

## HS/NMREB Continuing Ethics Review (CER) 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 1.0 - GENERAL INFORMATION

1.1 \*If this is the first time you are submitting this particular CER 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 CER Submission

☐ Response to REB Recommendations

**#HELP TEXT: If this is the FIRST TIME this Continuing Ethics Review application is being submitted, please select "Initial Submission". If this is a Continuing Ethics Review re-submission please select "Response to REB recommendations".**

← Note, the below information is the lay/non-scientific summary that was provided in the initial application. You cannot change the information in this question. It is here to aid the REB review. If the fields below are missing information you are still able to submit this form without this information.

1.2 **HS\***Provide a brief lay/non-scientific summary of the study (max 250 words)

**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>**

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

The questions below reflect the information that has previously been provided to the REB. If changes are required, please update this information by completing and submitting an amendment form.

← 1.3 \* Use the Search field to enter the Principal Investigator (PI) details from the WREM user directory:  
    \*Prefix:  
    \*First Name:  
    \*Last Name:

- \*Address:
- \*City:
- \*Province:
- \*Postcode:
- \*Telephone:
- \*Email:

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

1.5 \*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>

1.6 \*

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 “Yes this study involves the London Hospitals and this form has been exported from ReDA”

\*What is the Lawson ReDA number associated with this study?

If “Yes this study involves the London Hospitals and this form has been exported from ReDA”

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

Email

If “No this study does not involve the London hospitals”

\*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 NM INITIAL FORM**

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

Name

Email

**1.7 \* SHARED FROM BOTH HS AND NM FORMS this question will appear twice in the form but only filled out in one depending on whether its HS or NM**

\*Is this research study supported/funded by the United States federal government or regulated by the FDA (Food and Drug Administration)?

☐ Yes ☐ No

**HELP TEXT: If your research study is supported by, conducted in collaboration with or is funded by an a United States government agency that is subject to the Common Rule or that is subject to the Food and Drug Administration (FDA) review and approval you must indicate "YES".**

**Through federal regulations, the U.S. government has established a system of protections for research participants. Eighteen federal agencies and departments adhere to the Federal Policy for the Protection of Human Subjects, or the Common Rule (45 CFR 46), which is a set of identical regulations codified by each agency.**

**SHARED FROM HS Initial Application form (1.8)**

1.8 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

## SECTION 2.0 - STUDY STATUS

2.1 \*What type of REB submission was this study initially reviewed, and approved, as?

**NOTE:** Refer to the Initial REB Application or Initial Approval Letter (see History tab).

- ☐ HSREB Full Board
- ☐ HSREB Delegated Level 2-Prospective data collection
- ☐ HSREB Delegated Level 1 –Retrospective study data and/or biological sample collection
- ☐ NMREB Full Board
- ☐ NMREB Delegated

2.2 \*Is the enrolment of new participants currently on hold, or temporarily suspended?

- ☐ Yes
- ☐ No

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

2.3 \*Provide a brief summary of the progress of the study to date and any other relevant information to support the review of the CER application: <Multi-Line Text Box>

2.4 \*Is there any new information from literature, or other recent studies, that would change the rationale or risk:benefit ratio for this study?

- ☐ Yes
- ☐ No

**If 'Yes':** \*Describe: <Multi Line Text Box>

2.5 \*Have any Unanticipated Problems occurred since initial REB approval was issued?

- ☐ Yes
- ☐ No

**If 'Yes':** \*Describe the Problem(s), the action(s) taken in response to the problem(s), and any resulting changes to procedures to prevent such problems: <Single Line Text Box>

2.6 \*Have there been any changes to the Conflict of Interest information disclosed to Western University's NMREB/HSREB, to date?

☐ Yes

☐ No

**If 'Yes':** \*Describe: <Multi Line Text Box>

2.7 \*Has this study expired (i.e., you are submitting this Continuing Ethics Review application form after the expiry date)?

