HSREB 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 "Response to REB Recommendations".

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

If applicable, please provide a protocol amendment reference number/ID (e.g., the identifier assigned by the lead group/Sponsor to the modification) that will appear in the REB letters: **<Single-Line Text Box>**

1.3 *Provide a brief lay/non-scientific summary of the study (max 250 words). Please do not re-write or edit the original lay summary to suit the amendment. A location for the amendment summary is found in Q1.5

HELP TEXT: Lay or non-scientific refers to language that is simple and non-technical and is used in every-day conversations; terminology that an average non-professional can understand. <Multi-Line Text Box>

1.4 *Which of the following changes are included in the Amendment? Select all that apply. The selections in this section will determine what questions WREM generate and what documents can be uploaded.

Ensure that the applicable options are indicated that best represent what is being revised as per this amendment. Once indicated, the applicable sections will be available within this amendment application. If inappropriate questions are being asked of the study team, please review this section to ensure the correct options have been indicated

☐Changes to the protocol/research plan

☐Changes to biological specimen collection/use

☐Changes to the Letter of Information/Consent and/or Assent Form(s) or the informed consent process

☐Changes to participant tool(s)/form(s) (such as study instruments/surveys/questionnaires, interviews/focus groups, recruitment materials, participant diaries, wallet cards, etc.) and/or other Data Collection Tools (e.g., Data collection Forms, Participant Observational Guides, Non-Participant Observational Guides, CRF, etc.)

☐Updated/new Investigator Brochure (IB) or Product Monograph (PM)

☐Translation of approved materials

☐Change to the data collected and/or how data is accessed, collected, used or stored

☐Changes in study funding, participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s)

☐Change/updates relating to the communication of results

☐Change in clinical trial registry information

☐ Updated Health Canada documentation (NOL, NOA, ITA) or other change in regulatory information (e.g., FDA)

☐ Change in name/contact information (e.g., for the PI, Co-I, Sponsor, Coordinating or Contract Research Organization) or change in study information (e.g., study title, study acronym/nickname/short name, sponsor's study ID)

☐New information about a rejection/disapproval of the study by another REB

☐Update to Conflict of Interest (actual, apparent, perceived, or potential) attestation

☐Change to Hospital Affiliated Location for utilizing any patient data/biological specimens, staff resources or facilities

☐Other

1.5 *Provide a brief lay summary of all of the proposed changes to this amendment (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".

Please note, the question below either (1) reflects the information that has previously been provided to 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 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).

1.6 *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).

1.7 Are there any additional study team members (from Western and/or it's affiliate institutions) who are working on this study**?**

☐ Yes there are additional study team members

☐ No other study members involved

If 'Yes' to 1.7

1.7 Complete the following information for other 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:

1.7 ROLE and RESPONSIBILITY in this study. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data.)

1.7 a Are there any additional study team members (from Western and/or it's affiliate institutions) who are working on this study**?**

☐ Yes there are additional study team members

☐ No other study members involved

1.7 a Complete the following information for other 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:

1.7a ROLE and RESPONSIBILITY in this study. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data.)

Etc. until 1.7o

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

1.10 *****Does this study involve the London hospitals (see HELP text if you are unsure):

☐ No this study does not involve the London hospitals

☐ Yes this study involves the London hospitals and this form has been exported from ReDA.

☐ This study involves the London Hospitals but a ReDA submission has not been completed. NOTE: You cannot submit this application until the ReDA submission has FIRST been completed and you exported from ReDA to WREM.

If "Box 2" is selected in Question 1.2 (HSREB initial application), then the following sub-question appears

* What is the Lawson ReDA number associated with this study? **<Numeric Box>**

* As this study is taking place in the hospital, copy and paste: lawsonapproval@lawsonresearch.com in the below email text box

***** Name:

*Email:

If "Box 1" is selected in Question 1.2 (HSREB initial application), then the following sub-question appears

*As this study is not taking place in the hospital, type in "Western Research Services" in the below Search User text box:

*Name:

*Email:

SHARED FROM INITIAL APPLICATION (1.8) - Editable

1.11 Are the investigators utilizing their hospital credentials or will the study utilize any patient data/biological specimens, staff resources or facilities within any of these sites? (Please indicate all applicable sites)

- ☐ No
- ☐ LHSC - Victoria Hospital (VH)
- ☐ LHSC - University Hospital (UH)
- ☐ LHSC – London Regional Cancer Program (LRCP)
- ☐ LHSC - Children's Hospital of Western Ontario
- ☐ St. Joseph's Health Care London
- ☐ Parkwood Institute Main Building
- ☐ Parkwood Institute Mental Health Care
- ☐ Southwest Centre for Forensic Mental Health Care
- ☐ Byron Family Medical Centre
- ☐ Victoria Family Medical Centre
- ☐ St. Joseph's Family Medical Centre
- ☐ Mount Hope
- ☐ Westmount Mall; Kidney Care Centre, Adult Eating Disorder Service,
- ☐ Southwest Ontario Regional Base Hospital Program

1.12*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 (e.g. Pharmaceuticals)
- ☐ External not-for-profit
- ☐ External PI
- ☐ Local PI
- ☐ Self

If industry sponsored is selected in Question 1.18:

*Enter the Sponsor's Study ID Number **<Single-Line Text Box>**

If any checkbox other than 'Self" is selected in Question 1.18:

*Complete the Sponsor details:

*Title:
*First Name:
*Last Name:
*Organisation:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

Please note, the question below either (1) reflects the information that has previously been provided to 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 initially submitted in ROMEO (in which case you will need to provide a response):

1.13 *Is there an external third party (Coordinating or Contract Research Organization) overseeing the study?

