

NMREB Amendment Form

Orange text indicates an upload or action feature

Red//bold indicates question/feature dependencies

Questions with an asterisk (*) are mandatory and must be completed prior to signatures/submission

← Indicates a shared question. If there is no associated data field in this form, the information is pulled into this form from another application (e.g., the Initial Application)

Section 1 - General Information

1.1 *If this is the first time you are submitting this particular application form to the REB, select “Initial Submission”. If this application form 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 Amendment application is being submitted, please select "Initial Submission". If this is an Amendment re-submission for modifications requested by the REB please select "Resubmission".

1.2 *Please provide a label for this amendment (e.g., an amendment identifier/description) that will appear in the project tree: <Single-Line Text Box>

Shared with 1.13 NMREB initial application form

← 1.3 *Provide a brief lay/non-scientific summary of the study (max 250 words) <Multi-Line Text Box>

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.

1.4 *What is the current overall status of this study? (select all that apply)

No Enrollment

Enrollment Ongoing

Enrollment Complete

Intervention and/or Data Collection Ongoing

Intervention and/or Data Collection Complete

Data Analysis or Transfer Ongoing

Data Analysis or Transfer Complete

Preparing Publication

Prematurely terminated

Other

If 'Other': *Specify other: <Multi-Line Text Box>

If 'prematurely terminated': *Please provide details on premature termination:
<Multi-Line Text Box>

If 'No enrollment, 'Enrollment ongoing', Intervention and/or Data Collection Ongoing', question 1.3 will appear:

1.5 *Is the enrolment of new participants currently on hold or temporarily suspended?

Yes No

If 'Yes': *Explain why enrolment is on hold/suspended: <Multi-Line Text Box>

1.6 *Which of the following changes are included in the Amendment(s) (Note: One change may impact more than one option below; ensure to select all that apply):

HELP TEXT: "Study protocol" refers to the already approved study information as described in the initial application and/or subsequent amendment applications.

- Changes to the study procedures/protocol/research plan
- Changes to/Addition of Letter of Information and Consent and/or Assent Form(s)
- Changes to study documents (study instruments/stimuli, recruitment materials, debriefing letters, etc.)
- Translation of new and/or approved materials
- Changes to privacy, data security, confidentiality and/or technology
- Changes to biological specimen collection/use
- Change in support from US Federal Government
- Changes in study funding
- Changes to study team, study title, and/or student project status
- Update to Conflict of Interest (actual, apparent, perceived, or potential) attestations
- Other

1.7 *Provide a brief lay summary of the proposed changes (maximum 5 lines): (Multi-Line Text Box)

HELP TEXT

Please note this is the description that the Full Board sees when reporting the amendment. Please include sufficient detail. For example: We are changing the PI from X to Y. We are changing the number of participants from X to Y. We propose additional questions to our demographics data collection tool. Instead of "New PI. Participant increase. Change to instruments".

1.8 Upload any additional information such as related correspondence, if applicable (e.g., cover letters, memos, or summary of changes):

Upload Document (Document Name, Document Date, Version) – Document Type:
Cover Letters/Memos
Add Another

Please note, the question below either (1) reflects the information that has previously been provided by the REB because the study was originally submitted in WREM (in which case you can update the information to reflect the changes being made with this amendment) OR (2) is currently blank because this study was originally submitted and approved in ROMEO (in which case you will need to provide a response).

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).

Shared with 1.2 NMREB initial application form

1.9 *Complete the Principal Investigator (PI) details:

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

*Complete the additional PI details:

- Academic Faculty:
- Academic Department:
- Hospital Department:
- Hospital Division:

Add ALL local study team members to WREM. If this is a study that was originally submitted and approved in ROMEO, this should include all those listed in the Western Protocol, not only those team members that may be changing due to this amendment.

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).

Shared with 1.3 NMREB initial application form

1.10 *Are there any additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or its affiliate institutions working on this study?

