NMREB Initial Application Form

Orange text indicates an upload or action feature
Red//bold indicates question/feature dependencies
Green text indicates a question that can be duplicated to provide multiple answers
Blue Text indicates the help text associated with the question
Questions with an asterisk (*) are mandatory and must be completed prior to signatures and submission
Indicates a shared question from the HSREB Initial Application.

SECTION 1 – GENERAL INFORMATION

1.1*If this is the first time you are submitting this particular application to the REB, select "Initial Submission". If this application has already been reviewed by the REB and they issued recommendations, select "Response to REB recommendations":

☐ Initial Submission

☐ Response to REB recommendations

HELP TEXT: If this is the FIRST TIME this application is being submitted, please select "Initial Submission". If this is a re-submission for modifications requested by the REB please select "Response to REB recommendations".

Once the PI is added to this form you MUST also add them into the ROLES tile (See ROLES tile in the action items on the left hand side of your screen). HELP TEXT: If you are the project/form owner (i.e., you created the application), AND you are the PI, you do not need to add yourself to the ROLES tab, as you already have access to the file. This guidance is specifically for other study team members creating the application to ensure the PI is given access to the WREM file.

1.2 *Use the Search field to enter the Principal Investigator (PI) details from the WREM user directory:

*Prefix:
*First Name:
*Last Name:
Address:
City:
Province:
Postcode:
Telephone:
*Email:

*Indicate the PI's departmental appointment: [drop down]
Western Academic Faculty/Department:
Hospital Department/Division:

Once study team members are added to this form you MUST also add them into the ROLES tile (See ROLES tile in the action items on the left hand side of your screen).

1.3* Are there any additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or its affiliate institutions working on this project? This question is repeated 15 times

☐ Yes there are additional study team members

☐ No other study team members involved

1.3 **If 'Yes':** *Complete the following information for additional study team members (from Western and or its affiliate institutions) who are working on this study: This question is repeated 15 times

HELP TEXT: NOTES: Be sure to include the Project Owner (i.e., the person creating the application) if this person is not the PI. All local study team members must have WREMaccounts (see "New User" button on log-in page to register). All study team members requiring access to this application need to be given a ROLE (see Actions at the left of the screen).

[search user directory]

*Prefix:

*First Name:

*Last Name:

Address:

City:

Province:

Postcode:

Telephone:

*Email:

1.3 ***Specify** ROLE,DUTIES, and DEPARTMENT/FACULTY (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data; Psychology/Social Sciences.): This question is repeated 15 times

1.3a *Are there any additional study team members (from Western and/or its affiliate institutions) who are working on this project? This question is repeated 15 times

☐ Yes there are additional study team members

☐ No other study team members involved

1.3a **If 'Yes':** *Complete the following information for other study team members (from Western and/or its affiliate institutions) who are working on this project: This question is repeated 15 times

HELP TEXT: NOTES: Be sure to include the Project Owner (i.e., the person creating the application) if this person is not the PI. All local study team members must have WREMaccounts (see "New User" button on log-in page to register). All study team members requiring access to this application need to be given a ROLE (see Actions at the left of the screen).

[search user directory]

*Prefix:

*First Name:
*Last Name:
Address:
City:
Province:
Postcode:
Telephone:
*Email:

1.3a *ROLE,DUTIES and DEPARTMENT/FACULTY in this study. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data, Psychology/Social Science.): This question is repeated 15 times

Etc. up to 1.3o

1.4 *Is this study taking place in collaboration with anyone outside Western University and/or its affiliate institutions?

☐ Yes ☐ No

If 'Yes': ***Complete the following information for all NON-Western affiliated team members who will be involved in study procedures and have access to participant(s) and/or personal information: **HELP TEXT: This includes other universities, community agencies, etc. which has ethics implications regarding who is involved in various study activities and who will have access to data.

*Name
*Position
*Organization
*ROLE and DUTIES in this study. (E.g. John Doe - Co-Investigator - responsible for recruitment, interviews and analysis of data.): **<Multi-Line Text Box>**
(ADD ANOTHER)

1.5 *Who is the Study Sponsor?

HELP TEXT: An individual, corporate body, institution or organization that takes responsibility for the initiation and management of the study.

☐ Industry Sponsored
☐ External not-for-profit
☐ External PI (outside of Western)
☐ Local Team Member (Western-affiliated team member other than PI on this REB application)
☐ Local PI (PI on this REB application)

If 'Industry Sponsor' selected:

*Complete the Sponsor details:
Title:
First Name:

Last Name:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

1.6 *Is this study contributing to any students' academic requirements? (select all that apply)

☐ No
☐ Yes-Undergraduate
☐ Yes-Masters
☐ Yes-PhD
☐ Yes-Other
If Other: *Specify Other: **<Multi-Line Text Box>**
If any option other than 'No' is selected: *Specify student(s): **<Multi-Line Text Box>**

1.7 *Is this research study supported by the United States federal government (including a study funded by a US government agency)?
☐ Yes ☐ No

1.8 *Enter the Complete Study Title: **<Multi-Line Text Box>**

1.9 *What is the acronym or nickname/short title for the study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and REB applications associated with this project.): **< Single-Line Text Box>**

1.10 *Is this study directly related to a previously approved study, or a study currently under review at this institution (e.g., is this study a sub-study, extension, rollover, subsequent to a pilot study, etc.)?
☐ Yes ☐ No

If Yes: *Who was/is the PI for the previous/pending study? **<Multi-Line Text Box>**
If Yes: *What is the REB number? **<Multi-Line Text Box>**
If Yes: *Indicate the study title of the related study. Provide a brief summary of the related study and indicate how it relates to this current study: **<Multi-Line Text Box>**

1.11 *Has the study been (or will the study be) reviewed and approved by another REB in Canada?
☐ Yes ☐ No ☐ Pending review/approval
If Yes: *Upload the approval letter(s) and/or relevant correspondence:

Upload Document (Document Name, Document Date, Version) – Document Type: Other REB approval letter

If 'Pending': ***Specify the other REB(s)who will be reviewing the study: **<Multi-Line Text Box>

1.12 ***Does this study involve the London hospitals**

☐ No this study does not involve the London hospitals

☐ This study involves the London Hospitals but a ReDA submission has not been completed. STOP: Contact both The Office of Human Research Ethics and Lawson Health Research Institute to determine if you may proceed submitting your REB application to the Non-Medical REB OR if you must submit a ReDA application, export to WREM, and submit a Health Sciences REB application.

If "Box 1" is selected in Question 1.12, then the following sub-questions appears

*Type in "Western Research Services" in the Search User text box:

***Name:**

***Email:**

If 'Box 2' is selected in Q1.12 then the following appears:

*Justify why proceeding with an NMREB application is appropriate in this case: **<Multi-Line Text Box>**

1.13 ***Provide a brief lay/non-scientific summary of the study (max 250 words).**

HELP TEXT: This summary provides a quick overview of the project for the REB across study documents and for reporting purposes. It should therefore be a clear, concise, and an accurate reflection of the project in lay, non-expert language. When writing this summary, think about it as an 'elevator pitch' or how you would describe this study to non-expert family members/friends.

<Multi-Line Text Box>

SECTION 2 – STUDY DESCRIPTION

2.1 *Briefly describe the rationale for this study in **lay language** (i.e., why is this study being done?). Include relevant background information from previous studies, with in-text citations. . **HELP TEXT: Define acronyms at first use, explain terms, and avoid jargon. If relevant to this research, include a positionality statement, if comfortable. . <Multi-Line Text Box>**

*Upload the reference list:

Upload Document (Document Name, Document Date, Version) – Document Type: References

2.2 * What are the research questions, hypotheses, and/or primary objective(s) (NOTE: If there are secondary objectives, please list those in addition to the primary objectives): **HELP TEXT: These questions, hypotheses and/or objectives should be clearly linked to the background/rationale provided in Q2.1. <Multi-Line Text Box>**

2.3 *Indicate your study design and methodology by checking off all relevant designs below:

- ☐ Quantitative
- ☐ Qualitative
- ☐ Mixed methods
- ☐ Survey research
- ☐ Pilot study/proof of concept
- ☐ Secondary data (secondary use of previously collected human participant information)
- ☐ Cross-sectional
- ☐ Longitudinal
- ☐ Randomized
- ☐ Observational
- ☐ Clinical trial: **According to Tri-Council Policy Statement 2nd Ed., a clinical trial includes an investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes (e.g., behavioural interventions, psychotherapeutic treatments). Clinical trials are used to determine whether new interventions are safe, efficacious, and effective.**
- ☐ Experimental
- ☐ Research involving human biological materials (living or deceased): **Note: Research that involves proposed genetic testing and/or may lead to findings relevant to the medical field or human health must be submitted to the HSREB. Non-medical research involving human biological materials would include non-invasive collection of samples from live participants and/or sample collection from deceased participants (i.e., historical/archaeological or cadaveric) for non-medical research purposes (e.g., sociocultural, psychological, etc.).** Research studies that have obtained or are looking to obtain cadaveric material(s) through the Body Bequeathal program in the Department of Anatomy and Cell Biology, Schulich Medicine & Dentistry, Western University must be submitted for REB review to the Cadaveric Research Ethics Board (CREB) using the CREB application within WREM.
- ☐ Collaborative community-based research methodologies (e.g., CBR, participatory action research, etc.)**: Help Text: Researchers have an ethical responsibility to the community during and after the research. Please refer to TCPS2 Chapter 9 for ethical principles in community engagement. (Note: These principles can be applied to all community-based research, not only in Indigenous contexts)**
- ☐ Other study design and/or methodology

If 'Secondary Data' selected in Q2.3: *Was the data previously collected for a research project?