☐ Yes ☐ No

If Yes: *Provide the name and contact information of the Coordinating or Contract Research Organization: **<Multi-Line Text Box>**

1.14 *Are you proposing to change any collection or storage of personal identifiers from what is already approved by the REB and is described in Q1.14 below:

☐ Yes ☐ No

Please note, the question below either (1) reflects the information that has previously been provided to 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 1.4 of this Amendment.

1.15 *Identify any personal identifiers collected for this study. Select all that apply.

Help Text: PHI should be collected at the lowest level of identifiably possible (e.g., initials instead of name, age instead of date of birth) and only kept as long as necessary

HELP TEXT: As date of birth is an identifying piece of information that is often collected but not necessarily needed, for *recruitment purposes*, before consent for participation in the study is obtained, consider collecting year only or year and month of birth or age of the patient in order to reduce risks of identification. For *study purposes*, consider collecting year only or year and month of birth or age

☐ Full Name
☐ Initials
☐ Health Card Number
☐ Address
☐ Full Postal Code
☐ Partial Postal Code
☐ Telephone Number
☐ Email address
☐ Family Physician or other care provider names
☐ Full Date of Birth
☐ Partial Date of Birth
☐ Full Date of Death
☐ Partial Date of Death
☐ Biological Sex
☐ Gender Identity
☐ Age
☐ Hospital Number
☐ Medical Device identifier
☐ Full face photograph
☐Voice/audio/video recording
☐ Other

If 'Full Name': ***Explain and justify full name and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Initials': ***Explain and justify initials and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Health Card Number': ***Explain and justify health card number and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Address': ***Explain and justify address and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Full Postal Code': ***Explain and justify full postal code and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Partial Postal Code': ***Explain and justify partial postal code and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Telephone Number': ***Explain and justify telephone number code and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Email address': ***Explain and justify email address code and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Family Physician or other care provider names': ***Explain and justify Family Physician or other care provider names code and if it will be stored on paper or electronically **<Multi-Line Text Box>

If 'Full Date of Birth': ***Explain and justify full date of birth and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Partial Date of Birth': ***Explain and justify partial date of birth and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Full Date of Death': ***Explain and justify full date of death and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Partial Date of Death': ***Explain and justify partial date of death and if it will be stored on paper or electronically **<Multi-Line Text Box>
**If 'Age': ***Explain and justify age and if it will be stored on paper or electronically
If 'Biological Sex/Gender Identity': ***Explain and justify sex/gender and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Hospital Number': ***Explain and justify hospital number and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Medical Device Number': ***Explain and justify medical device number and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Full Face Photograph': ***Explain and justify full face photograph and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Voice/Audio/Video Recording': ***Explain and justify voice/audio recording and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Other': ***Explain and justify other and if it will be stored on paper or electronically **<Multi-Line Text Box>

Section 2 – Amendment Details

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

☐No Enrollment to Date
☐Enrollment Ongoing Locally
☐ Enrollment Ongoing Non-Locally
☐ Enrollment Complete
☐ Intervention and/or Data Collection Ongoing Locally
☐ Intervention and/or Data Collection Ongoing Non-Locally
☐ Intervention and/or Data Collection Complete
☐ Data Analysis or Transfer Ongoing
☐ Data Analysis or Transfer Complete
☐ Preparing Publication
☐Prematurely terminated
☐Other

If 'Other': ***Specify: **<Multi-Line Text Box>
If 'prematurely terminated': ***Provide details: **<Multi-Line Text Box>

If 'No enrollment, 'Enrollment ongoing locally, 'Enrollment ongoing non-Locally', Intervention and/or Data Collection Ongoing Locally', 'Intervention and/or Data Collection Ongoing Non-Locally', question 2.2 will appear:

2.2 *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>

2.3 If applicable, protocol amendment reference number/ID (e.g., the identifier assigned by the Sponsor to the modification): **<Multi-Line Text Box>**

2.4 *Is this application associated with or related to a previously submitted Reportable Event?

☐Yes ☐No

If 'Yes': ***Enter the Review Reference # of the corresponding Reportable Event Form: **<Multi-Line Text Box>

2.5 * Specify the type of review requested (e.g., if this is a sponsored study and the sponsor request a Full Board review indicate "Full Board")

☐ Full Board

☐ Delegated

☐ Not Specified

2.6 * Please upload a protocol or research plan showing ALL changes as "tracked". Please use MS Word "Track Changes" feature and not any manual highlighting or colour changes.

