HS/NMREB Study Closure 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 Provincial Initial Application)

SECTION 1.0 - GENERAL INFORMATION

1.1 *

If this is the first time you are submitting this particular Study Closure 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 Study Closure application is being submitted, please select "Initial Submission". If this is a re-submission for modifications requested by the REB please select "Resubmission".

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.

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)
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>**

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 Application has not been completed.

NOTE: You cannot submit this application until the ReDA Application 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 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 regulated by the FDA or supported by the United States federal government (including a study funded by a US government agency)?

☐Yes

☐No

SHARED from HS Initial Application (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 INFORMATION

2.1 *I confirm that there will be no further:

- Participant contact or involvement
- Data collection, data transfer, or data sharing
- Secondary analyses for a new purpose (outside of what has been explicitly stated in the approved research protocol/REB application), unless new REB approval or exemption is sought.

☐ I Confirm

2.2 *What type of REB submission was this study initially reviewed as?

☐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

2.3 *Date that the study was completed or terminated: **<Date Field>**

2.4 *Was this study terminated prematurely?

☐Yes
☐No

If 'Yes': *Provide the reason(s) (Select all that apply):

☐ Funding issues
☐ Recruitment issues
☐ Safety issues
☐ Terminated by the PI
☐ Terminated by study sponsor
☐ Other

If 'Funding Issues': *Describe the funding issues: <Multi-Line Text Box>
If 'Recruitment Issues': *Describe the recruitment issues: <Multi-Line Text Box>
If 'Safety Issues': *Describe the safety issues: <Multi-Line Text Box>
If 'Terminated by centre PI': *Explain why the study was terminated by the PI: <Multi-Line Text Box>
If 'Terminated by study sponsor': *Explain why the study was terminated by the study sponsor: <Multi-Line Text Box>
If 'Other': *Describe "Other" reason(s) for premature study termination: <Multi-Line Text Box>

2.5 *Summarize the progress of the study overall:**<Multi-Line Text Box>**

2.6 Upload any documents relevant to the study closure (e.g., sponsor correspondence, newsletter):
Upload Document (Document Name, Document Date, Version) – Document Type: Sponsor Correspondence/Newsletter

2.7 *Have any results from this research been published, submitted for publication or presented at a meeting or seminar?
☐Yes
☐No
If 'Yes': ***Specify: **<Multi-Line Text Box>
If 'Yes': Upload any abstracts, presentations or publications (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Abstracts/Presentations/Publications

2.8 *Where there any reportable events during the conduct of the study?
☐Yes
☐No

If 'YES':
Have all reportable events been submitted for REB review?
☐Yes
☐No
If 'No': * Describe: **<Multi-Line Text Box>**

2.9 ***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>

2.10 ***Has this study expired (i.e., you are submitting this Study Closure application form after the expiry date)?
☐Yes this study has expired
☐No this study has not expired

2.10*Provide an explanation as to why the study lapsed in REB approval. Why was the Study Closure form not submitted before the study expired? **<Multi-Line Text Box>**

2.10b * 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>**

2.10c *Indicate if any data has been transferred outside of Western University (or its affiliated institutions) after the study expired: **<Multi-Line Text Box>**

2.10d *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 Q2.1, question 3.1 will appear:

3.1 ***Did your study involve the recruitment of any of the following?

☐ NON-PATIENT participants

☐ PATIENT participants

HELP TEXT:

Examples of a non-patient participant can include:

- caregivers/study partner
- employees
- students
- Healthy Volunteers

Non-patient participants may have a health problem(s) but they are not actively seen AND recruited from the hospital/clinic (e.g., individuals with hearing impairment that are not being seen in clinic for their hearing impairment and not being recruited from the hospital/clinic)

A patient participant is considered those that are actively seen in the hospital/clinic and recruited from the hospital/clinic

If 'Non-Patient Group' is selected in question 3.1, question 3.2-3.7 will appear:

3.2 ***How many NON-PATIENT participants were consented? *NOTE: The information provided in questions 3.3 – 3.7 should add up to the number of participants indicated in this question.***<Number Box>**

3. 3 *How many NON-PATIENT participants were deemed **ineligible** (i.e., did not meet eligibility requirement) after consent was obtained? **<Number Box>**

3.4 ***Have any NON-PATIENT participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study)?