☐ **Yes** ☐ **No**

If yes: *State the REB that approved the project, the project ID number, the PI, and the study title. **<Multi-Line Text Box>**

If 'Secondary Data' selected in Q2.3: *Upload all relevant information/documents (e.g., consent to future use, permission to access):

Upload Document (Document Name, Document Date, Version) – Document Type: Other

<Add another>

If 'Secondary Data' selected in Q2.3: *Describe the original/primary purpose of the data that will now be used for secondary purposes: **<Multi-Line Text Box>**

If 'Secondary Data' selected in Q2.3: *What were the participants who originally contributed the data informed about how their information would be used? (Note: Indicate 'see document' if this information is already provided in an attached document) **<Multi-Line Text Box>**

If 'Secondary Data' selected in Q2.3: *Describe what data is being used for this secondary purpose: *Note: A document illustrating the data/variables must also be submitted to Q2.5 (e.g., as 'Other') – otherwise the application will be returned incomplete prior to review.* **<Multi-Line Text Box>**

If 'Secondary Data' selected in Q2.3: *Describe how and from whom this secondary data is being collected/accessed by the researcher(s): **<Multi-Line Text Box>**

If 'Clinical trial' selected in Q2.3: *Has this study been or will this study be registered on a publicly accessible clinical trial registry? (e.g., www.clinicaltrials.gov, www.controlled-trials.com/isrctn/)

☐ **Yes** ☐ **No**

If Yes: *Indicate the registry name and registration number. NOTE: REB approval will not be issued until this is received. **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *How do you define "community" for this project? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3:*How have you engaged with the community to design your project? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *How long have you been collaborating with this community? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *How will you engage with the community during the project? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *How will you engage with the community after the project? (e.g., how will you engage the community in the dissemination of results) **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *Who is your key contact person in the community and how was this person identified? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *Is this person able to make decisions about the research on behalf of the community? **<Multi-Line Text Box>**

If 'Community-based' selected in Q2.3: *Does the community have their own ethics or research approval process?

☐ Yes ☐ No

If 'yes':

***Upload any Letters of Support, MOUs or Principles of Collaboration, etc.

Upload Document (Document Name, Document Date, Version) – Document Type: Other REB approval letter

<Add another>

If 'Other' selected in Q2.3: *Specify "Other study design and/or methodology": **<Multi-Line Text Box>**

2.4 *Describe your study procedures involving human participants (i.e., what are you doing and how are you doing it?)

For primary data collection: What will a participant experience in this study? Required details include anticipated time commitments, number of sessions/activities, total duration, study locations, etc.

For Multi-Jurisdictional Research: Describe the research activities being conducted by the Western-affiliated study team members.

For Secondary data: Indicate N/A.

See help text for more information:

HELP TEXT: 1. The Board needs to understand everything that a participant will experience in order to approve the application. 2. If there are multiple procedures, ensure to describe each of them. 3. Include study locations, number of sessions, anticipated time commitments, use of audio/video-recording, if/how study procedures may evolve and why, if procedures are optional or mandatory, etc.

<Multi-Line Text Box>

2.5 ***Indicate which of the following study instruments will be used in this study:

Note:

Everything a participant will see/experience, the REB needs to see/experience.

The REB needs to understand exactly what data is being collected/used for research purposes.

- ☐ Paper Survey(s)/Questionnaire(s)
- ☐ Online Survey(s)/Questionnaire(s)/Task(s)
- ☐ Interview Guide(s)
- ☐ Focus Group Guide(s)
- ☐ Non-Participant Observation Guide(s)
- ☐ Participant Observation Guide(s)

- ☐ Other (e.g., visual/auditory stimuli, data collection forms, participant instructions, etc.)
- ☐ None

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Paper Survey(s)/Questionnaire(s)': *Upload "Paper survey(s)/Questionnaire(s)":
Upload Document (Document Name, Document Date, Version) – Document Type: Paper Survey
Add Another

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Online Survey(s)/Questionnaire(s)/Task(s)': *Upload "Online Survey(s)/Questionnaire(s)/Task(s)":
Note: Do NOT include the letter of information/consent or debriefing content in this document
Upload Document (Document Name, Document Date, Version) – Document Type: Online Survey
Add Another

If 'Online Survey(s)/Questionnaire(s)/Task(s)': *Specify what online platform is being used to collect the data (e.g., Western's Qualtrics available at mysurveys.uwo.ca): **<Multi-Line Text Box>**

If 'Online Survey(s)/Questionnaire(s)/Task(s)': *After consent, can all questions/tasks be skipped by the participant?
Note: Make sure this answer aligns with the programmed online survey and the letter of information/consent.
☐ Yes ☐ No

If 'No':* Specify which questions/tasks are not able to be skipped and provide justification: **<Multi-Line Text Box>**

If 'Online Survey(s)/Questionnaire(s)/Task(s)': *Provide the URL for any online material(s). Note: Review of the URL is required, for testing purposes, prior to REB Approval.
.**<Multi-Line Text Box>**

If 'Online Survey(s)/Questionnaire(s)/Task(s)':
TIP: Consider how you will protect your online research from illegitimate, fraudulent, or otherwise unusable data (e.g., bots, careless responders, etc.).

Note: Refer to the NMREB Ethical Challenges in Online Research: Bots, suspicious data, and other issues document for more information (see WREM Help tab > Templates OR our Guidelines & Templates page on our website).

If 'Interview Guide(s)':

*Will the interview be audio-recorded?

☐ Yes ☐ No

If 'No' *How will data be recorded/collected? **<Multi-Line Text Box>**

If 'YES' *Who will transcribe the audio-recordings?
Help Text: Please ensure this is clearly stated in the Letter of Information and Consent document.

If 'YES'*Is audio-recording optional or mandatory?
☐ Mandatory ☐ Optional

If 'Optional" *How will you record the data if participants do not want to be audio-recorded during the interview?

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

*Upload "Interview Guide(s)":
Upload Document (Document Name, Document Date, Version) – Document Type: Interview Guide
Add Another

If 'Focus Group Guide(s)':
*Will the focus group interview be audio-recorded?

☐ Yes ☐ No
If 'No' *How will data be recorded/collected? **<Multi-Line Text Box>**

If 'YES' *Who will transcribe the audio-recordings?
Help Text: Please ensure this is clearly stated in the Letter of Information and Consent document.
If 'YES'* Is audio-recording optional or mandatory?
☐ Mandatory ☐ Optional
If 'Optional" *How will you accommodate participants who do not want to be audio-recorded in the focus group(s)?**<Multi-Line Text Box>**

If 'Optional" *How will you record data for participants who do not want to be audio-recorded in the focus group(s)? **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Focus Group Guide(s)': *Upload "Focus Group Guide(s)":
Upload Document (Document Name, Document Date, Version) – Document Type: Focus Group(s) Guide
Add Another

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Non-Participant Observation Guide': Upload "Non-Participant Observation Guide(s)":
Upload Document (Document Name, Document Date, Version) – Document Type: Non-Participant Observation Guide
Add Another

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Participant Observation Guide': Upload "Participant Observation guide(s)":
Upload Document (Document Name, Document Date, Version) – Document Type: Participant Observation Guide
Add Another

If 'Other': *Describe "Other" instrument(s) and how they will be used in this study: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Other': Upload "Other" instruments:
Upload Document (Document Name, Document Date, Version) – Document Type: Other Data Collection Instruments

2.6 *Will any technological tool(s)/platform(s)/software/device(s) be used, that is beyond an institutional network or hard drive, throughout the project (e.g., data collection, analysis, transfer, storage, etc.)?

Note: This includes, but is not limited to, Western-hosted Zoom, Qualtrics, cloud-based analysis tools, third-party transcription platforms, recording devices, etc.

☐ Yes ☐ No

If 'Yes': *Specify the tool(s)/platform(s)/software(s)/device(s): **<Multi-Line Text Box>**

If 'Yes': *Has the tool(s)/platform(s)/software(s)/device(s) received any of the following:

- Technology Risk Assessment by Western's Technology Risk Assessment Committee (TRAC)?
- Authorized Technology Review at LHSC or SJHC?
- Review by a local institutional privacy office (e.g., Western's privacy office, hospital privacy, or other collaborating institution privacy office)?

☐ Yes ☐ No ☐ Unsure

If 'Yes': Upload any relevant reports and/or other review/approval documentation.
Upload Document (Document Name, Document Date, Version) – Document Type: Technology Review Document
Add Another

If 'Yes': *Specify what information will be collected through and/or entered into the tool(s)/platform(s)/software(s)/device(s) and for what purpose: **<Multi-Line Text Box>**

If 'Yes': *Specify who will have access to this information and for what purpose (incl. third party vendors and any future use, if applicable): **<Multi-Line Text Box>**

If 'Yes': *Specify how long will the information be accessible in the tool(s)/platform(s)/software/device(s): **<Multi-Line Text Box>**

If 'Yes': * Specify how the information will be removed from the tool(s)/platform(s)/software/device(s): **<Multi-Line Text Box>**

2.7 *Do you have any supplementary tables or figures to accompany your study procedures description?

☐ Yes ☐ No

If 'Yes': *Upload the accompanying attachment(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Supplementary Tables/Figures
Add Another

2.8 *Do you have a separate protocol or research plan document for this study?

☐ Yes ☐ No

HELP TEXT: A protocol/research plan provides a blueprint that specifies all aspects of a study's conduct. This includes pre-specifying research questions, hypotheses, outcomes, analysis plans and the duration of follow-up (i.e., the "who", "what", "when", "where" and "how" of the project).