- Yes there are additional study team members
- No study team members involved

1.10 If 'Yes': *Use the Search field to enter the following information for additional study team members (from Western and or its affiliate institutions) who are working on this study: **HELP TEXT: All local study team members must have an Infonetica account. Please use the "Add Another" button to add a new entry for each study team member.**

- *Prefix: (drop down)
- *First Name:
- *Last Name:
- Academic Faculty
- Academic Department
- Hospital Department
- Hospital Division
- *Address:
- *City:
- *Province:
- *Postcode:
- *Telephone:
- Fax
- *Email:

1.10 *Specify ROLE, DUTIES, and DEPARTMENT/FACULTY. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data; Psychology/Social Sciences.):

- ◀ 1.10a *Are there any additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or its affiliate institutions working on this study?
- Yes there are additional study team members
 - No other study members involved

1.10a *Use the Search field to enter the following information for additional study team members (from Western and or its affiliate institutions) who are working on this study: **Please use the “Add Another” button to add a new entry for each study team member.**

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

1.10a *Specify ROLE, DUTIES, and DEPARTMENT/FACULTY. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data; Psychology/Social Sciences.):

Etc. until 1.10o

Add ALL NON-Western affiliated team members to WREM. If this is a study that was originally submitted and approved in ROMEO, this should include all those listed in the Western Protocol, not only those team members that may be changing due to this amendment.

Shared with 1.4 NMREB initial application form

- 1.11 *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. Please use the "Add Another" button to add a new entry for each study team member.**

- a. *Name
- b. *Position
- c. *Organization
- d. *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>

Shared with 1.8 NMREB initial application form

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

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- 1.13 *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 submissions.) **<Single-Line Text Box>**

Please note, the question below either (1) reflects the information that has previously been provided by the REB because the study was originally submitted in WREM (in which case, if applicable, update the information to reflect the changes being made with this amendment) OR (2) is currently blank because this study was initially submitted in ROMEO (in which case ensure to include all identifiers you wish to collect in this study).

Shared with 1.5 NMREB initial application form

- 1.14 *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 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" is selected in 1.14 the following will appear:

-  *Complete the Sponsor details:
- Title:
 - First Name:
 - Last Name:
 - *Organization:
 - *Address:
 - *City:
 - *Province/State:
 - *Postcode/Zip:
 - *Telephone:
 - *Email:

The question below either (1) reflect the information that has previously been provided to the REB because the study was originally submitted in WREM (in which case, if applicable, you can update the information to reflect the changes being made with this amendment) OR (2) is currently blank because this study was originally submitted and approved in ROMEO (in which case you will need to provide a response).

Shared with 1.7 NMREB initial application form

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

If 'Change in support from US Federal Government' is selected in Q1.6 the below question appears:

*Describe the change in support from US Federal Government. <Multi-Line Text Box>

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-  1.16 *Does this study involve the London hospitals (see HELP text if you are unsure):
- No this study does not involve the London hospitals
 - This study involves the London Hospitals but a ReDA application 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 the following question appears:

Shared with 1.12a NMREB initial application form

-  1.16a *Type in "Western Research Services" in the above Search User text box:
- Name
 - Email

Shared with 12.3a NMREB initial application form

- 1.16b *As funds for this study are held in a research account at Western, please type in "Western Research Services" in the above Search User text box:

Shared with 1.6 NMREB initial application form

- 1.17 *Is this a student project? (select all that apply)

Note: This includes any study contributing to a student researcher's academic requirements.

- a. No
- b. Yes-Undergraduate
- c. Yes-Masters
- d. Yes-PhD
- e. 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>

Please note, the question below either (1) reflects the information that has been approved by the REB because the study was originally submitted in WREM (in which case, if applicable, update the information to reflect the changes being made with this amendment) OR (2) is currently blank because this study was initially submitted in ROMEO (in which case ensure to include all identifiers you wish to collect in this study). NOTE: If scenario (1) ensure you selected "Change to the data collected and/or how data is accessed, collected, used or stored" in Question 1.5 of this Amendment.

- 1.18 *Are you proposing to change any collection or storage of personal identifiers from what is already approved by the REB and is described in Q1.19 below:

Yes No

Shared with Q7.2 of initial NMREB application form (editable)

- 1.19 *Identify all directly and indirectly identifiable information that will be collected for this study. (Select ALL that apply) **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 'Photograph': *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>

Shared from Q2.4 in the Initial NMREB Application (editable):

If any changes will be made to the Study Procedures of this project, ensure that "Changes to the Study procedures/protocol/research plan" is selected in question 1.6.

2.1 *Describe your study procedures involving human participants (i.e., what are you doing and how are you doing it?) <Multi-Line Text Box>

If 'Changes to the study procedures/protocol/research plan is selected in question 1.6, Q2.2-2.4 will appear:

2.2 *Which of the following are included in the proposed protocol/research plan changes (select all that apply)?