☐ Yes

☐ No

2.7a \*Provide an explanation as to why the study lapsed in REB approval. Why was the Continuing Ethics Review form not submitted before the study expired? <Multi-Line Text Box>

2.7b \* Indicate what study activities (e.g., communication with participants, data analysis, manuscript preparation) have taken place since the study expired, and if any data has been collected since the study expired?: <Multi-Line Text Box>

2.7c \*Indicate if any data has been transferred outside of Western University (or its affiliated institutions) after the study expired: <Multi-Line Text Box>

2.7d \*Describe what procedure(s) are in place to prevent similar events from occurring in the future: <Multi-Line Text Box>

## SECTION 3.0 – PARTICIPANT INFORMATION

**If 'HSREB Full Board', or 'HSREB Delegated Level 2-Prospective data collection' is selected in 2.1, question 3.1-3.37 will appear:**

3.1 \*What is the current enrollment status (Select ALL that apply)?

☐ No Participants Enrolled to date

☐ Enrollment Ongoing

☐ Enrolment 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

☐ Other

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

3.2 \*Does this study include a NON-PATIENT population (see help text)?

☐ Yes

☐ No

**If “yes” to question 3.2, then 3.3-3.13 appear**

3.3 **If ‘Yes’:**\* How many non-patient participants have been approved to be included in this study by the HSREB? *NOTE: this number should be consistent with the number most recently approved in your protocol/research plan/REB application.* **<Number Box>**

**The Following Question is related to the conduct of the study for this review period:**

3.4 **If ‘Yes’ to question 3.2:** \* How many non-patient participants have been consented, **in the last year** (Since the last approved CER, if no enrollment, indicate 0)? **<Number Box>**

**The Following Questions are related to the overall conduct of this study to date:**

3.5 **If ‘Yes’ to question 3.2:** \* How many non-patient participants have been consented, **since initial approval was issued** (If no enrollment indicate 0)? *NOTE: The information provided in questions 3.6 – 3.12 (excluding 3.7) should add up to the number of participants indicated in this question.* **<Number Box>**

3.6 **If ‘Yes’ to question 3.2:** \* How many of these NON-PATIENT participants are **waiting to start study activities** after providing consent? **<Number Box>**

3.7 **If ‘Yes’ to question 3.2:**\* Are any of these non-patient consented participants individuals who are involved in the study but not directly receiving the treatment or intervention (for example, a caregiver(s), parent(s), or guardian(s))?

☐ Yes

☐ No

☐ N/A

**If ‘Yes’ to question 3.7:** \*How many? **<Number Box>**

3.8 **If ‘Yes’ to question 3.2:**\* Since initial approval was issued, how many non-patient participants were deemed ineligible after signing a consent/assent form (e.g., screen-failed)? **<Number Box>**

3.9 **If ‘yes’ to question 3.2:** \*Were any non-patient participants withdrawn , or withdrawn consent themselves, or are considered lost to follow-up since initial approval was issued?

☐ Yes ☐ No

**If ‘Yes’ to question 3.9:** \*How many? **<Number Box>**

**If ‘Yes’ to question 3.9:** \*Provide an explanation for those non-patient participants who were withdrawn , or withdrawn consent themselves, or are considered lost to follow-up since initial approval was issued:<Multi Line Text Box>

3.10 **If ‘Yes’ to question 3.2:** \*How many of these non-patient participants are actively engaged in study related activities/ intervention? <Number Box>

3.11 **If ‘Yes’ to question 3.2:**\*How many of these non-patient participants are currently in the post-intervention period (e.g. completed study activities but may still be involved in study follow-up, member checking and/or data collection)? <Number Box>

3.12 **If ‘Yes’ to question 3.2:**\*How many non-patient consented participants have completed all necessary study activities with no further planned contact and no further planned data collection for study purposes? <Number Box>

3.13 **If ‘Yes’ to question 3.2:**\* How many non-patient participants still remain to be included in this study? <Number Box>

3.14 \*Does this study include a PATIENT population?