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Yes': *Upload the protocol/research plan for this study:

Upload Document (Document Name, Document Date, Version) – Document Type: Protocol/research plan

2.9 *Does this study include any deception or withholding of key information?

HELP TEXT: This includes withholding the true purpose of the project from participants to avoid priming effects that may occur from knowing the purpose upfront.

☐ Yes ☐ No

If 'Yes' to deception (Q2.9): * Explain and justify the use of deception or withholding of key information:

<Multi-Line Text Box>

If 'Yes' to deception (Q2.9): **Will participants be debriefed following deception or withholding of key information?

☐ Yes ☐ No

If 'Yes' to deception (Q2.9) AND 'yes' to debriefing (Q2.9): *Describe how and when the participants will be debriefed: **<Multi-Line Text Box>**

**If 'Yes' to deception (Q2.9) AND 'yes' to debriefing (Q2.9): ***Upload the debriefing document (e.g., verbal debriefing script, debriefing letter to participant, etc.):

Upload Document (Document Name, Document Date, Version) – Document Type: Debriefing Document

Add Another

If 'Yes' to deception (Q2.9) AND 'No' to debriefing (Q2.9):*Justify why participants will not be debriefed following deception or withholding of key information: **<Multi-Line Text Box>**

2.10 **If 'No' to deception (Q2.9)** *Will participants be debriefed following their participation?

☐ Yes ☐ No

HELP TEXT: Debriefing is separate from recruitment/consent and occurs after participation. This debriefing form would not include a summary of results (see Q2.18).

If 'Yes' to debriefed (Q2.10): *Describe how and when the participants will be debriefed: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

**If 'Yes' to debriefed (Q2.10): ***Upload the debriefing document (e.g., verbal debriefing script, debriefing letter to participant, etc.):
Upload Document (Document Name, Document Date, Version) – Document Type: Debriefing Document
Add Another

2.11 *Will this research take place in a K-12 education system or child-care system [onwards "the school"]?
☐ Yes ☐ No

If 'Yes' to Q2.11, then Q2.12-Q2.13 will appear.

2.12 *Indicate which groups you will recruit from the school. (Please select all that will apply):
☐ Students
☐ Teachers
☐ Principals
☐ Vice Principals
☐ Parents
☐ Volunteers
☐ Other
If 'Other': *Specify Other: **<Multi-Line Text Box>**

If 'Student' *Specify student grade/level (e.g., Grade 3/Primary):
If 'Student' *Explain what non-consenting students will do during study activities:

2.13 *Will you be requesting any information from the school or the board (e.g., student achievement scores, report card grades)?
☐ Yes ☐ No
If 'Yes': *Indicate the type of information that will be requested from the school or the board, and whether this is optional or mandatory for participation in this study: **<Multi-Line Text Box>**

2.14 *What is the sample size? Consider minimum and maximum numbers, in the context of your research methods/objectives.

For primary data collection: What is the anticipated number of participants and/or what will be the rationale/decision-making framework for ending recruitment?

For secondary data: How many participants/cases are included in the dataset? ***<Multi-Line Text Box>***

2.15 *What are the inclusion criteria for participating in this study?

For secondary data: Indicate N/A. **<Multi-Line Text Box>**

2.16 ***Will anyone be excluded on the basis of attributes such as culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, gender or age?

See TCPS2 Chapter 4 for more information. Consider also socioeconomic status, physical attributes, means of transportation, access to & proficiency with technology/internet, etc.?

<Multi-Line Text Box>

☐ Yes ☐ No

If 'Yes': *Describe and justify: <Multi-Line Text Box>

2.17.1 ***Will your research affect the welfare of Indigenous Peoples or communities, or is it anticipated Indigenous Peoples/communities will be overrepresented in your sample?*Note: This includes urban Indigenous Peoples or communities, in Canada or internationally. Welfare may be affected positively or negatively, directly or indirectly. When answering this question, researchers must consider the TCPS2 core ethical principles from the Indigenous perspective (e.g., including but not limited to acknowledging the interconnectedness of humans/nature, concern for the collective rights and interests of Indigenous Peoples and communities, and ongoing power imbalances within society and research; see TCPS2 Chapter 9, Section B)*

Help Text: Review TCPS2 Chapter 9 for more information.

☐ Yes ☐ No

If 'No' to Q2.17.1 then question 2.17.1a appears:

Q2.17.1a*Which of the following apply to this research?

- ☐ Indigenous Peoples may meet the inclusion criteria. Information pertaining to their Indigenous identity will not be collected.
- ☐ Indigenous Peoples may meet the inclusion criteria. Information pertaining to their Indigenous identity will be collected – solely for reporting participant demographics. No inferences will be made about Indigenous Peoples/communities in the results.
- ☐ Indigenous Peoples will not be involved in this research.

If 'Yes' to Q2.17.1, then questions 2.17.1b-2.17.1e appear:

Q2.17.1b *Which of the following apply to this research? (select ALL that apply)

- ☐ The research will be conducted on, or have implications for, Indigenous land (as defined by TCPS2 or internationally)
- ☐ The recruitment inclusion criteria include Indigenous identity as a variable for the entire study or a sub-group of the study.
- ☐ The research requires input from participants regarding an Indigenous community's cultural heritage, artifacts, traditional knowledge, or unique characteristics.
- ☐ Indigenous identity or membership in an Indigenous community is used as a variable for analysis.
- ☐ Interpretation of research results will refer to Indigenous Peoples'/communities' data, language, history, or culture.

Help text: TCPS2 refers to First Nations, Inuit, and Métis lands in Canada, which includes Indian reserves, Métis settlements, and lands governed under a self-government agreement or an Inuit or First Nations land claim agreement. Internationally, ensure you are aware of the lands in which your research is taking place and the local nations whose territories may be implicated by your work. Exercise due diligence in adhering to local policies and protocols.

Q2.17.1c *Is the PI an Indigenous scholar conducting this Indigenous research?

☐ Yes ☐ No

If 'no': As a non-Indigenous scholar, describe how the PI came to be involved in this work and/or with this community? (multi-line text box)

Q2.17.1d *In the context of this specific project, which Indigenous community or organization is being engaged in this research? **<Multi-Line Text Box>**

Q2.17.1e ***Have you already engaged with this community to design this project?

☐ Yes ☐ No

If 'No' to question 2.17.1e, then question 2.17.1.f appears

Q2.17.1f ***STOP: Given the nature of this research, evidence of Indigenous Community Engagement (or exemption) is required before REB approval can be issued. Please complete this REB application after you have engaged the appropriate community/organization(s).**

If 'Yes' to question 2.17.1e then question 2.17.1.g-2.17.1m appears

Q2.17.1g ***Does this community have their own research ethics approval or consent process?

☐ Yes ☐ No

If 'yes' to question 2.17.1g: *Please elaborate and/or include a link to the community's website: **<Multi-Line Text Box>**

*Upload evidence of community engagement (e.g., email from the Community Partner, Letter of Support, MOU, Principles of Collaboration, etc.)

Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials
<Add another>

If 'no' to question 2.17.1g *****Please upload evidence of appropriate community engagement (Article 9.2). As per TCPS2, Article 9.11, one or more of the following will count as evidence: "a) a preliminary or formal research agreement between the researcher and the responsible body at the research site; (b) a written decision or documentation of an oral decision made in a group setting to approve the proposed research or to decline further participation; and (c) a written summary of advice received from a culturally informed advisory group or ad hoc committee (e.g., an urban community of interest)."
Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials
<Add another>

Q2.17.1h: *Indicate how long you have been collaborating with this community to develop this project*:* (Note: If described in the community engagement document, state 'see document') **<Multi-Line Text Box>**

Q2.17.1i: *How will you engage with this community during this project? (e.g., to inform recruitment/data collection, in the interpretation and dissemination of results) (Note: If described in the community engagement document, state 'see document') **<Multi-Line Text Box>**

Q2.17.1j: *How will you engage with this community after this project? (Note: If described in the community engagement document, state 'see document') **<Multi-Line Text Box>**

Q 2.17.1k: *In the context of this specific project, who is your key contact person in this community and how was this person identified? (Note: Include their contact information if not already provided in the above documentation) **<Multi-Line Text Box>**

Q2.17.1l: *Is the person specified in the prior question able to communicate decisions about this research on behalf of this community? (Note: If described in the community engagement document, state 'see document') **<Multi-Line Text Box>**

Q2.17.1m: *Describe your research data management plan for this project. How will you honour Indigenous Data Sovereignty? Has this Indigenous community/organization agreed to this plan? Please explain: (Note: If described in the community engagement document, state 'see document') **<Multi-Line Text Box>**

Q2.17.2 *Will your research affect the welfare of equity-deserving communities (other than Indigenous groups), or is it anticipated these communities will be overrepresented in your sample?
Tip:

(1) Consider if/how equity-deserving groups will be impacted by the outcomes.
(2) Given the principle of 'nothing about us without us', consider the benefits to your research as a result of consultation with these groups.
(3) While evidence of community engagement may not be an REB requirement, it may be good practice and can inform the REB review.

Help Text: TCPS2 defines vulnerability as limited decision-making capacity, or limited access to social goods, such as rights, opportunities, and power. For this question, equity-deserving communities include, but are not limited to, persons with disabilities, members of visible minority/racialized groups, and members of 2SLGBTQIA+ communities. This question does not include Indigenous communities, as that is captured separately in Q2.17.1.