Your protocol or research plan may be a Western protocol/ROMEO application, sponsor protocol, and/or other stand-alone document outlining the study (if there is no study protocol for this project or you also have a separate summary of changes document)

Upload Document (Document Name, Document Date, Version) – Document Type: Summary of Changes

2.7 Upload any related sponsor correspondence: (e.g., sponsor cover letters or memos, including Action Letters even if they were previously submitted with a reportable event), if applicable:

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

Section 3.0 – Changes To The Protocol/Research Plan

If 'Changes to the Protocol' is selected in question 1.2, the following questions appear:

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

☐Study objectives, procedures or design

☐Study instruments embedded within the protocol (e.g., questionnaires)

☐Duration of study

☐Number of participants/sample size/charts/records
☐Participant recruitment methods
☐Eligibility criteria (inclusion/exclusion)
☐Known or anticipated harms/risks/benefits
☐Safety monitoring
☐Addition of sub-studies/correlative studies
☐Addition of new product [e.g., drug (biologic (including vaccines), genetic therapy or radiopharmaceutical or health product (natural or non-prescription)/device] to the study
☐Administrative updates
☐Other
If "Number of participants/sample size/charts/records"
***Clarify the change in participant number, same size, number of charts/records:<Multi-Line Text Box>**
If 'Other': ***Specify other changes: **<Multi-Line Text Box>

3.2 * Provide a rationale for the change(s) (NOT a repeated list of the changes. This should explain the reason for your proposed changes). 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>**

3.3 *Upload the revised protocol/research plan (this must be a 'clean' version): **Upload Document (Document Name, Document Date, Version) – Document Type: Protocol**

3.4 *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>

If 'Addition of new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device to the study' is selected in 3.1:

3.5 *Is the new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device subject to an application to Health Canada under the Food and Drugs Act (select all that apply)?

☐Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations;
☐Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations;
☐Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations;
☐No

If 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in 3.5, question 3.6 - 3.9 appear:

3.6 *Indicate the status of the new product(s) covered under the CTA with Health Canada (select all that apply):

☐Approved (e.g., has Drug Identification Number (DIN)), but being used in the study outside the conditions of use approved by Health Canada

☐Investigational

If 'Approved (e.g. has Drug Identification Number (DIN)), but being used in the study outside the conditions of use approved by Health Canada':

*Describe how the new product(s) is/are being used in the study outside the conditions of use approved by Health Canada: **<Multi-Line Text Box>**

3.7 *Indicate which of the following document(s) were submitted to Health Canada for the new product(s) covered under the Clinical Trial Application (CTA) (select all that apply):

☐Investigator Brochure (IB)

☐Product Monograph (PM)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

If 'Investigator Brochure (IB)':

*Upload Investigator Brochure (IB):

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

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

If 'Product Monograph (PM)':

*Upload Product Monograph (PM):

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

3.8 *Indicate the status of Health Canada Clinical Trial Application (NOL):

☐ No Objection Letter Enclosed

☐ No Objection Letter pending

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Upload only the clean version here (i.e., not the tracked copy). Do not include "clean" in the document name.

If 'No Objection Letter Enclosed':

*Upload Health Canada NOL document:
Upload Document (Document Name, Document Date, Version): Document Type: NOL

3.9 IF this is an investigator-initiated study, please upload the CTA that was submitted to Health Canada (Industry sponsored studies need not provide this documentation):
Upload Document (Document Name, Document Date, Version): Document Type: CTA

If 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' was selected from list in question 3.5, questions 3.9-3.13 appear:

3.10 *Indicate the status of the new health product(s) covered under the CTA with Health Canada (select all that apply):

☐Approved (e.g., has Natural Product Number (NPN or Homeopathic Medicine Number (DIN-HM)), but being used in the study outside the conditions of use approved by Health Canada

☐Investigational

If 'Approved (e.g has Natural Product Number (NPN or Homeopathic Medicine Number (DIN-HM)), but being used in the study outside the conditions of use approved by Health Canada':

*Describe how the new Health Product is being used in the study outside of the parameters of the conditions of use approved by Health Canada: **<Multi-Line Text Box>**

3.11 *Indicate which of the following document(s) were submitted to Health Canada for the new health product(s) covered under the Clinical Trial Application (CTA) (select all that apply)?

☐Investigator Brochure (IB)

☐Product Monograph (PM)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., HC NOL, control#, date). Label your tracked version as TRACKED, but there is no need to include "clean" in the clean version. Avoid using slang, student names, etc.

If 'Investigator Brochure (IB)':

*Upload Investigator Brochure (IB):
Upload Document (Document Name, Document Date, Version) – Document Type: Investigator Brochure

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., HC NOL, control#, date). Label your tracked version as TRACKED, but there is no need to include "clean" in the clean version. Avoid using slang, student names, etc.

If 'Product Monograph (PM)':

*Upload Product Monograph (PM):
Upload Document (Document Name, Document Date, Version) – Document Type: Product Monograph

3.12 *Indicate the status of Health Canada Clinical Trial Application:
☐ Notice of Authorization enclosed
☐ Notice of Authorization pending

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., HC NOC, date). Label your tracked version as TRACKED, but there is no need to include "clean" in the clean version. Avoid using slang, student names, etc.