- Study design, data collection methods and/or procedures
- Informed consent process (e.g., change in method of collecting consent, requesting a waiver of consent, etc.)
- Duration of study
- Participant recruitment methods
- Eligibility criteria (inclusion/exclusion)
- Known or anticipated harms/risks/benefits
- Addition of sub-studies/correlative studies
- Participant compensation/reimbursement/incentives/entry in a draw
- Administrative updates
- Other

If 'Other': *Specify other changes: <Multi-Line Text Box>

2.3 *Describe all changes to the study, and provide a rationale for the change(s). If all changes/rationale are also identified in a document uploaded into this application (e.g., summary of changes), please indicate so: <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 you have a separate protocol/research plan document, please upload the "clean" version of the protocol/research plan.

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

If you have a separate protocol/research plan, please upload the “tracked” versions of the protocol/research plan (i.e., showing all changes from the currently approved version):
**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Protocol**

2.4 *Did the changes to the protocol/research plan require immediate implementation to reduce or eliminate immediate hazard to current participants?

Yes No

If ‘Yes’: *Identify the changes that required immediate implementation, and provide the rationale for implementing these changes immediately: **<Multi-Line Text Box>**

Section 3.0 – Changes To Letter of Information and Consent/Assent Form(s)

If “Changes to/Addition of Letter of Information and Consent and/or Assent form(s)” is selected in question 1.6, the following questions appear:

3.1 *Identify the revisions to the letter(s) of information and consent/assent form(s) as a result of this amendment (select all that apply):

- Changes to previously approved letter(s) of information and consent/assent form(s)
- Addition of new letter(s) of information and consent/assent form(s)

If “Changes to previously approval letter(s) of information and consent/assent form(s)” is selected in question 3.1, the following questions (Q3.2 – Q3.4) appear:

3.2 *Select the reason(s) for the proposed letter of information and consent/assent form change(s) (select all that apply):

- Changes to the study protocol
- Administrative changes
- Other

If ‘Other’: *Specify “Other” reason: **<Multi-Line Text Box>**

3.3 *Did the new information require urgent oral communication with current/past participants, to eliminate an apparent/potential immediate hazard, for which approval from the REB was obtained prior to the submission of this amendment?

Yes No

3.4 *Which of the following forms have been changed (select all that apply)?

- Written Consent/Assent Form(s)
- Verbal Consent/Assent Form(s)
- Implied Consent/Assent Form(s)

If ‘Written Consent/Assent Form(s)’ is selected in 3.4, question 3.5 and 3.6 will appear:

3.5 *Upload the “tracked” versions of all applicable letters of information and written consent and/or assent forms (i.e., showing all changes from the currently approved version):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Written Consent/Assent**
[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.

3.6 *Upload “clean” versions of the revised letters of information and written consent/assent form(s) (i.e., with the changes accepted):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Written Consent/Assent**
[Add Another](#)

If ‘Verbal Consent/Assent Form(s)’ is selected in 3.4, question 3.7 and 3.8 will appear:

3.7 * Upload the “tracked” versions of all applicable letters of information and verbal consent and/or assent forms (i.e., showing all changes from the currently approved version):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Verbal Consent/Assent**
[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.

3.8 *Upload “clean” versions of the revised letters of information and verbal consent/assent form(s) (i.e., with the changes accepted):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Verbal Consent/Assent**
[Add Another](#)

If ‘Implied Consent/Assent Form(s)’ is selected in 3.4, question 3.9 and 3.10 will appear:

3.9 * Upload the “tracked” versions of all applicable letters of information and implied consent and/or assent forms (i.e., showing all changes from the currently approved version):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Implied Consent/Assent**
[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.

3.10 *Upload “clean” versions of the revised letters of information and implied consent/assent form(s) (i.e., with the changes accepted):

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

Implied Consent/Assent

Add Another

If any option other than ‘No enrollment’ is selected in 1.4, then Q3.11 will appear:

3.11 *Will the new/updated information be communicated to current or past participants (e.g., participants already enrolled in the study), if applicable?

Yes No Not Applicable

If ‘No’: *Justify: **<Multi-Line Text Box>**

If ‘Yes’ in 3.11, questions 3.12 – 3.14 will appear:

3.12 *Describe how this information will be communicated to participants who are currently enrolled in the study: **<Multi-Line Text Box>**

3.13 *Will this information be communicated to participants who are no longer being followed for the purposes of the study?