☐ Yes ☐ No

***If 'no' to Q2.17.2* then Q2.17.2a appears:**

Q2.17.2a: **Note:** If any population is unexpectedly overrepresented after data collection OR if interpretation of research results will refer to demographic categories, community engagement may be needed before reporting. The analysis, interpretation, and dissemination of results needs to be conducted in a way that minimizes potential harm to communities and groups. For example, if research has the potential to stigmatize communities or groups, care is needed to ensure they will not be misrepresented. Researchers must consult the Office of Human Research Ethics if any information is learned during the study that may affect the ethical evaluation of this research, prior to sharing the findings.

If yes to Q2.17.2, then questions 2.17.2b-2.17.2d appear:

Q2.17.2b *Has the PI worked with this community before?

☐ Yes ☐ No

If 'no': *Describe how the PI came to be involved in this work and/or with this community? **<Multi-Line Text Box>**

Q2.17.2c *Describe any engagement that has been or will be carried out with the relevant community, as it pertains to this project: **<Multi-Line Text Box>**

Q2.17.2d *Upload any relevant documents that provide evidence of community engagement (e.g., email from the Community Partner, Letter of Support, MOU, Principles of Collaboration, recommendations from an advisory council, etc.**)**

Upload Document (Document Name, Document Date, Version) – Document Type: Other REB approval letter
<Add another>

2.18 *Will you utilize a screening form/questionnaire to determine eligibility after participants have been recruited but before they are consented?

☐ Yes ☐ No

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Yes': *Upload the screening form/questionnaire:
Upload Document (Document Name, Document Date, Version) – Document Type: Screening Form/Questionnaire
Add Another

2.19 * How will the results will be communicated to **participants** and other **stakeholders** (e.g.; advocacy groups, scientific community):

To Participants:
☐ Summary report or presentation in lay language
☐ Videos, infographics
☐ Exhibition
☐Group debriefing of results (meeting, presentation)
☐ Participants will be invited to co-analyze/interpret data and/or engage in dissemination
☐End of study letter
☐Publication(s)
☐Participants will be invited to contact researchers
☐Other (e.g., creative knowledge exchange plan)
☐No Plan
If 'Other': *Describe "Other": **<Multi-Line Text Box>**
If 'No plan': *Justify "No Plan": **<Multi-Line Text Box>**

If 'Group debriefing' is selected in 2.19, the following questions will appear:
*Describe "Group debriefing": **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

Upload the group debriefing document/script (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Group Debriefing

If 'End of study letter' is selected in 2.19, the following questions will appear:
*Describe when, how, and who will send the End of Study letter to participants:

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

Upload the end of study letter (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: End of Study Letter

To Other Stakeholders:
☐Thesis/Dissertation
☐Presentation(s)
☐Publication
☐Other (e.g., creative knowledge exchange plan)
☐No plan
If 'Other': *Describe "Other": **<Multi-Line Text Box>**
If 'No plan': *Justify "No Plan": **<Multi-Line Text Box>**

SECTION 3 – Biospecimen Collection

If 'human biological materials' selected in question 2.3

3.1.*What type of biological specimen(s) will be collected from the study participants?
<Multi-Line Text Box>

3.2.*How will the biological specimens be collected (select all that apply)?

HELP TEXT: Research studies that have obtained or are looking to obtain cadaveric material(s) through the Body Bequeathal program in the Department of Anatomy and Cell Biology, Schulich Medicine & Dentistry, Western University must be submitted for REB review to the Cadaveric Review Ethics Board (CREB) using the CREB application within WREM.

☐Prospectively collected from live participants for the purposes of this study (i.e., samples have not yet been collected)
☐ Secondary use of previously collected samples from live participants
☐ From deceased human materials (incl. historical/archeological remains and cadavers)

If 'Prospectively collected from live participants for the purposes of this study (i.e., samples have not yet been collected)' is selected in Q3.2, question 3.3-3.9 appear:

3.3.*Indicate whether the biological specimen collection for the purposes of this study is:
☐Mandatory
☐ Optional (separate LOI/C required)

3.4.*Describe how the biological specimens, collected for the purpose of this study, will be used: **<Multi-Line Text Box>**

3.5.*Will the biological specimens, collected for the purpose of this study, be sent outside of the institution for processing and/or analysis?

☐ Yes ☐ No

If 'Yes': *Provide the address and contact details of where the processing and/or analysis of biological specimens will take place for each type of sample. **<Multi-Line Text Box>**

3.6.*Indicate how long the biological specimens will be retained: **<Multi-Line Text Box>**

3.7.*Describe what will happen to the biological specimens, collected for the purpose of this study, at the end of that period (e.g., destroyed, returned): **<Multi-Line Text Box>**

3.8.*Indicate to what extent the study participant is able to withdraw biological specimens collected for the purposes of the study, and any limitations to the withdrawal: **<Multi-Line Text Box>**

3.9.*Will biological specimens be stored or retained or banked for any future research?

☐ Yes ☐ No

If 'yes' to question 3.9, questions 3.10-3.16 appear:

3.10. *Indicate whether the biological specimens to be stored or retained or banked for any future testing is:

☐Mandatory

☐Optional (separate LOI/C required)

3.11.*Where will the biobank(s)/repositories be located (e.g., name of bank & address including country)? **<Multi-Line Text Box>**

3.12. *Where will the associated data be located (e.g., name & address including country)? **<Multi-Line Text Box>**

3.13.*Who will be the custodian of the biological specimens that will be stored or retained or banked for any future testing? **<Multi-Line Text Box>**

3.14.*Who will have access to the banked biological specimens? **<Multi-Line Text Box>**

3.15.*Describe what will happen to the biological specimens (e.g., destroyed, returned) at the end of the banking period (e.g., at the end of the retention period, or if a participant withdraws their consent): **<Multi-Line Text Box>**

3.16. *Indicate to what extent the study participant is able to withdraw banked biological specimens, and any limitations to the withdrawal: **<Multi-Line Text Box>**

If 'Secondary use of previously collected samples from live participants' is selected in Q3.2, question 3.17-3.22 appear:

3.17. *For the secondary use of previously collected samples, describe how the biological specimens will be used in this study: **<Multi-Line Text Box>**

3.18. *Has informed consent been obtained from participants for this secondary purpose?
☐Yes ☐No

3.19. *Will the previously collected biological specimens be sent outside of the institution for processing and/or analysis?
☐Yes ☐No

If 'Yes': * Provide the address and contact details of where the processing and/or analysis of the biological specimens will take place for each type of sample. **<Multi-Line Text Box>**

3.20. *For secondary use of previously collected samples, indicate how long the biological specimens will be retained: **<Multi-Line Text Box>**

3.21. *For secondary use of previously collected samples, describe what will happen to the biological specimens at the end of that period (e.g., destroyed, returned): **<Multi-Line Text Box>**

3.22. *For the secondary use of previously collected samples, indicate to what extent the study participant is able to withdraw biological specimens and any limitations to the withdrawal: **<Multi-Line Text Box>**

If biological specimens were collected from 'deceased human materials' is selected in Q3.2, question 3.23-3.38 appear

3.23. *What type of biological specimens from deceased human materials will be collected for the purpose of this study? **<Multi-Line Text Box>**

3.24. *From where are the deceased human materials being accessed for the purpose of this study? **<Multi-Line Text Box>**

3.25. *Has the use of these deceased human materials for the purpose of this study been reviewed/approved by any regulatory body (e.g., ministry, museum, institution, committee, etc. responsible for overseeing the use/protections of these biological materials)?
☐Yes ☐No

If yes: *Name the entity which has been consulted regarding the use of the proposed human remains for the purpose of this study: **<Multi-Line Text Box>**

If yes: *Upload any applicable correspondences, permissions, etc. related to the use of these biological materials for the purpose of this study:

Upload Document (Document Name, Document Date, Version) – Document Type: Consultation Correspondence or Documentation
Add Another

If no: *Explain why you have not obtained the proper approvals from a regulatory body: **<Multi-Line Text Box>**

If no: *Outline the process that will be undertaken to obtain any necessary permissions regarding the collection/use of biological specimens from deceased humans for the purposes of this study: **<Multi-Line Text Box>**

3.26. *Describe and justify how the biological specimens collected from deceased human participants for the purpose of this study will be sampled: **<Multi-Line Text Box>**

3.27. *Describe and justify how the biological specimens collected from deceased human participants for the purpose of this study will be used: **<Multi-Line Text Box>**

3.28. *Will the biological specimens from deceased human participants, collected for the purpose of this study, be sent outside of the institution for processing and/or analysis?

☐ Yes ☐ No

If 'Yes': *Provide the address and contact details of where the processing and/or analysis of biological specimens will take place for each type of sample: **<Multi-Line Text Box>**

3.29. *Indicate how long the biological specimens from deceased human participants will be retained: **<Multi-Line Text Box>**

3.30. *Describe what will happen to the biological specimens from deceased human participants, collected for the purpose of this study, at the end of that period (e.g., destroyed, returned, curated): **<Multi-Line Text Box>**

3.31. *Has the overseeing body communicated any limitations/stipulations regarding the use of the biological materials for research purposes and/or requested any opportunity to retract the samples (or use of the samples)?

☐ Yes ☐ No

If 'yes': Describe any stipulations on the use of the biological materials and/or opportunities for the overseeing body to retract the samples (or use of the samples): **<Multi-Line Text Box>**

3.32. ***Will biological specimens from deceased human participants be stored or retained or banked for any future research?