If 'Authorization enclosed':
*Upload the Notice of Authorization document:
Upload Document (Document Name, Document Date, Version) – Document Type: NOA

3.13 *IF this is an investigator-initiated study, please upload the CTA that was submitted to Health Canada (Industry sponsored studies need not provide this documentation):
Upload Document (Document Name, Document Date, Version): Document Type: CTA

If 'Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations' selected in question 3.5, questions 3.12-3.18 appear
3.14 *Name of all new device components, parts and/or accessories as per product label for devices covered under the ITA with Health Canada: **<Multi-Line Text Box>**
Add Another

3.15 *Indicate the status of the new device(s) with Health Canada (select all that apply):
☐Licensed (e.g., has Medical Device License (MDL)), but being used outside of current Health Canada authorization
☐Investigational

If 'Licensed (e.g. has Medical Device License (MDL)), but being used outside of current Health Canada authorization':
*Describe how the new device component, parts and/or accessories is/are being used in the study outside of the parameters of the conditions of use approved by Health Canada:
<Multi-Line Text Box>

3.16 *Does this new device contain drug(s)?
☐Yes ☐No
If 'Yes': ***Drug(s) used: **<Multi-Line Text Box>

3.17 *For each new device covered under the ITA, upload the Product Monograph (PM) or equivalent:
Upload Document (Document Name, Document Date, Version) – Document Type: Product Monograph

3.18 IF this is an investigator-initiated study, please upload the ITA that was submitted to Health Canada (Industry sponsored studies need not provide this documentation):
Upload Document (Document Name, Document Date, Version) – Document Type: NOL/NOA/ITA

Section 4.0 – Changes To Biological Specimen Collection/Use

If 'Changes to biological specimen collection/use' is selected in question 1.2, the following questions appear:

4.1 *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 question 4.2 appear

4.2 *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>

4.3 *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' questions 4.4 – 4.9 appear:

4.4 *What type of new biological specimens will be collected from the study participants?
<Multi-Line Text Box>

4.5 *Will stem cells be collected or used in this study?
☐Yes ☐No
If 'Yes': ***Describe the stem cell component of the study: **<Multi-Line Text Box>

4.6 *How will the new biological specimens be collected (select all that apply)?
☐Previously acquired clinical specimens (i.e., leftover or archived specimens)
☐Prospectively collected for this study (i.e., not yet collected)
☐Other
If Other: ***Specify Details: **<Multi-Line Text Box>

4.7 *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>

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

4.9 *Select the purpose(s) for which the new biological specimens will be collected (select all that apply):

☐For the purposes of this study (excluding specimens taken as part of normal care or for safety)

☐For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)

☐Stored or retained or banked for any future testing

☐Secondary use of previously collected samples

If 'For the purposes of this study (excluding specimens taken as part of normal care or for safety)' is selected in 4.9, questions 4.10- 4.16 appear:

4.10 *Indicate whether the biological specimen collection for the purposes of this study is (select all that apply):

☐Optional (separate LOI/C required)

☐Mandatory

4.11 *Describe how the biological specimens will be used in this study: **<Multi-Line Text Box>**

4.12 *Will the 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 biological specimens will take place for each type of sample. **<Multi-Line Text Box>**

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

4.14 *Describe what will happen to the new biological specimens at the end of that period (e.g., destroyed, returned): **<Multi-Line Text Box>**

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

If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 4.9, questions 4.16-4.23 appear:

4.16 *Indicate whether the sample collection for genetic testing is (select all that apply):

☐Optional (separate LOI/C required)

☐Mandatory

4.17 *Describe the planned genetic testing: **<Multi-Line Text Box>**

4.18 *Will the 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>

4.19 *Clarify who will have access to the biological specimen(s) **<Multi-Line Text Box>**

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

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

4.22 *Indicate to what extent the study participant is able to withdraw specimens collected for genetic testing, and any limitations to the withdrawal: **<Multi-Line Text Box>**

4.23 *Will study participants or their family members or their health care providers be informed of any genetic testing results?

☐Yes ☐No

If 'Yes': *Describe what information will be shared and with whom? <Multi-Line Text Box>

If 'Yes': *How will consent be obtained to release this information? <Multi-Line Text Box>

If 'Yes': *Describe whether participants will be given the option of not receiving information about themselves: <Multi-Line Text Box>

If 'No': *Explain/justify: <Multi-Line Text Box>

If 'stored or retained or banked for any future testing' is selected in 4.8, questions 4.24-4.30 appears:

4.24 *Indicate whether the sample collection to be stored or retained or banked for any future testing is (select all that apply):

☐Optional (separate LOI/C required)

☐Mandatory

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

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

4.27 *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>**

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

4.29 *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>**

4.30 *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' is selected in 10.4, questions 4.31- 4.36 appears:

4.31 *Describe how the biological specimens will be used in this study: **<Multi-Line Text Box>**

4.32 *Has informed consent been obtained from participants for this secondary purpose?

☐Yes ☐No

4.33 * Will the 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>**

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

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

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

Section 5.0 – Changes To Consent/Assent Form(S)

If "Changes to the consent and/or assent form(s)" is selected in question 1.2, the following questions appear:

5.1 *Please select the reason(s) for the proposed consent/assent form change(s) (select all that apply):

☐Changes to the protocol/research plan

☐Updated adverse effects profile

☐Administrative changes

☐Adding a new LOI/C (new population, sub-study etc.)

☐Changes to how consent is obtained

☐Other

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

5.2 ***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

5.3 ***Which of the following forms are being changed (select all that apply)?