☐ Yes

☐ No

**If “yes” to question 3.14, then 3.15-3.24 appear**

3.15 **If ‘Yes’ to question 3.14:**\* How many patient participants have been approved to be included in this study by the HSREB? NOTE: this number must be consistent with the number most recently approved in your protocol/research plan/ REB application<Number Box>

**The Following Question is related to the conduct of the study for this review period**

3.16 **If ‘Yes’ to question 3.14:** \* How many patient participants have been consented, **in the last year** (since the last approved CER, if no enrollment indicate 0)? <Number Box>

3.17 **The Following Questions are related to the overall conduct of this study to date:****If ‘Yes’ to question 3.14:**\* How many patient participants have been consented, **since initial approval was issued** (If no enrollment indicate 0)? *NOTE: the information provided in questions 3.18 – 3.23 should add up to the number of participants indicated in this question.* <Number Box>

3.18 **If ‘Yes’ to question 3.14:**\*How many of these patient participants are **waiting to start study activities** after providing consent?<Number Box>

- 3.19 **If 'Yes' to question 3.14:** \*How many of these patient participants are screen-failed, since initial approval was issued (i.e. consented and then were found to be ineligible)? **<Number Box>**
- 3.20 **If 'Yes' to question 3.14:** How many of these patient participants have been withdrawn, or withdrawn consent themselves, or are considered lost to follow-up since initial approval was issued? **<Number Box>**
- 3.21 **If 'Yes' to question 3.14:** \*How many of these patient participants are actively engaged in study related activities/ intervention?? **<Number Box>**
- 3.22 **If 'Yes' to question 3.14:** \*How many of these patient participants are currently in the post-intervention period (e.g. have completed study intervention but may still be involved in study follow-up, member checking, or will continue to passively supply data for study)? **<Number Box>**
- 3.23 **If 'Yes' to question 3.14:** \*How many consented patient participants have completed all necessary study activities with no further planned contact and no further planned data collection for study purposes? **<Number Box>**
- 3.24 **If 'Yes' to question 3.14:** \*How many patient participants still remain to be included in this study? **<Number Box>**
- 3.25 If this study involves the use of radiation above the standard of care, have any safety related events occurred?
- ☐ Yes
- ☐ No
- ☐ N/A

**If 'Yes' to question 3.25:** \*Describe the Problem(s), the action(s) taken in response to the problem(s), and any resulting changes to procedures to prevent such problems: **<Multi Line Text Box>**

- 3.26 \*Does this study include Secondary use of Retrospective data (Records/Charts, Participant DATA from an existing database or registry, or Biological Specimens)?
- ☐ Yes
- ☐ No

**HELP TEXT: Retrospective data/sample collection within a prospective study. This includes:**

- Participant/patient data or samples already collected prior to the initial submission of the REB application, AND
- A waiver of consent to collect this information has been obtained

**NOTE: the conduct of a prospective study, while also accessing previously collected or retrospective medical records/data or samples as source or for pre-screening does NOT need to be included here.**

3.27 **If 'Yes' to question 3.26:** \*Does this study include collecting (Select all that apply):

- ☐ Records/Charts
- ☐ Participant data from an existing database or registry
- ☐ Biological Specimens

3.28 **If 'Yes' to question 3.26:** \*What is the current enrolment status?

- ☐ Study not yet started
- ☐ Data/Biological Specimen Collection Ongoing
- ☐ Data/ Biological Specimen Analysis or Transfer Ongoing
- ☐ Data/ Biological Specimen or Transfer Complete
- ☐ Preparing Publication
- ☐ Other

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

**If yes to 'Records/Charts' is selected in Q3.27, question 3.29-3.31 appears**

3.29 \*What was the total number of Records/Charts approved by the HSREB?  
<Number Box>

3.30 \* How many Records/Charts were included in this study, since initial approval was issued? <Number Box>

3.31 If the number of Records/Charts collected exceeds the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of data/specimens above and beyond the approved total: <Multi-Line Text Box>

**HELP TEXT: If it is appropriate, an amendment and/or protocol deviation may be required.**

**If yes to 'Participant data from an existing database or registry' is selected in question 3.27 14 questions 3.32-3.34- appears**