☐ Yes ☐ No

If 'yes' to question 3.32, questions 3.33-3.37 appear:

3.33. ***Where will the repository/collection be located (e.g., name & address including country)? **<Multi-Line Text Box>**

3.34. ***Where will the associated data be located (e.g., name & address including country), if applicable (if not applicable, indicate N/A)? **<Multi-Line Text Box>**

3.35. ***Who will be the custodian of the biological specimens from deceased human participants that will be stored or retained or banked for any future testing? **<Multi-Line Text Box>**

3.36. ***Who will have access to the banked biological specimens from deceased human participants? **<Multi-Line Text Box>**

3.37. ***Describe what will happen to the biological specimens (e.g., destroyed, returned, curated) at the end of the banking period (e.g., at the end of the retention period), if applicable (note: if not applicable, indicate N/A): **<Multi-Line Text Box>**

3.38. ***Are you using bioarchaeological materials?

☐ Yes ☐ No

If 'yes': ***Given the precious and non-renewable nature of these materials, describe how will you maximize the research possibilities/benefits of the limited samples available (i.e., justify the approach within the context of the research objectives and opportunities): **<Multi-Line Text Box>**

SECTION 4 – RECRUITMENT PROCESS

4.1 *What recruitment method(s) are being used? (select ALL that apply)

Note: Refer to the REB Guidelines for Participant Recruitment and sample templates (see WREM Help tab > Templates OR our Guidelines & Templates page on our website):

☐ None (e.g., secondary data with an REB approved waiver of consent OR multi-jurisdictional project without recruitment by local study team)

☐ Brochures, flyers, posters

☐ Newspaper
☐ Radio
☐ Telephone call
☐ Email (Note: If email communication will be used please ensure participants understand that email communication is not a secure form of communication) _
☐ Website (e.g., Facebook, Twitter)
☐ Video
☐ In-person recruitment
☐ Recruitment database (e.g., SONA)
☐ Third-party organization or recruitment company
☐ Survey Panel (e.g., Mechanical Turk, Qualtrics)
☐ Snowball sampling
☐ Mail
☐ Other

4.1.1a **If 'Brochure, flyer, poster' ***Specify where brochures, flyers, or posters will be distributed/posted: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.1b **If 'Brochure, flyer, poster' ***Upload brochures, flyers, posters:
Upload Document (Document Name, Document Date, Version) – Document Type: Brochure, flyer, poster
Add Another

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.2 **If 'newspaper' ***Upload newspaper ad:
Upload Document (Document Name, Document Date, Version) – Document Type: newspaper ad
Add Another

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.3 **If 'radio' *Upload radio ad script:**

Upload Document (Document Name, Document Date, Version) – Document Type: newspaper ad
Add Another

4.1.4a **If 'telephone call'*** Specify how you have access to or will obtain potential participants' telephone numbers: **<Multi-Line Text Box>**

4.1.4b **If 'telephone call'*** Specify who is making initial telephone contact with potential participant(s): **<Multi-Line Text Box>**

4.1.4c **If 'telephone call'*** Does the person making initial telephone contact have a relationship with potential participant(s)?
☐ Yes ☐ No

4.1.4d **If 'telephone call'*** Describe the nature of the relationship: **<Multi-Line Text Box>**

4.1.4e **If 'telephone call'*** Describe what steps will be taken to ensure this relationship does not exert undue influence on the person to participate: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.4f **If 'telephone call'** *Upload telephone script:
Upload Document (Document Name, Document Date, Version) – Document Type: telephone script
Add Another

4.1.5a **If 'email'*** Specify how you have access to or will obtain potential participants' email addresses: **<Multi-Line Text Box>**

4.1.5b **If 'email'*** Specify who is making initial email contact with potential participant(s): **<Multi-Line Text Box>**

4.1.5c **If 'email'*** Does the person making initial email contact have a relationship with potential participant(s)?
☐ Yes ☐ No

4.1.5d **If 'email'*** Describe the nature of the relationship: **<Multi-Line Text Box>**

4.1.5e **If 'email'*** Describe what steps will be taken to ensure this relationship does not exert undue influence on the person to participate: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.5f **If 'email'** *Upload email script:
Upload Document (Document Name, Document Date, Version) – Document Type: email script
Add Another

4.1.6a **If 'website'** *Specify the website and/or online group/community through which recruitment will occur
Note: If using social media, specify whose accounts/pages the recruitment will be posted from/to and confirm that the 'comments' feature will be turned off to protect participants' confidentiality: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.6b **If 'website'** *Upload website ad:
Upload Document (Document Name, Document Date, Version) – Document Type: website ad
Add Another

4.1.7a **If 'video'** *Specify where this video will be played: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.7b **If 'video'** *Upload video (or provide URL in a document):
Upload Document (Document Name, Document Date, Version) – Document Type: video
Add Another

4.17c **If 'video'** *Upload video script:
Upload Document (Document Name, Document Date, Version) – Document Type: video
Add Another

4.1.8a **If 'In-person recruitment'** *Specify where potential participants will be approached in person: **<Multi-Line Text Box>**

4.1.8b **If 'In-person recruitment'** *Specify who is making initial contact with potential participants in person: **<Multi-Line Text Box>**

4.1.8c **If 'In-person recruitment' *** Does the person making initial in-person contact have a relationship with the participant?
☐ Yes ☐ No

4.1.8d **If 'In-person recruitment' *** Describe the nature of the relationship: **<Multi-Line Text Box>**

4.1.8e **If 'In-person recruitment' *** Describe what steps will be taken to ensure this relationship does not exert undue influence on the potential participant to participate: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.8f **If 'In-person recruitment'** *Upload verbal recruitment script:
Upload Document (Document Name, Document Date, Version) – Document Type: email script
Add Another

4.1.9a **If 'recruitment database' *** Specify the recruitment database: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.9b **If 'recruitment database' *** Upload the recruitment information that will be presented to potential participants recruited through this database:
Upload Document (Document Name, Document Date, Version) – Document Type: verbal recruitment database script
Add Another

4.1.10a **If 'third-party' *** Name the third-party organization or recruitment company: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.10b **If 'third-party' *** Upload the recruitment information that will be presented to potential participants recruited through this third-party organization or recruitment company:
Upload Document (Document Name, Document Date, Version) – Document Type: third-party recruitment script
Add Another

4.1.11a **If 'survey panel' *** Name the survey panel: **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

4.1.11b **If 'survey panel' *** Upload recruitment information that will be presented to potential participants recruited through the survey panel:
Upload Document (Document Name, Document Date, Version) – Document Type: survey panel recruitment script
Add Another

4.1.12 **If 'snowball sampling' *** Describe the snowball sampling strategy. Note: The NMREB recommends that recruitment information be provided to potential participants who can contact the researchers directly for more information if interested.

4.1.13a **If 'Mail': *** Specify how you have access to or will obtain potential participants' mailing addresses: **<Multi-Line Text Box>**

4.1.13b **If 'Mail': *** Upload the recruitment letter:
Upload Document (Document Name, Document Date, Version) – Document Type: survey panel recruitment script
Add Another

4.1.14a **If 'Other' *** Describe your other recruitment strategy: **<Multi-Line Text Box>**

4.1.14b **If 'Other':** Upload the recruitment information that will be presented to participants through this other strategy, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: recruitment materials
Add Another

SECTION 5 – CONSENT PROCESS

5.1 * Is a waiver of the requirement to obtain informed consent being requested for any aspect of this study? (Note: If you are obtaining consent for part of the study and requesting a waiver for another aspect of the study select both Yes AND No.)

☐ Yes I am requesting a waiver of consent
☐ No I am not requesting a waiver of consent

If 'Yes' *Specify for what type of data the waiver is being requested?
☐ Prospective data collection
☐ Secondary use of identifiable information
☐ Secondary use of non-identifiable information

If 'Prospective data collection' *In accordance with Tri-Council Policy Statement 2, Article 3.7A, confirm that ALL of the following conditions apply:

- The research involves no more than minimal risk to the participants.
- The waiver of consent is unlikely to adversely affect the welfare of participants.
- It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required.

☐ I confirm

If "I confirm" is selected then:
***Explain why not obtaining consent is unlikely to adversely affect the welfare of individuals to whom the information relates: <Multi-Line Text Box>**

If 'I confirm' is selected: *Explain why it is impossible or impracticable to conduct the research without prior consent: **<Multi-Line Text Box>**

If 'I confirm' is selected: *Is there a plan to debrief participants about this research?
☐Yes ☐No

If 'Yes': * Describe your plan to provide debriefing (which may also offer participants the possibility of refusing consent and/or withdrawing data): **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If "Yes" *Attach copy of debriefing material(s), script, and/or form:
Upload Document (Document Name, Document Date, Version) – Document Type: Debriefing Script
Add Another

***If 'No* plan to provide a debriefing':** ***Justify why participants will not be debriefed: <Multi-Line Text Box>**

If 'Secondary use of identifiable information' *In accordance with Tri-Council Policy Statement 2, Article 5.5A, please confirm that ALL of the following conditions apply:

- Identifiable information is essential to the research
- The use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates
- The researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information
- The researchers will comply with any known preferences previously expressed by individuals about any use of their information
- It is impossible or impracticable to seek consent from individuals to whom the information relates
- The researchers have obtained any other necessary permission for secondary use of information for research purposes

☐ I confirm

If "I confirm" is selected then:
***Explain why identifiable information is essential to the research: <Multi-Line Text Box>**
If "I confirm" is selected then:
***Explain why not obtaining consent is unlikely to adversely affect the welfare of individuals to whom the information relates: <Multi-Line Text Box>**
If "I confirm" is selected then:
***Explain what measures will be taken to protect the privacy of individuals, and to safeguard the identifiable information: <Multi-Line Text Box>**
If "I confirm" is selected then:
*Explain why it is impossible or impracticable to obtain consent: **<Multi-Line Text Box>**

If 'Secondary use of non-identifiable information' *In accordance with Tri-Council Policy Statement 2, Article 5.5B (**secondary use of non-identifiable information**), please describe how, in the context of the proposed research, the information to be used can be considered non-identifiable for all practical purposes:**<Multi-Line Text Box>**

If "No" is selected in 5.1, then 5.2-5.6 appears:

5.2 *Indicate the age and/or decision-making capacity of your participants to determine what type of consent is needed (select all that apply). **HELP TEXT: This section seeks information on who will be giving consent/assent. The determination of what type of consent is needed is based on both age and capacity to make an informed decision.**

☐ Participants are persons aged 18 or older who do not have diminished capacity. Only participant consent is required.