☐Consent Form(s)

☐Assent Form(s)

If 'Consent Form(s) is selected in 5.3', question 5.4 and 5.5 will appear:

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

5.4 ***Upload the "Clean" version of the revised or new consent form(s):

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

5.5 ***Upload "Tracked Changes" versions of the revised consent form(s):

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

If 'Assent Form(s) is selected in 5.3', question 5.6 and 5.7 will appear:

5.6 ***Upload the "Clean" version of the assent form(s):

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

5.7 ***Upload "Tracked Changes" versions of the revised assent form(s)

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

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

☐Yes ☐No

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

If 'Yes' in 5.8, questions 5.9 will appear:

5.9 ***Describe how this information will be communicated to current and past participants: **<Multi-Line Text Box>**

5.10 *Are there proposed changes to the process of obtaining or documenting informed consent? (e.g. adding remote consent options)

☐Yes ☐No

Please note, the question below either (1) reflects the information that has previously been provided to 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 "Changes to how consent is obtained" in question 5.1 AND "Yes" in Question 5.10 of this Amendment.

NOTE: if there was something described in 12.11 of the initial HSREB form then the information will be shared and described below in 5.11a. If Q12.11 was blank in the initial application form then the below 5.11a will be blank

12.1 a. Describe the consent process in an itemized fashion for EACH participant group and recruitment scenario including any engagement of substitute decision makers (SDMs). Please include details around **how** and **when:**
a) the LOI/C will first be provided (e.g. email, in person etc.),
b) the informed consent discussion will take place (e.g. by phone, in person etc.)
c) consent will be documented (e.g. verbally, implied, written, electronic **including the URL**) and d) the fully signed LOI/C will be provided to the participant/SDM as applicable. **<Multi-Line Text Box>**

If 'Yes' in Q5.10, question 5.11b (changes to the process of obtaining or documenting informed consent) will appear:

5.11b *Describe the changes to the process of obtaining or documenting consent (for a patient and/or non-patient population). Please ensure that if you have multiple populations, the consent process for each is explained separately: **<Multi-Line Text Box>**

Section 6.0 – Changes To Participant Materials and/or Other Data Collection Tools

If 'Changes to participant materials (such as study instruments/surveys/questionnaires, interviews/focus groups, recruitment materials, participant diaries, wallet cards, etc.) and/or other Data Collection Tools (e.g., Data collection Forms, Participant Observational Guides, Non-Participant Observational Guides, CRF, etc.)' is selected in question 1.2, the following questions appear:

6.1 *Identify the revisions to the participant tool(s)/forms and/or other data collection tools as a result of this amendment (select all that apply):

☐Addition of data collection tool(s)/form(s) (e.g., paper survey(s), online survey(s), interview(s) guide, focus group(s) guide, non-participant observation guide, participant observation guide, etc.)

☐Changes to previously approved data collection tool(s)/form(s) (e.g., paper survey(s), online survey(s), interview(s) guide, focus group(s) guide, non-participant observation guide, participant 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)t to be provided to study participants (e.g., diaries, wallet cards)
☐Changes to previously approved other tool(s)/form(s) that will be provided to study participants (e.g., diaries, wallet cards)
☐Other tool(s)/form(s)
If 'Other': ***Specify: **<Multi-Line Text Box>

If 'Addition of data collection tol(s)/form(s) (e.g., paper survey(s), online survey(s), interview(s) guide, focus group(s) guide, non-participant observation guide, participant observation guide, etc.)' is selected in 6.1, 6.2 appears:

6.2 * Please 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)
- ☐ 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.)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

If 'Paper Survey(s)/Questionnaire(s)': *Please upload the paper survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Paper Survey

If 'Online Survey(s)/Questionnaire(s)': *Please upload the online survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Online Survey

If 'Interview(s) Guide': *Please upload the interview guide attachment (including the general questions/probes):
Upload Document (Document Name, Document Date, Version) – Document Type: Interview Guide

If 'Focus Group(s) Guide': *Please upload the focus group guide attachment (including the general questions/probes):
Upload Document (Document Name, Document Date, Version) – Document Type: Focus Group(s) Guide

If 'Non-Participant Observation Guide': Please upload the observation guide attachment, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: Non-Participant Observation Guide

If 'Participant Observation Guide': Please upload the participant observation attachment that will guide your interactions, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: Participant Observation Guide

If 'Other': Upload any other new data collection tool(s)/form(s) that will be used during the study:):
Upload Document (Document Name, Document Date, Version) – Document Type: Other Data Collection Instruments

If 'Changes to previously approved data collection method(s) (e.g., paper survey(s), online survey(s), interview(s) guide, focus group(s) guide, non-participant observation guide, participant observation guide, etc.)' is selected in 6.1, 6.3-6.4 appear:

6.3 *Provide a rationale for the change(s) to previously approved data collection toolt(s)/form(s). If all changes/rationale are also identified in a document uploaded into this application (e.g., summary of changes), indicate so: **<Multi-Line Text Box>**

6.4 *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)
- ☐ 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, CRF, etc.)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

If 'Paper Survey(s)/Questionnaire(s)':
*Upload the "Clean" version of the paper survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

*Upload the "Tracked Changes" version of the paper survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Paper Survey

If 'Online Survey(s)/Questionnaire(s)':
*Upload the "Clean" version of the online survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

*Upload the "Tracked Changes" version of the online survey(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Online Survey

If 'Interview(s) Guide':
*Upload the "Clean" version of the interview guide attachment (including the general questions/probes):
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

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

If 'Focus Group(s) Guide':
*Upload the "Clean" version of the focus group guide attachment (including the general questions/probes):
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

*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: Focus Group(s) Guide

If 'Non-Participant Observation Guide':
Upload the "Clean" version of the observation guide attachment, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

Upload the "Tracked Changes" version of the observation guide attachment, if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: Non-Participant Observation Guide

If 'Participant Observation Guide':
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: tracked changes

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: Participant Observation Guide

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

If 'Other':
Upload any "Clean" version of the data collection instruments that will be used during the study:
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

Upload any "Tracked Changes" version of the data collection instruments that will be used during the study:
Upload Document (Document Name, Document Date, Version) – Document Type: Other Data Collection Instruments

If 'addition of new recruitment tool(s)/form(s)' is selected in 6.1, 6.5-6.6 appears:

6.5 *What recruitment tool(s)/form(s) are being added (select all that apply)?

