter, research agreement). If more than one document, upload as separate documents, identifying by title and version date in file name and on each document.

If more than one document, upload as separate documents, identifying by title and version date in file name and on each document.

### **Methodology/ Procedures**

**\*Q8.** Answer all the points below for each method and procedure used to obtain data:

**Q8a.** Describe in detail what data is needed to answer the research questions/objectives and what activities and/or procedures will be used to collect the data.

**Q8b.** For each activity/procedure, specify where it will be done, the approximate time commitment and frequency (as applicable).

**Q8c.** For each activity/procedure, describe the methods to be used (e.g., paper/online surveys, interviews, focus groups, questionnaires, video-recording, etc.). List and attach all measures that will be used such as surveys, interview guides, observation guides. If a published scale, the link can be provided. Attachments can be uploaded below.

**Q8d.** Identify who will do the data collection if not the Principal Investigator.

**Q8e.** Please upload all relevant methodology documents (e.g., measures to be used, surveys, interview guides). If more than one, upload as separate documents, identifying by title and version date in file name and on each document.

**\*Q9.** Will any participants be photographed or video-recorded?

**\*Q9a.** Describe the nature of the images and why these are needed. Indicate how the images may be used (e.g., only for the purpose of analysis by the researcher, for public dissemination, etc.).

**\*Q10.** Will any participants be audio-recorded?

**\*Q10a.** Indicate how the recordings may be used (e.g., only for the purpose of analysis by the researcher, for public dissemination, etc.).

**\*Q11.** Will you collect and use any materials created or provided by the participants such as photos, writings, video-recordings, drawings?

**\*Q11a.** 11a. Please describe. Indicate how these materials may be used (e.g., only for the purpose of analysis by the researcher, for public dissemination, etc.).

**\*Q12.** Will there be participant observation?

**\*Q12a.** Please describe in detail (e.g., who is being observed, what is being observed, how is data being collected).

## RECRUITMENT

**\*Q1.** Estimate the number of participants needed for each category of participants and methodology (e.g., adults, youth, surveys, focus groups, etc.). Provide a rationale for how this was determined.

**\*Q2.** Describe in detail how potential participants are identified, contacted and invited to participate in the study. If applicable, describe any screening procedures. Identify who will be doing the recruitment. Attach all documentation to be used.

**\*Q3.** Is there a relationship between the study participants and the person recruiting and/or any of the members of the research team?

**\*Q3a.** Please explain the nature of the relationship, and outline the steps that will be taken to avoid/reduce the perception of undue influence/coercion/pressure to participate.

**\*Q4.** Describe any compensation/reimbursement/incentives participants will receive. Describe how compensation will be allocated if they choose to withdraw before completing the study.

**\*Q5.** Describe any organizational or community approvals that may be needed to recruit or access the target population (e.g., school board/principal; website manager; camp director). Explain how this will be obtained and attach relevant documentation to be provided to any third parties). Attach support letters if already obtained.

**Q6.** Please upload all recruitment/permission materials for participants and any third parties (e.g., posters, letters, emails, oral scripts). Upload as separate documents, identifying by title and version date in description and on the documents.

### CONSENT PROCESS

**\*Q1.** Will the participant population include those aged 18 and older who are competent to consent?

**\*Q1a.** Describe the procedures that will be followed to obtain consent. Identify who will explain and obtain consent. If alternate processes to written consent are planned (e.g., verbal, online, waiver), please provide a rationale and outline the procedure for obtaining and documenting consent. See the [TCPS2, Chapter 3](#) for detailed guidance.

**\*Q2.** Will the participant population include those aged 18 and older who are NOT competent to consent?

**\*Q2a.** Describe the process by which capacity/competency will be assessed. Describe the procedures that will be followed to obtain consent and identify who the authorized representative will be. Identify who will explain and obtain consent. If alternate processes to written consent are



planned (e.g., verbal, online), please provide a rationale and outline the procedure for obtaining and documenting consent. See the [TCPS2, Chapter 3](#) for detailed guidance.