- ☐ Participants are university students (age is not relevant). Only participant consent is required.
- ☐ Participants are aged 13-17 and I will be seeking participant consent only. I do not wish to seek parental/guardian consent.
- ☐ Participants are aged 13-17 and I will be seeking both parental/guardian consent and participant assent.
- ☐ Participants are aged 7-12. Both parental/guardian consent and participant assent are required.
- ☐ Participants are under the age of 7. Parental/guardian consent is required. Written assent is not required, but a verbal assent process is needed (with age-appropriate information about their voluntary participation).
- ☐ Participants have diminished capacity (age is not relevant). I will be seeking Substitute Decision Maker (SDM) consent and participant assent (if possible).

If 'Participants are aged 13-17 and I will be seeking participant consent only. I do not wish to seek parental consent.': * The waiving of parental/guardian consent must be justified based on the risks of the study and the participant's capacity to make an informed decision about participation. Please indicate why you think parental/guardian consent is not needed: **<Multi-Line Text Box>**

If "Participants have diminished capacity (age is not relevant) and I will be seeking Substitute Decision Maker (SDM) consent." is selected: ***Describe how capacity will be assessed for these individuals noted above. If participants are incapable of giving consent, provide information on how substitute decision makers will be identified and how their consent will be obtained to contact them for use of the participant's information for research. Note, discuss what safeguards will be employed to ensure the rights of the research participant are protected: **<Multi-Line Text Box>

5.3 ***List any anticipated communication difficulties (Ensure this information aligns with the inclusion/exclusion criteria (Q2.15/Q2.16) and use of translations (Q11.1):

- ☐ None
- ☐ Individuals who may require translation
- ☐ Individuals who may require accessibility features embedded in study-related communications (e.g., screen readers, audio descriptions).
- ☐ Individuals who are illiterate
- ☐ Individuals who are unable to communicate
- ☐ The need for culturally situated knowledge, protocols, and language
- ☐ Other communication difficulties

If 'Other communication difficulties' then:
Describe other anticipated communication difficulties: **<Multi-Line Text Box>**

If any answer other than 'None' is selected in 4.3, the following appears:
***Describe the procedures to address any communication difficulties: **<Multi-Line Text Box>**

5.4 ***Describe the informed consent/assent procedures:

Note: Choose the most appropriate method of obtaining consent for your population and procedures. Consider where, when, and how consent will be obtained, including when/how participants will receive the Letter of Information. Include links for electronic consent, if applicable. **<Multi-Line Text Box>**

5.5 *Which of the following types of consent/assent will be collected? (select ALL that apply)
Note: Refer to the NMREB Letter of Information and Consent Guidance Document and Use of Qualtrics for Informed Consent guidance document (see WREM Help tab > Templates OR our Guidelines & Templates page on our website):

HELP TEXT: Refer to NMREB Letter of Information and Consent Guidance Document and Template and NMREB Assent Letter Guidance Document and Template for more information and required language.

☐ Written consent/assent (e.g., paper/hard copy, electronically via Qualtrics) *Note: Written consent/assent is the default option recommended by TCPS II as it provides clear documentation*

☐ Verbal consent/assent (e.g., for a telephone interview)

☐ Implied consent/assent (e.g., by submitting a survey)

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Written consent/assent (this is the default option recommended by TCPS II; it provides clear documentation of consent/assent)': *Upload clean versions of all applicable letters of information and written consent and/or assent forms:
Upload Document (Document Name, Document Date, Version) – Document Type: Written Consent/Assent
Add Another

If 'Verbal consent/assent (e.g., for a telephone interview)': *Justify why verbal consent/assent will be obtained instead of written consent/assent: **<Multi-Line Text Box>**

If 'Verbal consent/assent (e.g., for a telephone interview)': *How will verbal consent/assent be documented/noted by the researcher? **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Verbal consent/assent (e.g., for a telephone interview)': *Upload clean versions of all applicable letters of information that will be provided/read to

participants/parents/guardians/SDMs and the verbal consent/assent script that will be used to obtain and document consent:
Upload Document (Document Name, Document Date, Version) – Document Type: Verbal Consent/Assent
Add Another

If 'Implied consent/assent (e.g., checking an explicit box indicating consent, accessing the survey, taking part in the interview, etc.)': *Justify why implied consent/assent will be obtained instead of written consent/assent. **<Multi-Line Text Box>**

If 'Implied consent/assent (e.g., checking an explicit box indicating consent, accessing the survey, taking part in the interview, etc.)': *How will implied consent/assent be documented/noted by the researcher? **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Implied consent/assent (e.g., checking an explicit box indicating consent, accessing the survey, taking part in the interview, etc.)': *Upload clean versions of all applicable letters of information that will be provided to participants/parents/guardians/SDMs with an explicit statement clearly indicating how implied consent/assent will be obtained:
Upload Document (Document Name, Document Date, Version) – Document Type: Implied Consent/Assent
Add Another

5.6 *Is there a relationship between the potential participant and the person obtaining consent?
☐ Yes ☐ No
If 'Yes': *Explain the nature of the relationship (e.g., supervisor of employees, teacher of students, family/friend/acquaintance, or other such relationships): **<Multi-Line Text Box>**

If 'Yes': *Describe what steps will be taken to ensure this relationship does not exert undue influence on the person to participate: **<Multi-Line Text Box>**

SECTION 6 – RISKS, BENEFITS AND SAFETY

6.1.*Are there any direct benefits to study participants? (i.e., is this study designed to benefit participants?)
Note: Compensation is not a direct benefit
☐ Yes ☐ No
If 'Yes': *Describe any direct benefits to the study participants: **<Multi-Line Text Box>**

6.2.*Describe the potential benefits to society (e.g., what is the significance of this research?): **<Multi-Line Text Box>**

6.3 *Describe any foreseeable risks, harms, vulnerabilities or inconveniences as a result of participating in this study (these could be social, behavioural, psychological, physical or economic, and **includes minimal risks**): **<Multi-Line Text Box>**
HELP TEXT: Examples may also include potential privacy breaches (if sensitive information is collected), emotional reactions (e.g., distress), employment-related consequences, reputational damage, etc.

6.4 *Indicate how any potential risks, harms, vulnerabilities or inconveniences will be mitigated: **<Multi-Line Text Box>**
HELP TEXT: Consider research team training/qualifications, safety protocol, contact list for relevant support resources, appropriate community engagement, etc.

Upload any supporting documents (e.g., list of support services, resources to provide to participant, confirmation of researcher training, etc.), if applicable and not uploaded elsewhere:
Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials
Add Another

6.5 *Is there a foreseeable likelihood that, in the course of this research, the researcher(s) will collect information that they have a legal or professional obligation to disclose (e.g., duty to report abuse or neglect of a child, reports of harm to self or others, etc.)? *See TCPS2 Articles 5.1 and 5.2 for more information.*
☐ Yes ☐ No
If 'Yes': *Confirm that the research team is equipped to respond to any applicable duties to report:
☐ Yes (Note: The REB cannot provide legal advice regarding researchers' reporting obligations.)
If 'Yes': *Describe how participants will be informed of any related limitations to their confidentiality. **<Multi-Line Text Box>**

SECTION 7 – CONFIDENTIALITY AND DATA SECURITY: Description of Study Records

7.1 *Will ANY information be collected during this study that could **directly or indirectly** reveal an individual participant's identity (including consent documentation, contact information, demographics, data, etc.)? For more information, refer to the Data Security and Confidentiality-Guidance Document available in the WREM Help tab under Templates OR on our Guidelines & Templates page on our website. **HELP TEXT: This refers to the**

whole study record, including contact information, signed consent forms, and study data. Please see the Data Security and Confidentiality-Guidance Document in WREM (applywesternrem.uwo.ca: go to Help (found along the top black navigation far)->Templates)

☐ Yes ☐ No

If 'Yes' is selected in Q7.1, then Q7.2 appears.

7.2 *Identify all directly and indirectly identifiable information that will be collected for this study. (Select ALL that apply)

NOTE: When justifying each identifier, indicate where/how it is being collected.

HELP TEXT: Participants must be informed of this in the Letter of Information and Consent.