Yes No

If ‘Yes’: *How do you plan to communicate the updated information to participants?

<Multi-Line Text Box>

If ‘No’: *Clarify why these individuals will not be informed: **<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.

3.14 Upload the document that outlines the information being communicated to participants if not already uploaded.

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

Information Update Letter

<Add Another>

If “Addition of letter of information and consent and/or assent form(s)” is selected in question 3.1, the questions 3.15 and 3.16 appear:

3.15 *Please, 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 (when 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 you will assess capacity for the individuals noted above. If participants are incapable of giving consent, explain how you will identify substitute decision makers and how you will obtain consent to contact them. Note, discuss what safeguards you will put in place to ensure the rights of the research participant are protected: <Multi-Line Text Box>

3.16 *Which of the following forms of consent/assent will be added? (select ALL that apply):
NOTE: this does not include revised forms of consent/assent which can be uploaded as part of Q3.4

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 (this is the default option recommended by TCPS II; it provides clear documentation of consent/assent).
- Verbal consent/assent (e.g., for a telephone interview).
- Implied consent/assent (e.g., checking an explicit box indicating consent, accessing the survey, taking part in the interview, etc.).

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 final, clean versions of all applicable written letters of information and consent and/or assent forms:

Upload Document (Document Name, Document Date, Version) – Document Type: Written Consent/Assent

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 you document/note verbal consent/assent? **<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 final, clean versions of all applicable letters of information that you will provide/read to participants/parents/guardians/SDMs and the verbal consent/assent script that you will use 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 you will obtain implied consent/assent 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 you document/note implied consent/assent? **<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 final, clean versions of all applicable letters of information that you will be provide to participants/parents/guardians/SDMs with an explicit statement clearly indicating how you will obtain implied consent/assent:

**Upload Document (Document Name, Document Date, Version) – Document Type:
Implied Consent/Assent**
[Add Another](#)

Section 4.0 – Changes To Participant tool(s)/form(s)

If ‘Changes to participant tool(s)/form(s) (e.g., study instruments/stimuli, recruitment materials, debriefing document, etc.)’ is selected in question 1.6, the following questions appear:

4.1 *Identify the revisions to the participant tool(s)/form(s) as a result of this amendment (select all that apply):

- Addition of new study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.)
- Changes to previously approved study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.)
- Addition of new recruitment tool(s)/form(s)
- Changes to previously approved recruitment tool(s)/form(s)
- Addition of new other tool(s)/form(s) to be provided to study participants (e.g., debriefing document, screening document, etc.)
- Changes to previously approved other tool(s)/form(s) that will be provided to study participants (e.g., debriefing document, screening document, etc.)
- Other

If ‘Other’: *Please specify other reason: [<Multi-Line Text Box](#)

If ‘Addition of new study instruments/stimuli (e.g., survey/questionnaire/interview/focus group, observation guide, etc.)’ is selected in 4.1, question 4.2-4.3 appears:

4.2 *How will the new study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.) be administered? (e.g., paper, electronic, in-person, etc.)? [<Multi-Line Text Box>](#)

4.3 * Indicate the new data collection tool(s)/form(s) by selecting the relevant option(s) below.

- 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 stimuli, participant diary, data collection forms, etc.)

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 the paper survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type:
Paper Survey
Add Another

If ‘Online Survey(s)/Questionnaire(s)’:

Provide the URL for any online tool(s)/form(s): Note: Review of the URL is required, for testing purposes, prior to REB Approval.

<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 ‘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)’:

*Upload the online survey(s)/questionnaire(s)/task(s):

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

Online 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)’:

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 for the interview?

Mandatory Optional

If 'Optional' *How will you record the data if participants do not agree to be audio-recorded for the interview? <Multi-Line Text Box>

If 'Interview Guide(s)': *Upload the interview guide attachment (including the general questions/probes):

Upload Document (Document Name, Document Date, Version) – Document Type: Interview 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 '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 for the focus group?