**\*Q2b.** Describe how assent will be obtained from those unable to consent on their own, given the nature of the research and the capacity of the individual.

**\*Q3.** Will the participant population include those under the age of 18?

**\*Q3a.** Describe the procedures that will be followed to obtain parental/legal tutor consent. Identify who will explain and obtain consent. If alternate processes to written consent are planned (e.g., verbal, online), please provide a rationale and outline the procedure for obtaining and documenting consent. In some cases, participants 14 and over can consent for themselves. If this is proposed, describe the rationale given the nature and context of the study and describe the process by which their capacity or competency to consent will be assessed. See the [TCPS2, Chapter 3](#) for detailed guidance.

**\*Q3b.** Describe how assent from those unable to consent on their own will be obtained, taking into consideration the age of the participants and the nature of the research.

**\*Q4.** Will deception or non-disclosure be used in this study?

**\*Q4a.** Please describe and provide justification. Explain how participants will be debriefed and attach the debriefing form. Justification must be provided if debriefing will not be provided.

**\*Q5.** Is there a relationship between the study participants and the person obtaining consent and/or the principal investigators?

**\*Q5a.** Please explain the nature of the relationship, and outline the steps that will be taken to avoid the perception of undue influence.

**\*Q6.** Consent can be withdrawn at any time. Please explain what will happen to participant information if they withdraw. If a participant withdraws consent, the participant can also request the withdrawal of their data. Describe any limitations on the feasibility of the withdrawal of data once collected (e.g., publication of data; when personal information has been anonymized and added to a data pool, etc.).

Q7. Please upload all Consent/Assent/Debriefing forms and scripts. If using an oral consent procedure, please upload the oral scripts which must contain the same elements as a written consent. See the consent template for guidance.

### **RISK/ BENEFIT ASSESSMENT**

**\*Q1.** Describe any known or reasonably foreseeable harms or discomfort, if any, that the participants or others might be subject to during or as a result of the research. Harm is anything that has a negative effect on the welfare of individuals or groups and may include psychological, physical, emotional, social, economic, or political harms.

**\*Q2.** Assess the potential risk of harms considering the expected magnitude or seriousness of a harm and the likelihood of someone actually experiencing harm. Consider the potential vulnerability of the participants within the specific research context. Detail the steps that will be taken to manage, reduce or eliminate potential harms or discomforts.

**\*Q3.** Describe the potential benefits (if any) of the research to the individual study participants or the population/community being researched (note that compensation/incentives are not a benefit). Explain why these potential benefits may justify any risks that were identified above.

### **CONFIDENTIALITY AND DATA SECURITY**

**Important definitions (see [TCPS2](#) glossary):**

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

**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.

**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).

**\*Q1.** Describe how the identity of research participants will be protected during recruitment and data collection and after the research, including how participants will be identified on data collection instruments and in publications.

Indicate if participants may be identified by name or otherwise (e.g. organization, job title) in any reports and indicate why this would be an appropriate option for participants to agree to.

Explain if participant confidentiality is not applicable (e.g. anonymous survey).

**\*Q2.** Describe how and where all identifiable study materials (e.g. consent forms, study data, contact information) will be kept secure during the conduct of the study, both in the field (if applicable) and at McGill University (e.g. password protection, encryption, unique codes).

As applicable, describe how physical or electronic materials will be securely transported or transmitted between data collection and data storage sites and/or amongst the research team.

If data is shared with non-McGill collaborators, will they employ the same data security measures?

**\*Q3.** Who will have access to identifiable study materials including data, consent forms, audio/video recordings, code keys, etc.?

**\*Q4.** If third party data collection or storage services will be used (e.g. cloud storage, online surveys, mobile apps) indicate which one(s), and include details on security and confidentiality of data including final disposition of the data.

Suitability of these services (legal and jurisdictional considerations) for this study is the responsibility of the researcher. For more information, please consult the [University's Cloud Data Directive](#).

**\*Q5.** Are there any reasonably foreseeable disclosure requirements (e.g., duty to disclose abuse or neglect of minors) considering the population and the nature of the research?