☐ Full Name
☐ Initials
☐ Address
☐ Full Postal Code
☐ Partial Postal Code
☐ Telephone Number
☐ Email Address
☐ Full Date of Birth
☐ Partial Date of Birth
☐ IP Address (tip: verify the settings for any technological tools)
☐ Audio Recording (i.e., any recording of voice)
☐ Video Recording (i.e., any recording of a person and/or identifiable environment such as a home)
☐ Photographs (i.e., any photograph of a person and/or identifiable environment such as a home)
☐ Student Number
☐ Age
☐ Gender
☐ Sex
☐ Race
☐ Ethnicity
☐ Additional demographic characteristics
☐ Professional details (title/role, organization)
☐ Survey panel ID (MTurk ID, Prolific ID, SONA ID, etc.)
☐ Other identifiers

If 'Full Name': ***Justify Full Name: **<Multi-Line Text Box>
If 'Initials': ***Justify Initials: **<Multi-Line Text Box>

If 'Address': *Justify Address: **<Multi-Line Text Box>**
If 'Full Postal Code': *Justify Full Postal Code: **<Multi-Line Text Box>**
If 'Partial Postal Code': *Justify partial Postal Code: **<Multi-Line Text Box>**
If 'Telephone Number': *Justify Telephone Number: **<Multi-Line Text Box>**
If 'Email Address': *Justify Email Address: **<Multi-Line Text Box>**
If 'Full Date of Birth': *Justify Full Date of Birth: **<Multi-Line Text Box>**
If 'Partial Date of Birth': *Justify Partial Date of Birth: **<Multi-Line Text Box>**
If 'IP Address': *Justify IP Address: **<Multi-Line Text Box>**
If 'Audio Recording': *Justify Audio Recording: **<Multi-Line Text Box>**
If 'Video Recording': *Justify Video Recording: **<Multi-Line Text Box>**
If 'Photographs':*Justify Photographs: **<Multi-Line Text Box>**
If 'Student Number': *Justify Student Number: **<Multi-Line Text Box>**
If 'Age:*Justify Age: **<Multi-Line Text Box>**
If 'Gender:*Justify Gender: **<Multi-Line Text Box>**
If 'Sex:*Justify Sex: **<Multi-Line Text Box>**
If 'Race:*Justify Race: **<Multi-Line Text Box>**
If 'Ethnicity:*Justify Ethnicity: **<Multi-Line Text Box>**
If "Additional demographic characteristics": Specify additional demographics and justify: **<Multi-Line Text Box>**
If 'Professional details': ***Specify Professional details and justify: **<Multi-Line Text Box>**
If 'Survey Panel ID': ***Specify Survey Panel ID and justify: **<Multi-Line Text Box>**
If 'Other': ***Describe Other identifiers and justify: **<Multi-Line Text Box>**

If 'yes' is selected in Q7.1, then Q7.3 appears.

7.3 *Will there be a master list of participants, linking their directly identifiable information (e.g., name, contact information) to their unique participant codes (e.g., study number, pseudonym)? (Help text: Master lists allow researchers to track participation, maintain de-identified study records, and facilitate participant withdrawal upon request.)

☐Yes ☐No

If 'Yes': *Who will have access to the master list? **<Multi-Line Text Box>**
If 'No': *Explain why, in the context of this research, a master list will not be used:**<Multi-Line Text Box>**

7.4 **Note: Q7.4-Q7.6 always appear.**

Note: Ensure this is also communicated to participants in the letter of information/consent.

7.4a.*Indicate the extent to which **study participants** are able to withdraw their data from the research study, and any limitations on the withdrawal: **<Multi-Line Text Box>**

NOTE: If there are multiple research activities, explain the withdrawal considerations/limitations for each (e.g., anonymous surveys cannot be withdrawn after submission; interview data can be ithdrawn prior to analysis/publication).

7.4b.*Describe the circumstances under which **an investigator would initiate** the withdrawal of a participant from the study and/or remove their data from analyses (if n/a, indicate this):

<Multi-Line Text Box>

7.5 *How will participants' data be reported in the dissemination of results (e.g., aggregated data, identifiable descriptors, de-identified descriptors, co-authors, direct quotes, paraphrased ideas, themes, photographs, recordings, artwork, etc.)
Note: Ensure this is also communicated to participants in the letter of information/consent. See template Photo/Video Release Form, if applicable (see WREM Help tab > Templates OR our Guidelines & Templates page on our website). **<Multi-Line Text Box>**

7.6 How will participants' demographic information be reported in the dissemination of results? (If no demographic information is being collected, indicate N/A) **<Multi-Line Text Box>**

SECTION 8 – CONFIDENTIALITY AND DATA SECURITY: Transfer/Transport of Study Records

8.1 *Will any study-related records (identifiable or de-identified) be collected, physically transported or electronically transmitted outside of Western and/or its affiliate institutions (incl. working remotely/from home, travelling between data collection sites, sharing with external collaborators/researchers, etc.)?
☐ Yes ☐ No

If 'Yes' is selected in Q8.1, then Q8.2 appears
8.2 *Will the transportation or transmission of study records conform to the requirements of the Data Security and Confidentiality-Guidance Document, Section A - Transportation and Transmission of Study Records?
☐ Yes ☐ No

If 'No': *Describe the deviations you are requesting with respect to the transportation or transmission of study records: **<Multi-Line Text Box>**

If 'No': *Explain why these deviations are essential to being able to conduct the study: **<Multi-Line Text Box>**

If 'Yes' is selected in Q8.1, then Q8.3 appears
8.3 *Will any individuals/groups/organizations outside of the study team members listed in Section 1 of this REB application have access to identifiable study records for any purpose ☐ Yes ☐ No

If 'Yes': *Explain why individuals/groups/organizations outside of the study team require access to identifiable study records: **<Multi-Line Text Box>**

If 'Yes': *List the individuals/groups/organizations outside of the study team who will have access to identifiable study records: **<Multi-Line Text Box>**

If 'Yes': *List the type of identifiable information that will be accessible to the individuals/groups/organizations outside of the study team: **<Multi-Line Text Box>**

SECTION 9 – CONFIDENTIALITY AND DATA SECURITY: Storage, Retention and Destruction of Study Records

9.1 *How are you storing your study records?

☐ Paper
☐ Electronic
☐ Both (Paper and Electronic)

9.2 *Will the storage of study records conform to the Data Security and Confidentiality-Guidance Document, Section B - Storage, Retention and Destruction of Study Records?

☐ Yes ☐ No

If 'No': *Describe any deviations you are requesting with respect to the storage, retention and destruction of study records: **<Multi-Line Text Box>**

If 'No': *Explain why those deviations are necessary for the conduct of the study: **<Multi-Line Text Box>**

9.3 *Will the study records be retained by the Principal Investigator (i.e., the PI) for a minimum of 7 years after project completion per Western University's Faculty Collective Agreement?

☐ Yes ☐ No

If 'no': *Explain why the PI will not retain the study records for 7 years: **<Multi-Line Text Box>**

If 'no': *Describe how the PI will have access to a copy of the study records for 7 years:**<Multi-Line Text Box>**

9.4 * After this project is complete, will any part of the study record (including de-identified data) be retained/stored/managed by anyone other than the PI? (e.g., another researcher, a data repository, for future unspecified use)*Note: Ensure this is also communicated to participants in the letter of information/consent.*

☐ Yes ☐ No

If 'Yes': *Specify what part of the study record will be retained by someone other than the PI: **<Multi-Line Text Box>**
If 'Yes': *Who will retain the study records: **<Multi-Line Text Box>**
If 'Yes': *Where the study records will be stored: **<Multi-Line Text Box>**

If 'Yes': *Describe how the study records will be secured: **<Multi-Line Text Box>**

If 'Yes' is selected in Q7.1, then Q9.5 appears

9.5

*Will identifiable information be retained for longer than 7 years? *Note: Ensure this is communicated to participants in the letter of information/consent.*

HELP TEXT: Participants must be aware of this, and if possible, this should be optional.

☐ Yes ☐ No

If 'Yes': *Why is it necessary for identifiable information to be retained for longer than 7 years? **<Multi-Line Text Box>**

If 'Yes': *How long will identifiable information be retained? **<Multi-Line Text Box>**

If 'Yes': *How will identifiable information be kept confidential during the extended retention period? **<Multi-Line Text Box>**

If 'Yes' is selected in Q9.5, then Q9.6 appears

9.6 *Will the identifiable information being retained for longer than 7 years be professionally archived?

☐ Yes ☐ No

If 'Yes': *Provide information on the professional archive repository: **<Multi-Line Text Box>**

SECTION 10 – COMPENSATION

If No to 4.1 Q10.1will appear

10.1 *Will participants receive any of the following? (Select all that apply)

Note: Refer to the Guidelines for Incentives, Reimbursement and, Compensation (see WREM Help tab > Templates OR on our Guidelines & Templates page on our website)

☐ Compensation for participation

☐ Incentives for participation

☐ Reimbursement for expenses that participants will accrue

☐ Entry into a draw

☐ None of the above

If 'Compensation for participation': *Describe any compensation the participants will receive: **<Multi-Line Text Box>**

HELP TEXT: Indicate specific amounts and process for receiving compensation. Compensation/incentives must be provided even if a participant withdraws or skips questions. Ensure this information is outlined in the Letter of Information and Consent.

If 'Incentives for participation': *Describe any incentive the participants will receive: **<Multi-Line Text Box>**

HELP TEXT: Indicate specific amounts and process for receiving incentives. Ensure this information is outlined in the Letter of Information and Consent.

If 'Reimbursement for expenses that participants will accrue: *Describe any reimbursement that participants will receive for expenses that participants they accrued: **<Multi-Line Text Box>**
HELP TEXT: Indicate specific amounts and process for receiving reimbursement. Ensure this information is outlined in the Letter of Information and Consent.

If 'Entry into a draw': *Provide details of the draw including how participants will be entered into the draw and how they will be notified of winning: **<Multi-Line Text Box>**
HELP TEXT: Ensure that the identifiable information for the draw is not associated with the data. Entry into the draw must occur even if a participant withdraws or skips questions.