- ☐Brochures, flyers, poster
- ☐Recruitment database
- ☐Third-party recruitment company
- ☐Newspaper ad
- ☐Telephone call scripts
- ☐Website
- ☐Video
- ☐Other

If 'Other': *Specify other type of recruitment tool(s)/form(s): **<Multi-Line Text Box>**

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

*Upload all new recruitment tool(s)/forms:
Upload Document (Document Name, Document Date, Version) – Document Type: Recruitment Materials

If 'Changes to previously approved recruitment tool(s)/form(s)' is selected in 6.1, questions 6.7-6.9 appears:

6.6 *Provide a rationale for the change(s) to previously approved recruitment tool(s)/form(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>**

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

*Upload the "Clean" version of the revised recruitment tool(s)/form(s):
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

*Upload the "Tracked Changes" version of the revised recruitment tool(s)/form(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Recruitment Materials

If 'Addition of new other tool(s)/form(s) to be provided to study participants' is selected in 6.1, questions 6.10 appears:

6.7 *Upload all new other tool(s)/form(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials

If 'changes to previously approved other too(s)/form(s) that will be provided to study participants' is selected in 6.1, questions 6.11-6.13 appear:

6.8 *Provide a rationale for the change(s) to previously approved other tool(s)/form(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>**

*Upload the "Clean" version of the revised previously approved other tool(s)/form(s) :
Upload Document (Document Name, Document Date, Version) – Document Type: tracked changes

Upload the "Tracked Changes" version of the revised previously approved other tool(s)/form(s)
Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials

If 'Other' is selected in 6.1, questions 6.9-6.11 appears:

6.9 *Describe the other change(s) : **<Multi-Line Text Box>**

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

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

6.10 *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>**

6.11 *How will the data collection tools/forms be administered (e.g., in person, paper, electronic)? **<Multi-Line Text Box>**

6.12 If you are directing participants to a website or electronic materials provide the web address (as applicable): **<Multi-Line Text Box>**

Add Another

Section 7.0 - Updated/New Investigator Brochure (IB) Or Product Monograph (PM)

If 'Updated/new Investigator Brochure (IB) or Product Monograph (PM)' is selected in question 1.3, the following questions appear:

7.1 *Please indicate which of the following document(s) is/are being updated (select all that apply):

☐Investigator Brochure (IB)

☐Product Monograph (PM)

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

If 'Investigator Brochure (IB)':

*Upload Investigator Brochure (IB):

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

If 'Product Monograph (PM)':

*Please upload Product Monograph (PM):

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

7.2 *Is this update to the IB/PM associated with any changes to the consent form(s) and/or changes to the protocol?

☐Yes ☐No

If 'Yes': *Are these changes included within this amendment submission?

☐Yes ☐No

If 'No': *When are the corresponding changes expected to be submitted to the REB? <Multi-Line Text Box>

Section 8.0 – Translation of Approved Materials

If 'translation of approved materials' is selected in question 1.3, the following questions appear:

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc. Do not include "clean" in the document name.

8.1 *Upload all translated approved material(s) (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.):
Upload Document (Document Name, Document Date, Version) – Document Type: Translated Documents

8.2 Upload all translation certificate(s), if applicable:
Upload Document (Document Name, Document Date, Version) – Document Type: Translation Certificate

Section 9.0 – 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 1.3, the following questions appear:

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

☐Change in the Personal Information (PI) or Personal Health Information (PHI) collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.)

☐Change in how data is accessed, collected, used or stored

☐Linking of data with any other data sets, databases or registries

If 'change in the Personal Information or Personal Health Information collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.)' is selected in question 9.1, question 9.2 appears:

9.2 *Describe the change(s) in the Personal Information (PI) or Personal Health Information (PHI) collected. **<Multi-Line Text Box>**

If 'change in how data is accessed, collected, used or stored' is selected in question 9.1, question 9.4-9.5 will appear:

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

9.4 *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>

If 'Linking of data with any other data sets, databases or registries' is selected in question 9.1, questions 9.6-9.7 will appear:

9.5 *Is there a plan to link any of the study data with any other data sets, databases or registries (e.g., health registries, Statistics Canada)?

☐Yes ☐No

If 'Yes': ***Identify the data sets, databases or registries to which it will be linked: **<Multi-Line Text Box>

If 'Yes': ***Explain the purpose for the linking: **<Multi-Line Text Box>

If 'Yes': ***Describe how the linking will be done: **<Multi-Line Text Box>

If 'Yes': ***Describe the likelihood that identifiable data will be created through the linkage: **<Multi-Line Text Box>

If 'Yes': ***Describe the security measures that will be in place to protect the confidentiality of the data: **<Multi-Line Text Box>

9.6 ***Is the purpose of this study to establish a registry/database?