Mandatory Optional

If ‘Optional’ *How will you accommodate participants who do not wish to be audio-recorded for the focus group? <Multi-Line Text Box>

If ‘Optional’ *How will you record data for participants who do not agree to be audio-recorded for the focus group? <Multi-Line Text Box>

If ‘Focus Group Guide(s)’: *Upload the focus group guide attachment (including the general questions/probes):
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(s)’: Upload the non-participant observation guide attachment, if applicable:
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(s)’: Upload the participant observation attachment that will guide your interactions, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: Participant Observation Guide
Add Another

If ‘Other’: *Specify other: <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 any other data collection instruments that will be used during the study:

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

Add Another

If ‘Changes to previously approved study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.)’ in 4.1, 4.4-appears:

4.4 *Provide a rationale for the change(s): **<Multi-Line Text Box>**

*Indicate which data collection tool(s)/form(s) are being revised by selecting the relevant option(s) below:

- 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 stimuli, participant diary, data collection forms, etc.)

If ‘Paper Survey(s)/Questionnaire(s)’:

*Upload the “tracked changes” version of the paper survey(s):

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes 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.

*Upload the “clean” version of the paper survey(s):

Upload Document (Document Name, Document Date, Version) – Document Type: Paper Survey

Add Another

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)’:

*Upload the “tracked changes” version of the online survey(s)/questionnaire(s)/task(s):

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes Online 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.

*Upload the "clean" version of the online survey(s)/questionnaire(s)/task(s):
**Upload Document (Document Name, Document Date, Version) – Document Type:
Online Survey**
Add Another

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)':

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(s) Guide':

*Upload the "tracked changes" version of the interview guide attachment (including the general questions/probes):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Interview 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.

*Upload the "clean" version of the interview guide attachment (including the general questions/probes):
**Upload Document (Document Name, Document Date, Version) – Document Type:
Interview Guide**
Add Another

If ‘Focus Group(s) Guide’:

*Upload the “tracked changes” version of the focus group guide attachment (including the general questions/probes):

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes 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.

*Upload the “clean” version of the focus group guide attachment (including the general questions/probes):

Upload Document (Document Name, Document Date, Version) – Document Type: Focus Group(s) Guide

Add Another

If ‘Non-Participant Observation Guide’:

Upload the “tracked changes” version of the observation guide attachment, if applicable:

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes 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.

Upload the “clean” version of the observation guide attachment, if applicable:

Upload Document (Document Name, Document Date, Version) – Document Type: Non-Participant Observation Guide

Add Another

If ‘Participant Observation Guide’:

Upload the “tracked changes” version of the participant observation attachment that will guide your interactions, if applicable:

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes 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.

Upload the “clean” version of the participant observation attachment that will guide your interactions, if applicable:

Upload Document (Document Name, Document Date, Version) – Document Type: Participant Observation Guide

Add Another

If ‘Other’: *Specify other: <Multi-Line Text Box>

If ‘Other’:

Upload any “tracked changes” version of the other data collection instruments that will be used during the study:

Upload Document (Document Name, Document Date, Version) – Document Type: Tracked Changes Other Data Collection Instruments

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.

Upload any “clean” version of the other data collection instruments that will be used during the study:

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

Add Another

If ‘addition of new recruitment tool(s)/form(s)’ is selected in 4.1, 4.5-4.6 appears:

4.5 *What new recruitment methods are being added? (select all that apply)

- 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 ad (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)
- Snowball sampling
- Mail
- Other recruitment strategy

4.5.1 (4.5.1a) If ‘Other’: *Describe your “Other” recruitment strategy: <Multi-Line Text Box>

4.5.1b **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: survey panel recruitment script
[Add Another](#)

4.5.2a If ‘Brochure, flyer, poster’ *Specify where brochures, flyers, 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.

4.5.2b 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.

4.5.3 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.

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

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

4.5.5a **If 'telephone call'***Specify how you have access to or will obtain potential participants' telephone numbers: **<Multi-Line Text Box>**

4.5.5b **If 'telephone call'***Specify who is making initial contact: **<Multi-Line Text Box>**

4.5.5c **If 'telephone call'***Does the person making initial contact have a relationship with the participant?

Yes No

4.5.5d **If 'yes to 4.5.5c'***Describe the nature of the relationship: **<Multi-Line Text Box>**

4.5.5e **If 'yes to 4.5.5c'** *Describe what steps will be taken to ensure it 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.

4.5.5f **If 'telephone call'** *Upload telephone script:

Upload Document (Document Name, Document Date, Version) – Document Type:
telephone script
Add Another

4.5.6a **If 'email'***Specify how you have access to or will obtain potential participants' email addresses: **<Multi-Line Text Box>**

4.5.6b **If 'email'***Specify who is making initial contact: **<Multi-Line Text Box>**

4.5.6c **If 'email'***Does the person making initial contact have a relationship with the participant?