3.32 \*How many participants DATA from an existing database or registry was approved by the HSREB? <Number Box>

3.33 \*How many participants DATA from an existing database or registry were included in this study, since initial approval was issued? <Number Box>

- 3.34 If more Participants data were included than the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of data/specimens above and beyond the approved total: **<Multi-Line Text Box>**  
**HELP TEXT: Note: An amendment and/or protocol deviation may be required prior to approval of this CER.**

**If yes to ‘Biological Specimens’ is selected in question 3.27, question 3.35-3.37 appears**

- 3.35 \*What was the total number of biological specimens approved by the HSREB?  
**<Number Box>**
- 3.36 \*How many biological specimens were included in this study, since initial approval was issued? **<Number Box>**
- 3.37 If the number of biological specimens collected exceeds the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of the specimens above and beyond the approved total: **<Multi-Line Text Box>**  
**HELP TEXT: If it is appropriate, an amendment and/or protocol deviation may be required.**

**If ‘Delegated Level 1-Retrospective study data and/or biological sample collection’, is selected in 2.1, question 3.38-3.39- will appear:**

- 3.38 \*Does this study include collecting (Select all that apply):  
☐ Records/Charts  
☐ Participant data from an existing database or registry  
☐ Biological Specimens
- 3.39 \*Was this study approved with a waiver of consent (i.e., no consent was required)? (Select Yes and No if applicable)  
☐ Yes  
☐ No

**If “No” to question 3.39, then 3.40-3.45 appear**

- 3.40 \*How many participant charts/records have been approved to be included in this study by the HSREB? NOTE: this number must be consistent with the number most recently approved in your protocol/research plan/ REB application **<Number Box>**

- 3.41 \*How many participants have been consented, **in the last year** (since the last approved CER, if no enrollment indicate 0)? **<Number Box>**
- 3.42 \* How many participants have been consented, **since initial approval was issued** (If no enrollment indicate 0)? **<Number Box>**
- 3.43 \*How many of these participants are screen-failed, since initial approval was issued (i.e. consented and then were found to be ineligible after reviewing their chart/records)? **<Number Box>**
- 3.44 \*How many of these participants have been withdrawn, or withdrawn consent themselves? **<Number Box>**
- 3.45 \*How many participants still remain to be approached to include their information in this study? **<Number Box>**
- 3.46 \*What is the current enrolment status?
- ☐ Study not yet started
  - ☐ Data/Biological Specimen Collection Ongoing
  - ☐ Data/ Biological Specimen Analysis or Transfer Ongoing
  - ☐ Data/ Biological Specimen or Transfer Complete
  - ☐ Preparing Publication
  - ☐ Other
- If 'Other':** \*Specify other: **<Multi Line Text Box>**

**If yes to 'Records/Charts' is selected in Q3.38, question 3.47-3.49 appears**

- 3.47 \*What was the total number of Records/Charts approved by the HSREB?  
**<Number Box>**
- 3.48 \*How many Records/Charts were included in this study, since initial approval was issued? **<Number Box>**
- 3.49 \*If the number of Records/Charts collected exceeds the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of data above and beyond the approved total: **<Multi-Line Text Box>**  
**HELP TEXT: If it is appropriate, an amendment and/or protocol deviation may be required.**

**If yes to 'Participant data from an existing database or registry' is selected in question 3.38  
14 questions 3.50-3.52- appears**

- 3.50 \*How many participants DATA from an existing database or registry was approved by the HSREB? **<Number Box>**
- 3.51 \*How many participants DATA from an existing database or registry were included in this study, since initial approval was issued? **<Number Box>**
- 3.52 \*If more Participants data were included than the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of data above and beyond the approved total: **<Multi-Line Text Box>**  
**HELP TEXT: If it is appropriate, an amendment and/or protocol deviation may be required.**