☐Yes ☐No

If 'Yes':

**If 'Yes': ***Will Personal Identifiers (PI) be stored in the registry/database?

☐ Yes ☐ No

If "Yes" What identifiers will be stored **<Multi-Line Text Box>**

If 'Yes': * Who maintains the registry/database? **<Multi-Line Text Box>**

If 'Yes': ***Where is the registry/database located? **<Multi-Line Text Box>

If 'Yes': ***Describe the security measures that will be in place to protect the confidentiality of the data: **<Multi-Line Text Box>

Section 10.0 – Changes In Study Funding, Participant Compensation/Reimbursement, Provision Or Access To Product(S)/Device(S), And/Or Financial Pressure(S)/Incentive(S)

If 'Changes in study funding, participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s)' is selected in question 1.3, the following questions appear:

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

☐Addition of new funder(s)

☐Change to previous funder(s)

☐Change to participant compensation/reimbursement

☐Change in provision of or access to agent(s)/devices used in the study

☐Change in financial incentive(s)/pressure(s)

☐Other

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

If 'Addition of new funder(s) is selected in 10.1, question 10.2 will appear:

10.2 ***New Study funder(s) (select all that apply):

☐ Industry-Sponsored

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

☐ External Grant (Tri-Council (e.g., CIHR, SSHRC, NSERC, , government, charitable foundation, etc.)

☐ Other

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

If 'Addition of new funder(s)' is selected in 10.1, question 10.3 will appear:
10.3 *What is the status of funding from this new source?

☐ Obtained ☐ Awarded but not received

If 'Awarded but not received' is selected
*Will you be able to proceed with the study? **<Multi-Line Text Box>**

If 'Change in previous funder(s)' is selected in 10.1, question 10.4-10.5 will appear:
10.4 ***Describe all changes in study funder(s): **<Multi-Line Text Box>**

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

If 'Addition of New funder or Change in previosu funder is selected in 10.1, questions 10.6will appear:
10.6 *Are there any research funds held in an account at Western or Lawson?

☐ Lawson ☐ Western ☐ 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:
Name:
Email:
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 'Change to participant compensation/reimbursement' is selected in 10.1, questions 10.7-10.8 will appear:
10.7 ***Describe all changes in participant compensation/reimbursement (if applicable): **<Multi-Line Text Box>**

10.8 ***Provide a rationale for the change(s) to participant compensation/reimbursement. 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>**

If 'Change in provision of or access to agent(s)/devices used in the study' is selected in 10.1, questions 10.7-10.8 will appear:
10.9 ***Describe all changes in provision/access: **<Multi-Line Text Box>**

10.10 *Provide a rationale for the change(s) in provision of or access. 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>**

If 'Change in financial incentive(s)/pressure(s)' is selected in 10.1, question 10.9 will appear:

10.11 *Are there any financial incentives or financial pressures associated with the study (e.g., recruitment incentives, higher payments per completed visit, or payments for procedures that exceed the standard amount) that might compromise or influence the conduct of the study?

☐Yes ☐No

If 'Yes': ***Describe the management plan: **<Multi-Line Text Box>

If 'No': ***Describe the changes in financial incentive(s)/pressure(s): **<Multi-Line Text Box>

If 'Other' is selected in 10.1, question 10.10 will appear:

10.12 *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>**

Section 11 - Change/Updates Relating To The Communication Of Results

If 'Change/updates relating to the communication of results' is selected in question 1.3, this section will appear:

11.1 *This change/update relates to communication of results to (select all that apply):

☐Stakeholders

☐Participants

11.2 *Describe the change/update relating to the communication of results: **<Multi-Line Text Box>**

11.3 *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>**

If 'participants' is selected in 11.1, question 11.4-11.5 will appear:

11.4 *Which of the following communications plans are being changed (select all that apply):

☐Debriefing script

☐Group debriefing

☐End of study letter

☐Publication

☐Other

If 'Other is selected in 11.4

*Specify other: **<Multi-Line Text Box>**

If 'Debriefing Script' is selected in 11.4

*Upload "clean" version(s) of the debriefing script

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

*Upload "Tracked Changes" version(s) of the debriefing script

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

If 'Group debriefing' is selected in 11.4

*Upload "clean" version(s) of the group debriefing

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

*Upload "Tracked Changes" version(s) of the group debriefing

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

If 'End of study letter' is selected in 11.4

*Upload "clean" version(s) of the end of study letter

Upload Document (Document Name, Document Date, Version) – Document Type: End of Study Letter

*Upload "Tracked Changes" version(s) of the end of study letter

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

Section 12 – Change In Clinical Trial Registry Information

If 'change in clinical trial registry information' is selected in question 1.3, this section will appear:

12.1 *Describe the change in registry information (including new registration number if applicable): **<Multi-Line Text Box>**

Section 13 – Change In Regulatory Information

If 'change in regulatory information' is selected in question 1.3, this section will appear:

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

☐Change in the US FDA application status

☐Change in support from US Federal Government.