Yes No

4.5.6d **If 'email'***Describe the nature of the relationship: **<Multi-Line Text Box>**

4.5.6e **If 'email'***Describe what steps will be taken to ensure it 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.

4.5.6f **If 'email'** *Upload email script:

Upload Document (Document Name, Document Date, Version) – Document Type:
email script

Add Another

4.5.7a **If 'website'** *Specify website and/or online group/community through which recruitment will occur (Note: If social media, specify whose accounts/pages the recruitment will be posted from/to): **<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.

4.5.7b **If 'website'** *Upload website ad:

Upload Document (Document Name, Document Date, Version) – Document Type:
website ad

Add Another

4.5.8a **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.

4.5.8b **If 'video'** *Upload video (or provide URL in a document):

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

Add Another

4.5.8c **If 'video'** *Upload video script:

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

4.5.9a **If ‘In-person recruitment’** *Specify where potential participants will be approached: **<Multi-Line Text Box>**

4.5.9b **If ‘In-person recruitment’** *Specify who is making initial contact: **<Multi-Line Text Box>**

4.5.9c **If ‘In-person recruitment’** *Does the person making initial contact have a relationship with the participant?
 Yes No

4.5.9d **If ‘In-person recruitment’** *Describe the nature of the relationship: **<Multi-Line Text Box>**

4.5.9e **If ‘In-person recruitment’** *Describe what steps will be taken to ensure it 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.

4.5.9f **If ‘In-person recruitment’** *Upload verbal recruitment script:
Upload Document (Document Name, Document Date, Version) – Document Type: email script
Add Another

4.5.10a **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.

4.5.10b **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

4.5.11a **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.

4.5.11b **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

4.5.12a **If ‘survey panel’** *Specify 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.

4.5.12b **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**

4.5.13 **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.

4.5.14a **If ‘Mail’**: *Specify how you have access to or will obtain potential participants’ mailing addresses: <Multi-Line Text Box>

4.5.14b **If ‘Mail’**: *Upload the recruitment letter:

Upload Document (Document Name, Document Date, Version) – Document Type: survey panel recruitment script

Add Another

If ‘Changes to previously approved recruitment tool(s)/form(s)’ is selected in 4.1, questions 4.6-4.10 appears:

4.6 *Provide a rationale for the change(s) to previously approved recruitment tool(s)/form(s).
<Multi-Line Text Box>

*Upload the “tracked” version of the recruitment tool(s)/form(s) showing the changes from the currently approved version (i.e., with the changes tracked):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Recruitment Materials**

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.

*Upload the “clean” version of the revised recruitment tool(s)/form(s) (i.e., with the changes accepted):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Recruitment Materials**

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 ‘Addition of new other material to be provided to study participants’ is selected in 4.1, questions 4.8 appears:

4.7 *Upload all new other tool(s)/form(s) to be provided to study participants:

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

Add Another

If ‘changes to previously approved other tool(s)/form(s) that will be provided to study participants’ is selected in 4.1, questions 4.9 appears:

4.8 * Provide a rationale for the change(s). <Multi-Line Text Box>

*Upload the “tracked” version of the other tool(s)/form(s) that will be provided to study participants showing the changes from the currently approved version (i.e., with the changes tracked):

**Upload Document (Document Name, Document Date, Version) – Document Type:
Tracked Changes Other Materials**

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.

*Upload the “clean” version of the revised other tool(s)/form(s) that will be provided to study participants (i.e., with the changes accepted):

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

[Add Another](#)

If ‘Other’ is selected in 4.1, questions 4.10-4.11 appears:

4.9 *Describe the Other change(s): [<Multi-Line Text Box>](#)

*Provide a rationale for the Other change(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.

4.10 Upload any additional information that will be provided to participants, if applicable:

Upload Document (Document Name, Document Date, Version) – Document Type: Additional Info provided to participants

[Add Another](#)

Section 5.0 – Translation of Approved Materials

If ‘translation of new and/or approved materials’ is selected in question 1.6, the following questions appear:

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.

5.1 *Upload all translated study material(s) (e.g., consent or assent forms, recruitment materials, and/or participant materials such as questionnaires, etc.):

Upload Document (Document Name, Document Date, Version) – Document Type: Translated Documents

[Add Another](#)

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

Yes No

If 'Yes' is selected in Q5.2: *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.