☐ Yes

☐ No
If 'Yes': *How many NON-PATIENT participants withdrew consent? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Text box>**

3.5 *How many NON-PATIENT participants consented and began study intervention but did not complete ALL study activities (e.g., were sent a series of surveys but only responded to some, lost to follow-up, etc.)? **<Number Box>**

3.6 *Were any NON-PATIENT participants taken off the study prematurely (for example, by a local investigator or sponsor)?
☐ Yes
☐ No
If 'Yes': *How many NON-PATIENT participants were taken off-study prematurely? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Multi-Line Text Box>**

3.7 ***How many NON-PATIENT participants have completed all aspects of the study? **<Number Box>**

If 'Patient participants' is selected in question 3.1, question 3.8-3.13 will appear:

3.8 ***How many PATIENT participants were consented? *NOTE: The information provided in questions 3.9 – 3.13 should add up to the number of participants indicated in this question.* **<Number Box>**

3.9 ***How many PATIENT participants were deemed **ineligible** (i.e., did not meet eligibility requirement) after consent was obtained? **<Number Box>**

3.10 ***Have any PATIENT participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study)?
☐ Yes
☐ No
If 'Yes': *How many PATIENT participants withdrew consent? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Number Box>**

3.11 ***Were any PATIENT participants taken off the study prematurely (for example, by a local investigator or sponsor)?
☐ Yes
☐ No
If 'Yes': *How many PATIENT participants were taken off-study prematurely? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Multi-Line Text Box>**

3.12 *How many PATIENT participants consented and began study intervention but did not complete ALL study activities (e.g., were sent a series of surveys but only responded to some, lost to follow-up)? **<Number Box>**

3.13 ***How many consented PATIENT participants completed all aspects of the study? **<Number Box>**

If 'Delegated Level 1-Retrospective study data and/or biological sample collection' is selected in Q2.1 question 3.14-will appear:

3.14 ***Did this study include collecting (Select all that apply):
☐ Records/Charts
☐ Participant data from an existing database or registry
☐ Biological Specimens

If yes to 'Records/Charts' is selected in Q3.14, question 3.15-3.17 appears
3.15 ***What was the total number of Records/Charts approved by the HSREB? **<Number Box>**

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

3.17 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 3.14 questions 3.18-3.20- appears
3.18***How many participants DATA from an existing database or registry was approved by the HSREB?**<Number Box>**

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

3.20 If the 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 3.14, question 3.21-3.23 appears
3.21 ***What was the total number of biological specimens approved by the HSREB? **<Number Box>**

3.22 *How many biological specimens were included in this study, since initial approval was issued? **<Number Box>**

3.23 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 Q2.1, question 3.24-3.29 will appear:

3.24 *How many participants had been consented? **<Number Box>**

3.25 *How many participants were deemed **ineligible** (i.e., did not meet eligibility requirement) after consent was obtained? **<Number Box>**

3.26 *How many participants consented and began study activities but did not ALL complete study activities (e.g., were sent a survey but never responded, lost to follow-up, etc.)? **<Number Box>**

3.27 *Have any participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study)?

☐ Yes
☐ No
If 'Yes': *How many patient participants withdrew consent? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Multi-Line Text Box>**

3.28 *Were any participants taken off the study prematurely (for example, by a local investigator or sponsor)?

☐ Yes
☐ No
If 'Yes': *How many patient participants were taken off-study prematurely? **<Number Box>**
If 'Yes': *Provide details for each participant: **<Single-Line Text Box>**

3.29 *How many participants have completed all aspects of the study? (Note: If the researchers plan (and are approved) to send results to participants, then the study must remain active).
<Number Box>

SECTION 4.0 - RE-SUBMISSION INFORMATION

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

4.1 *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**

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

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:

5.2 ***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 confirm that all contact or interaction with participants have ended, and no data transfer/sharing will occur.
- I confirm that no further secondary analyses for a new purpose outside of what has been explicitly stated in the research protocol will occur unless new ethics approval or exemption is sought.
- 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.