☐Other change relating to US regulatory information

☐Change in the Health Canada application status

If 'Change in the US FDA application status' is selected in question 1.3, question 13.2 appears:

PLEASE NOTE: the question below either (1) is currently blank or the question does not appear because this study was originally submitted and approved in ROMEO OR

(2) reflects 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)

13.2 *Has this study been submitted to the US Food and Drug Administration (FDA) under an Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application?

☐Yes ☐No ☐N/A

13.2b *Describe the change in US FDA application status. **<Multi-Line Text Box>**

If 'Change in support from United States Federal Government' is selected, question 13.3 appears:

PLEASE NOTE: the question below either (1) is currently blank or the question does not appear because this study was originally submitted and approved in ROMEO OR (2) reflects 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)

13.3 *Is this research supported by the United States federal government ((including a study funded by a US governmental agency)?

☐Yes ☐No

13.3b *Describe the change in support from the United States federal government. **<Multi-Line Text Box>**

If 'Other change relating to US regulatory information' is selected, question 13.4 appears:

13.4 *Describe the other type of change relating to US regulatory information: **<Multi-Line Text Box>**

If 'Change in the Health Canada application status' is selected in 13.1, question 13.5a,b appears:

13.5a *Do these changes require authorization from Health Canada?

☐Yes, a No Objection Letter (NOL)/Notice of Authorization (NOA)/revised Investigational Testing Authorization (ITA) will be issued

☐Notification to Health Canada only

☐No

If 'Yes, a No Objection Letter/Notice of Authorization/revised Investigational Testing Authorization', question 13.5c will appear:

13.5b *Has Health Canada authorization been received?

☐Yes

☐Pending

**If 'Yes': ***Upload Health Canada authorization letter:

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

Section 14 – Change In Name/Contact Information Or Study Information

If 'Change in name/contact information (e.g., for the PI, Co-I, Sponsor, or Coordinating or Contract Research Organization) or change in study information (e.g., study title, study acronym/nickname/short name, sponsor's study ID)' is selected in question 1.2, the following section appears:

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

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

- ☐ Addition/Removal of Principal Investigator (Update Question 1.5)
- ☐ Change to acting Principal Investigator's contact information (Update Question 1.5)
- ☐ Addition/Removal of Co-Investigator (Update Question 1.6)
- ☐ Change to other study team members contact information (Update Question 1.6)
- ☐Study Title (Update Question 1.7)
- ☐Study acronym/nickname/short title (Update Question 1.8)
- ☐Main Sponsor Contact (Update Question 1.9)
- ☐Sponsor's Study ID/Number (Update Question 1.9)
- ☐Main Coordinating or Contract Research Organization Contact (Update Question 1.10)
- ☐Change to data collected (1.11)

Section 15 – 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 1.2, then the following question appears:

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

15.2 Upload any relevant documents:

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

Section 16 - Other

If 'Other' is selected in question 1.2, the following section appears:

16.1 ***Describe the 'other' changes made with this amendment: **<Multi-Line Text Box>**

16.2 ***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>**

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

Please note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., debriefing script, date). Avoid using slang, student names, etc.

16.4 Upload any associated documents that have not been uploaded elsewhere (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Other Materials

Section 17.0 – Conflict of Interest (actual, apparent, perceived, or potential)

If 'Updates to Conflict of Interest (actual, apparent, perceived, or potential) attestation' is selected in question 1.4, the following section appears:

17.1 ***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': ***State how much money (in Canadian dollars) is paid by the funder and to whom it is being paid, over and above the direct cost of conducting this study (e.g., recruitment incentives consulting fees, advisor fees): **<Multi-Line Text Box>

If 'Yes': ***Explain what this amount covers with respect to the direct costs associated with doing this research: **<Multi-Line Text Box>

If 'Yes': ***In the last three years, how much money (in Canadian dollars) or other benefits has the investigator or sub-investigator or anyone connected to them through their interpersonal relationship including their family members, friends, or their former or current professional associates (or any company owned or managed by the investigator or sub investigator or anyone connected to them through their interpersonal relationships) received from the sponsor and/or funder? **<Multi-Line Text Box>

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>

17.2 ***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>

17.3 ***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: **<Multi-Line Text Box>

17.4 ***Is the PI to 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>**

17.5 ***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>

17.6 ***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>**

17.7 ***Is this an Investigator-initiated study?

☐ Yes ☐ No

**If 'Yes': ***Are you or your institution the sponsor of this investigator-initiated/sponsored study?

☐ Yes ☐ No

If 'Yes': ***Describe any real, potential, or perceived conflict of interest: **<Multi-Line Text Box>

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

17.8 ***Are there any other real, potential or perceived conflict of interest to declare 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 18 – Resubmission Information

This section appears only if 'Response to REB recommendations' is selected in 1.1.

18.1 *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

18.2 Provide any additional comments for the REB to consider (if applicable):

<Multi-Line Text Box>

Section 19 - Confirmation of Responsibility

If "Initial Submission" is selected in Question 1.1, then question 18.1 appears:

19.1 ***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 the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);

- 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 health information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations, and the Tri-Council Policy Statement.

If "Response to REB recommendations" is selected in Question 11.1, then question 18.2 appears:

19.2 ***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;
    - 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.

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 PHI/PI is maintained in accordance with the Personal Health Information Protection Act (PHIPA) and Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.

If 14.1 "add removal/removal of Principal Investigator (Update Question 1.5)" is selected 18.3 appears

19.3 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