5.3 If 'No' is selected in Q5.2: * 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 (Document Name, Document Date, Version) – Document Type: Translation Certificate
Add another

Section 6.0 – Change To The Data Collected And/Or How Data Is Accessed, Collected, Used Or Stored

If 'Change to the data collected and/or how data is accessed, collected, used or stored' is selected in question 1.6, the following questions appear:

6.1 *This change involves the following (select all that apply):

- Change in the identifiable information collected
- Change in how data is accessed, collected, used or stored

If 'Change in the identifiable information collected' is selected in question 6.1, question 6.2 appears:

6.2 *Describe the change(s) in the identifiable information collected. Please ensure these changes have also been made and justified in Question 1.19 of this amendment application. **<Multi-Line Text Box>**

If 'Change in how data is accessed, collected, used or stored' is selected in question 6.1, question 6.3-6.4 will appear:

6.3 *Describe all changes to data access/collection/use/storage: **<Multi-Line Text Box>**

6.4 *Provide a rationale for the change(s). **<Multi-Line Text Box>**

Section 7.0 – Changes To Biological Specimen Collection/Use

If ‘Changes To Biological Specimen Collection/Use’ is selected in question 1.6, the following questions appear:

7.1 *The changes to the biological specimen collection/use include (select all that apply):

- Changes to previously approved biological specimen collection/use information
- Addition of new biological specimen collection/use

If ‘Changes to previously approved biological specimen collection/use information’ is selected in Q7.1, question 7.2 and 7.3 appear

7.2 *Identify the changes being made to the previously approved biological specimen collection/use, and provide a rationale. If all changes/rationale are also identified in a document uploaded into this application (e.g., summary of changes), please indicate so:
<Multi-Line Text Box>

7.3 *Are there any changes to the security measures to protect the confidentiality of the biological specimens?

- Yes
- No

If ‘Yes’: *Describe the changes: <Multi-Line Text Box>

If ‘Addition of new biological specimen collection/use’ is selected in Q7.1, questions 7.4 – 7.7 appear:

7.4 *What type of new biological specimens will be collected from the study participants?

<Multi-Line Text Box>

7.5 *Will the new biological specimens be linked to any study participant identifying information, directly or indirectly via a code or link?

- Yes
- No

If ‘Yes’: *Specify Details: <Multi-Line Text Box>

7.6 *Describe the security measures to protect the confidentiality of the new specimens: <Multi-Line Text Box>

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

- 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 Q7.7, question 7.8-7.14 appear:

7.8 *Indicate whether the biological specimen collection for the purposes of this study is:

- Mandatory

Optional (separate LOI/C required)

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

7.10 *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>**

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

7.12 *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>**

7.13 *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>**

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

Yes No

If 'yes' to question 7.14, questions 7.15-7.21 appear:

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

Mandatory

Optional (separate LOI/C required)

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

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

7.18 *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>**

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

7.20 *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>

7.21 *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 Q7.7, question 7.22-7.27 appear:

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

7.23 *Has informed consent been obtained from participants for this secondary purpose?
Yes No

7.24 *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>

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

7.26 *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>

7.27 *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 ‘From deceased human materials (incl. historical/archeological remains and cadavers)’ is selected in Q7.7, question 7.28-7.43 appear

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

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

7.30 *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: *Please 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: *Please 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: *Please explain why you have not obtained the proper approvals from a regulatory body: <Multi-Line Text Box>

If no: *Please 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>

7.31 *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>

7.32 *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>

7.33 *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>

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

7.35 *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>

7.36 *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>

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

Yes No

If 'yes' to question 7.37, questions 7.38-7.42 appear:

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

7.39 *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>

7.40 *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>

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

7.42 *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>

7.43 *Are you using bioarcheological 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 8.0 – Changes In Study Funding

If 'Changes in study funding' is selected in question 1.6, the following questions appear:

8.1 *Select the type of change (select all that apply):

- Addition of new funder(s)
- Change to previous funder(s)
- Other

If Other: *Specify: <Multi-Line Text Box>

If 'Addition of new funder(s) is selected in 8.1, question 8.2 will appear:

8.2 New Study funder(s) (select 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 '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>

If 'industry sponsored', 'internal grant', 'external grant', 'other' is selected in 8.2 question 8.3 will appear:

8.3 *What is the status of funding from this new source?