If any option other than 'None' is selected in Q10.1, then the following appears:

10.2 *Is there any circumstance under which a consented participant will NOT be compensated?
☐ Yes ☐ No

If yes: *Please describe the circumstances under which a participant would not be compensated: **<Multi-Line Text Box>**

If yes: *Justify why this is ethically appropriate in the context of your research: **<Multi-Line Text Box>**

SECTION 11 – TRANSLATIONS

11.1 *Are any participant-facing study documents being provided in a language other than English? (e.g., letter of information and consent/assent forms, recruitment materials, participant materials such as questionnaires, etc.) *Note: Refer to the Guidelines for Translated Documents (see WREM Help tab > Templates OR on our Guidelines & Templates page on our website)*
☐Yes ☐No

If 'Yes' is selected in Q11.1 then 11.2 appears

11.2 *Are the translated materials available for REB review?
☐Yes ☐No

If 'No': *Confirm when the translated materials will be submitted:
☐ Once available, prior to initial approval (pending REB confirmation of English versions).
☐ As an amendment, once available.

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'Yes' is selected in Q11.2 then 11.3 and 11.4 appear:

11.3 *Upload all translated materials (e.g., letter of information and consent/assent forms, recruitment materials, participant materials such as questionnaires, etc.):

Upload Document

Add another

11.4 *Is any member of the study team qualified to attest to the accuracy of the translations?

☐ Yes ☐ No

If 'Yes' is selected in Q11.4: * Specify the name of the study team member(s) confirming the translations are accurate and complete representations of the English versions attached elsewhere in the application. **<Multi-Line Text Box>**

Note that this document's name will appear on the approval notice issued by the REB. Please make sure you give your document a name that reflects its content (e.g., paper survey, date). Avoid using slang, student names, etc. Do not upload documents including tracked changes here. Documents should not include 'clean' in their file name.

If 'No' is selected in Q11.4: *Upload the translation certificate(s) (i.e., attestation letter from the translator confirming the translations are accurate and complete representations of the English versions):

Upload Document

SECTION 12 – FUNDING

12.1 ***Is this study funded? *Note: This includes 'self-funded' projects*

HELP TEXT: If you are receiving any funds from any sources for this project please indicate "yes"

☐ Yes ☐ No

If 'Yes' to Q12.1, then Q12.2-12.4 will appear:

12.2 *How is the study funded? (Check all that apply)

☐ Self-funded

☐ Industry-Sponsored

☐ Internal Grant (departmental/faculty, VP, IRF/SRF, etc.)

☐ External Grant (CIHR-grant/award, CIHR-sub, SSHRC-grant, NSERC-grant, Industry-grant, etc.)

☐ Other

If 'Self-funded': *Specify: **<Multi-Line Text Box>**

If 'Industry-Sponsored': *Specify Industry-Sponsor funder(s): **<Multi-Line Text Box>**

If 'Industry-Sponsored': *For Industry Sponsored studies, provide the complete contact information for REB fee invoicing:

Name:
Organization:
Address:
City:
Country:
Postcode:
Telephone:
Email:

If 'Internal Grant(s)': *Specify Internal funder(s): **<Multi-Line Text Box>**

If 'External Grant(s)': *Specify External funder(s): **<Multi-Line Text Box>**

If 'Other': *Specify other funder(s): **<Multi-Line Text Box>**

12.3 *Are there any research funds held in an account at Western or Lawson?

☐ Western University

☐ Lawson

☐ No

If 'Western University' is selected in Q12.3 then the following appears:

12.3a*As funds for this study are held in a research account at Western, please type in "Western Research Services" in the below Search User text box:

If 'Western University' is selected in Q12.3 then the following appears:

12.3b*For research award(s) held through Western, please provide the one of the following for each award supporting this study: ROLA Reference number, Agency reference number or account speedcode: *Note: This information facilitates the release of funds*

HELP TEXT: If you don't know the ROLA Reference number, Agency reference number or account speed code, contact Research Services.

If 'No' is selected in Q12.3 then the following appears:

*Where are the funds being held, if not at Western or Lawson? (Help Text: If the researcher is using institutional resources, credentials and/or time to do the research, the funds should be managed through institutional research accounts.)
<Multi-Line Text Box>

If 'Lawson' is selected in Q12.3 then the following appears:
STOP: Why is this application being submitted to the NMREB rather than submitted through ReDA and then to the HSREB? Consult with Lawson prior to submitting this application.

SECTION 13 - Conflict of Interest (actual, apparent, perceived, or potential)

13.1 *Will the PI or Co-Investigator(s) or anyone connected to them though their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal financial benefit in connection with this study?

☐ Yes ☐ No
If 'Yes': ***For what purpose did they receive these funds? **<Multi-Line Text Box>
If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>

13.2 *Will the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) receive any personal (financial or otherwise) benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?

☐ Yes ☐ No
If 'Yes': ***Please describe the benefits: **<Multi-Line Text Box>
If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>

13.3 *Is the PI or Co-Investigator(s) aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?

☐ Yes ☐ No
If 'Yes': ***Describe the relationships, interests or incentives: **<Multi-Line Text Box>
If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest: **<Multi-Line Text Box>

13.4 * Is the PI or Co-Investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?

☐ Yes ☐ No
If 'Yes': ***Describe the institutional conflicts of interest: **<Multi-Line Text Box>

**If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest:
<Multi-Line Text Box>

13.5 * Does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?
☐ Yes ☐ No
If 'Yes': ***Describe the interest: **<Multi-Line Text Box>
**If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest:
<Multi-Line Text Box>

13.6 *Will or does the PI or Co-Investigator(s) or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)
☐ Yes ☐ No
If 'Yes': ***Describe the association or connection: **<Multi-Line Text Box>
**If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest:
<Multi-Line Text Box>

13.7 * Are there any other real, perceived, or potential conflicts of interest to be declared to the REB?
☐ Yes ☐ No
If 'Yes': ***Please Specify: **<Multi-Line Text Box>
**If 'Yes': ***Describe the proposed management plan to mitigate the conflict of interest:
<Multi-Line Text Box>

SECTION 14 RESUBMISSION INFORMATION

14.1 *Upload the Response Letter, listing all REB recommendations/questions/comments and an explicit response to each:
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: REB RESPONSE LETTER

14.2 If changes have been made to any previously submitted Letter of Information and Consent/Assent forms, please upload the corresponding track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES DOCUMENT

14.3 If changes have been made to any previously submitted study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.), please upload the corresponding track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES STUDY INSTRUMENTS/STIMULI

14.4 If changes have been made to any previously submitted recruitment materials, please upload track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES RECRUITMENT MATERIALS

14.5 If changes have been made to any previously submitted other participant materials (e.g., debriefing document, screening document, etc.), please upload track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES OTHER MATERIALS

14.6 If changes have been made to the protocol/research plan previously submitted, please upload track-changes version(s):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES OTHER MATERIALS

14.7 Upload any additional materials requested by the REB (if applicable):
Upload Document (Document Name, Document Date, Version) VARIABLE NAME: OTHER MATERIALS

14.8 Provide any additional comments for the REB to consider (if applicable):
<Multi-Line Text Box>

SECTION 15 CONFIRMATION OF RESPONSIBILITY

15.1 **Principal Investigator Signature/Attestation**

- I attest that this application as submitted is in compliance with the TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Personal Health Information Protection Act (PHIPA) and/or the Freedom of Information Protection of Privacy Act (FIPPA), and its applicable Regulations; AND with all other applicable laws, regulations or guidelines;
- • I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- • I attest that this application contains the current and complete protocol, including, if applicable, any sub-studies;
    - • I acknowledge that I am responsible for promptly reporting any of the following to the REB: modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), changes to the consent form, etc.;
    - -all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of thestudy;
    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - study completion or termination.

- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.
- As the PI, I have made efforts to ensure that the research intent, purpose, and impact of this study will be free from bias or discrimination in accordance with the Canadian Charter of Rights and Freedoms.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, as the PI, I am aware of my obligations in maintaining the importance of maintaining the confidentiality of all human participant information and the privacy of individuals with respect to that information;
- I will ensure that the personal information is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of the study participants' personal health information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the personal information is maintained in accordance with the Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.
-

If "Response to REB recommendations" is selected in Question 1.1, then question 15.2 appears:

15.2 ***Principal Investigator OR Delegate Signature:**

The Principal Investigator may choose to sign off electronically on all **re-submissions** (i.e., response to REB recommendations) or he/she may delegate this task to another qualified individual. **NOTE:** The PI is still fully responsibility for the scientific and ethical conduct of the study at this institution.

- I attest that this application as submitted is in compliance with the TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Personal Health Information Protection Act (PHIPA) and/or the Freedom of Information Protection of Privacy Act (FIPPA), and its applicable Regulations; AND with all other applicable laws, regulations or guidelines;
- • I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- • I attest that this application contains the current and complete protocol, including, if applicable, any sub-studies;
    - • I acknowledge that I am responsible for promptly reporting any of the following to the REB: modifications or amendments, such as changes in PI, changes in Co-

investigator (if applicable), specific required changes to the Letter of Information/consent form, etc.;
    - all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the study;
    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - completion or termination (e.g., End of Study Form);
- I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the study.
- I have made efforts to ensure that the research intent, purpose, and impact of this study will be free from bias or discrimination in accordance with the Canadian Charter of Rights and Freedoms.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, I recognize the importance of maintaining the confidentiality of personal health information (PHI)/Personal Information (PI) and the privacy of individuals with respect to that information;
- I will ensure that the PHI/PI is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of the study participants' personal information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.