**If yes to 'Biological Specimens' is selected in question 3.38, question 3.53-3.55 appears**

- 3.53 \*What was the total number of biological specimens approved by the HSREB? **<Number Box>**
- 3.54 \*How many biological specimens were included in this study, since initial approval was issued? **<Number Box>**
- 3.55 \*If the number of biological specimens collected exceeds the number approved by the HSREB, explain why an amendment and/or protocol deviation was not submitted to address the inclusion of the specimens above and beyond the approved total: **<Multi-Line Text Box>**  
**HELP TEXT: If it is appropriate, an amendment and/or protocol deviation may be required.**

**If 'NMREB 'Full Board', or 'NMREB Delegated', is selected in 2.1 question 3.56-3.57 will appear:**

- 3.56 \*What is the current enrollment status (Select ALL that apply)?

- ☐ No Participants Enrolled 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 and/or Transfer Ongoing
- ☐ Data Analysis and/or Transfer Complete

☐ Preparing Publication

☐ Other

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

3.57 \*Was this study approved with a waiver of consent (i.e., no consent was required)?  
(Select Yes and No if applicable)

☐ Yes

☐ No

**If No in 3.57 - 3.58-3.63 appear:**

3.58 \*How many participants have been consented since initial approval was issued? If there are more than one participant group, indicate the different groups and the number for each group.

NOTE: the information provided in questions 3.59 – 3.63 should add up to the number of participants indicated in this question. < Multi Line Text Box>

3.59 \*How many consented participants are currently engaged in this study (eg. Study activities, follow-up, member checking, or other contact for research purposes, etc.)?  
? <Number Box>

3.60 \*Have any consented participants been withdrawn, or withdrawn consent themselves, or been lost to follow up since initial approval was issued?

☐ Yes

☐ No

**If 'Yes':** \*How many? <Number Box>

**If 'Yes':** \*Provide an explanation: <Multi Line Text Box>

3.61 \*How many of these patient participants are screen-failed, since initial approval was issued (i.e. consented and then were found to be ineligible)? <Number Box>

3.62 \*How many participants consented to study activities but have yet to begin any study activities? <Number Box>

3.63 \*How many consented participants have completed all aspects of the study with no further planned contact for the current study purposes?

Note: Planned contact includes sending results to participants. <Number Box>

**If Yes to 3.57 - question 3.64 appears:**

3.64 \* How many participants/cases were included in this research? (e.g., total number of cases in the secondary dataset; total number of participants enrolled as per the REB approved waiver of consent) <Number Box>

If “Initial Submission” or “Response to REB Recommendations” is selected in 1.1, question 3.65 will appear:

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

## SECTION 4.0 – RE-SUBMISSION INFORMATION

If “Response to REB recommendations” is selected in Question 1.1, then question 4.1 appears:

4.1 \*Upload the Response Letter, listing all REB recommendations/questions/comments and an explicit response to each:

## SECTION 5.0 - CONFIRMATION OF RESPONSIBILITY

If “Initial Submission” is selected in Question 1.1, then question 5.1 appears:

5.1 \*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 modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), etc.
- As the PI, I acknowledge that I am responsible for promptly reporting to the REB progress report (renewal/ continuing review form), annually or as often as requested by the REB
- As the PI, I acknowledge that I am responsible for promptly reporting to the REB when the study completed or terminated (e.g., End of Study)
- 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 1.1, then question 5.2 appears:**

#### **5.1 \*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 the provisions of the Personal Health Information Protection Act (PHIPA) and/or the Freedom of Information Protection of Privacy Act (FIPPA), and its applicable Regulations; AND with all other applicable laws, regulations or guidelines;
- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that this application contains the current and complete protocol, including, if applicable, any sub-studies;
- I acknowledge that I am responsible for promptly reporting any of the following to the REB:
  - - modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), specific required changes to the Letter of Information/consent form, etc.;
    - all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the study;
    - progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - completion or termination (e.g., End of Study Form);
  - I certify that REB approval and all external and local institutional approvals will be obtained before the study will commence;
  - I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;

- I certify that all information provided in this application represents an accurate description of the conduct of the study.

**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.