- Obtained
- Awarded but not received

If 'awarded but not received': *will you be able to proceed with the study? <Multi-Line Text Box>

If 'Change in previous funder(s)' is selected in 8.1, question 8.4-8.5 will appear:

8.4 *Describe all changes in study funder(s): <Multi-Line Text Box>

8.5 *Provide a rationale for the change(s) <Multi-Line Text Box>

If ‘Change in previous funder(s) or Addition of new funder(s)’ is selected in 8.1, question 8.6 will appear:

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

- Western
- Lawson
- No

If ‘Western’: *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’: *For research award(s) held through Western, provide one of the following for each award supporting this study: (1)ROLA reference number, or (2)Agency reference number, or (3) Account speed code:

If ‘No’ is selected in Q8.6 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 Q8.6 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 and the Ethics Officer prior to submitting this application.

Section 9.0 – Change In Name/Contact Information Or Study Information

If ‘Change in name/contact information (e.g., for the PI, Western-affiliated project team members, non-Western-affiliated project team members) or change in study information (e.g., study title, study acronym/nickname/short name)’ is selected in question 1.6, the following section appears:

Ensure that the corresponding information is updated in Section 1 of the application.

9.1 *The change(s) relate to (select all that apply):

- Existing Principal Investigator (Question 1.9)
- New Principal Investigator (Question 1.9).
- Western-affiliated project team members (Question 1.10)
- Collaboration with NON-Western-affiliates (Question 1.11)
- Study title (Question 1.12)
- Study acronym/nickname/short title (Question 1.13)
- Student project status (Question 1.17)

Section 10.0 – New Information About A Rejection/Disapproval Of The Study By Another Reb

If ‘New information about a rejection/disapproval of the study by another REB’ is selected in 1.6, then the following question appears:

10.1 *If another REB has rejected this study, or required an amendment to this study (e.g., required protocol change(s)), please describe: <Multi-Line Text Box>

10.2 Upload any relevant documents:

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

Other REB Rejection Letter

Add Another

Section 11.0 - Other

If ‘Other’ is selected in question 1.4, the following section appears:

11.1 *Describe the ‘other’ changes made with this amendment: <Multi-Line Text Box>

11.2 *Provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so: <Multi-Line Text Box>

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

11.4 Upload any associated documents that have not been uploaded elsewhere (if applicable):

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

Other Materials

Add Another

Section 12.0 – Conflict of Interest (actual, apparent, perceived, or potential)

If ‘Updates to Conflict of Interest (actual, apparent, perceived, or potential) attestation’ is selected in question 1.6, the following section appears:

12.1 *Will the PI or Co-Investigator(s) or anyone connected to them through 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>

12.2* 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>

12.3* 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>

12.4* 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>

12.5* 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>

12.6*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>

12.7*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 13.0 – Resubmission Information

This section appears only if 'Resubmission' is selected in 1.1.

13.1 *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**

13.2 Upload any other documents that have not yet been uploaded elsewhere:
Upload Document (Document Name, Document Date, Version)

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

Section 14.0 - Confirmation of Responsibility

If "Initial Submission" is selected in Question 1.1, then question 14.1 appears:

14.1 *Principal Investigator Signature:

- As the PI, I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- As the PI, I assume full responsibility for the scientific and ethical conduct of the study at this institution;

- As the PI, I agree to conduct this study in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with all other applicable laws, regulations or guidelines;
- As the PI, I certify that all Co-investigator(s), researchers and other personnel (research team) involved in this project at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this project;
- As the PI, I acknowledge that I am responsible for promptly reporting to the REB, through the electronic application system, any proposed specific:
 - 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 the trial;
 - 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 personal health information and the privacy of individuals with respect to that information;
- As the PI, 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;
- As the PI, 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 14.2 appears:

14.2 *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 responsible 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 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;
- 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.

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.

If 8.1 “*New Principal Investigator (Question 1.7)” is selected 12.4 appears

14.3 Is this outgoing PI available to sign this form?

Yes outgoing PI can sign this form

No the outgoing PI is not available to sign this form

If “No the outgoing PI is not available to sign this form” the following sub question appears

What circumstances is preventing the outgoing PI from signing this form?

If “Yes outgoing PI can sign this form”, the following sub question appears:

*Outgoing Principal Investigator’s Signature