**\*Q5a.** Describe what these disclosures might be and how they will be handled.

**\*Q6.** Is it expected that any clinically relevant results may be generated (e.g. high scores on depression measures, blood test results, poor vision)?

**\*Q6a.** Describe if, and what, individual results will be returned to participants and under what conditions. How will this information be communicated in a confidential manner?

**\*Q7.** Are there any other factors which may limit the confidentiality of participants due to context or procedures (e.g. sample size, focus groups, location, recruitment, use of translator or transcriptionist)?

**\*Q7a.** Please describe and discuss how the issue will be addressed.

NOTE: Use of third party services such as translators requires a confidentiality agreement.

**Q7b.** Attach any confidentiality agreements, as applicable.

**\*Q8.** Will any bio specimens (e.g. blood, urine, saliva, hair) be collected?

**\*Q8a.** Describe the procedures for storage, handling, transportation and disposal for each type collected.

**\*Q9.** Describe how the study data and other materials (e.g. consent forms) will be stored at completion. Provide details of final disposal or storage. Include details of the storage location (e.g. PI lab at McGill), storage conditions (e.g. encrypted external hard drive, cloud storage, locked drawer) and how long they will be retained.

Specify if, and what, identifiable information will be retained once data collection is complete, and explain why retention of identifiable information is necessary.

Indicate if someone other than the PI will store the data and describe what data is involved.

**\*Q10.** Identifiable or anonymized data collected as part of a research project can only be shared or used in the future with the explicit consent of participants.

In current best practices in many fields of research, electronic data is to be preserved for future use in open access initiatives. Data is normally uploaded to an online repository and/or provided to other qualified researchers, stripped of any information that could identify participants (e.g., names, email addresses, audio recordings), to ensure confidentiality.

If data will be shared with other researchers or users, please describe how and any restrictions that will be made regarding access.

## **CONFLICTS OF INTEREST**

**\*Q1.** Will the researcher(s), members of the research team, and/or their partners or immediate family members receive any personal benefits, financial or otherwise (outside of expected standard salary/conference/expenses) directly related to this study?

**\*Q1a.** Please describe.

**\*Q2.** Are there any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the researcher(s) including any publication restrictions by any third parties.

**\*Q2a.** Please describe.

**\*Q3.** Does any member of the research team have a dual role or any other relationship, financial or non-financial, that may be, or could be seen to be, a conflict of interest in relation to the study participants or any aspect of the research (e.g. teaching or clinical relationship, family member, supervisory relationship)?

**\*Q3a.** Please describe and address how these conflicts will be managed.

**\*Q4.** Are there any other issues or information that need to be considered by the Research Ethics Board in the review of this application?

**\*Q4a.** Please specify.

### **ADDITIONAL DOCUMENTATION**

Please upload any additional documentation relevant to the study. If more than one, upload as separate documents, identifying by title and version date in file name and on each document.

### **SUBMISSION APPROVAL**

As the Principal Investigator (PI) of this study, I confirm that I have reviewed the McGill University Policy on the Ethical Conduct of Research Involving Human Participants, and I agree

to comply with this and any other relevant University policies, as well as the Tri-Council Policy Statement Ethical Conduct of Research Involving Humans ([TCPS2](#)), and those of my profession or discipline regarding the ethical conduct of research.

I have read and approved the content of this application.

I allow release of my nominative information as required by these policies and procedures.

\*Select the appropriate response below:

You can save this document and return later to complete and submit it. If you are ready to submit your application, you have two submission options:

- a. Advance your application to your supervisor for review and electronic signature within eRAP (this system).
- b. If your supervisor cannot access eRAP to review and approve your application electronically, you can download a PDF of your application for your supervisor to review and approve. In this case, your supervisor will also have to sign a [Supervisor Assurance Statement](#) form. Once the signature is obtained, the form must be uploaded to this application and then you can advance this application submission directly to the REB Office.

\*Given the options above, select the desired response below: