Health Sciences Research Ethics Board Application Form

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

Section 1 - General Information

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

☐ Initial Submission
☐ Response to REB recommendations

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

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

#HELP TEXT:

If this study is taking place at the hospital OR involves criteria for Lawson Health Research Institute oversight (see below) you will need to indicate "Yes" as your answer

Criteria for Lawson Health Research Institute Approval:

- **The PI or a member of the research team will rely on their hospital professional staff credentials to conduct the research.**
- **Your study uses any resources (e.g. funding, data, facilities, computers/servers, services, space), hospital staff or patients, biological specimens, or data from any of the sites affiliated with London Health Sciences Centre and St. Joseph's Healthcare London.**
- **Investigators and/or study staff participate from the sites listed below.**

London Health Sciences Centre

- Adult Eating Disorder Service (Riverview)
- Byron Family Medical Centre
- Children's Hospital
- Fowler Kennedy Sports Medicine

St. Joseph's Health Care London

- St. Joseph's Hospital
- Parkwood Institute – Main Building
- Parkwood Institute - Mental Health Care

- Kidney Care Centre (Westmount)
- London Regional Cancer Program (LRCP)
- Southwestern Ontario Regional Base Hospital Program
- Stroke Prevention & Atherosclerosis Research
- University Hospital (UH)
- Victoria Family Medical Centre
- Victoria Hospital (VH)
- Southwest Centre for Forensic Mental Health Care
- St. Joseph's Family Medical and Dental Centre
- Mount Hope Centre for Long Term Care

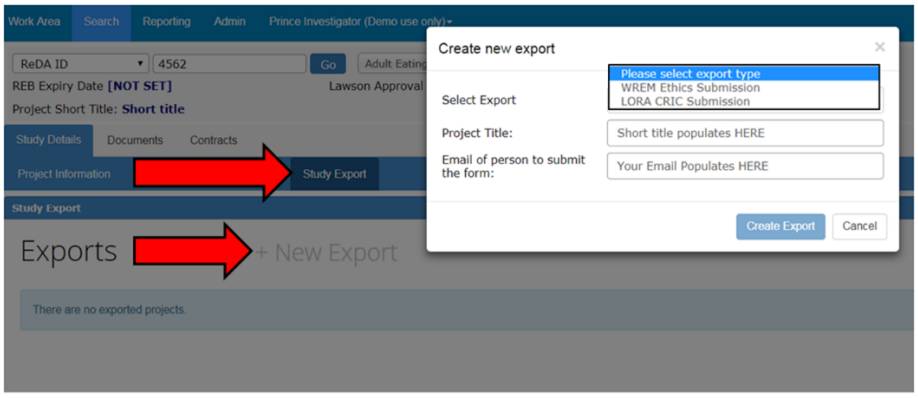
☐ No this study does not involve the London hospitals

☐ 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 "Box 3" is selected in Question 1.2, then the following appears

Please see instructions below on how to export from ReDA to WREM



NOTE: If this study involves the London hospitals (see help text) you must FIRST complete a ReDA application form in order to register your study with Lawson. If you have not first completed a ReDA application and exported from ReDA to WREM you will have to withdraw this application and FIRST fill out a ReDA application form.

If "Box 2" is selected in Question 1.2, then the following sub-questions appears

***What is the Lawson ReDA number associated with this study? <Single-Line Text Box>**

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

*Email:

If "Box 1" is selected in Question 1.2, then the following sub-questions appears

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

* Name:
*Email:

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

1.3 *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:

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

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

1.4 *Are there any additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or it's affiliate institutionsworking on this study**?**

☐ Yes there are additional study team members
☐ No other study team members involved

If "Yes" is selected in 1.4, then the following appears

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

Prefix:
*First Name:

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

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

1.4 *Specify ROLE, DUTIES, and DEPARTMENT/FACUTY in this study. (E.g. John Doe - Research Assistant - assisting with recruitment, interviews and analysis of data, Psychology/Social Sciences.) **<Multi-Line Text Box>**

1.4a*Are there any additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or it's affiliate institutions working on this study**?**

☐ Yes there are additional study team members

☐ No other study team members involved

If "Yes" is selected in 1.4, then the following appears

1.4a *Complete the following information for additional study team members (incl. students, postdocs, coordinators, managers, etc.) from Western and/or its affiliate institutions 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:

1.4a *Specify ROLE, DUTIES, and DEPARTMENT/FACULTY in this study. (E.g. John Doe - Research Assistant - responsible for recruitment, interviews and analysis of data, Psychology/Social Science.) **<Multi-Line Text Box>**

Etc. up to 1.4o

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

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

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.7 appears

1.7 *What type of REB application is this?

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

HELP TEXT: To qualify as retrospective, study data and/or biological samples must have been collected prior to your application.

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.8 appears

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

If "Box 1" or "Box 2" is selected in Question 1.2, Q1.9 appears

1.9 *Is this study directly related to a study at this institution (e.g., is this study an, extension, rollover, subsequent to a pilot study)?

- ☐ Yes – This study relates to a previously approved study at this institution
- ☐ Yes –This study relates to a study currently under Western's REB review, but has not yet been approved
- ☐ No - This study does not relate to a previous study at this institution

If Yes this study relates to a previously approved study…: *Who is the PI for the previous study? <Single-Line Text Box>

If Yes this study relates to a previously approved study…: *What is the HSREB number? <Single-Line Text Box>

If Yes this study relates to a previously approved study…: ***Indicate the study title of the previous study. Provide a brief summary of the previous study and indicate how it relates to this current study:<Multi-Line Text Box>**

If Yes this study relates to a study currently under review: ***Who was the PI for the study? **<Single-Line Text Box>
If Yes this study relates to a study currently under review: ***What is the HSREB number? **<Single-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.10 appears

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., protocol/research plan, 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.

1.10 ***Upload the protocol/research plan for this study: **Upload Document (Document Name, Document Date, Version) – Document Type: Protocol**

HELP TEXT:
A protocol/research plan is a document (e.g., sponsor protocol, working group protocol) that describes the objectives, design, methodology, statistical considerations and organization of a research project.

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

Ensure the version date and number indicated within the document is consistent with what is contained in the footer of the document.

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.11 appears

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

HELP TEXT: Investigator-initiated Study refers to a research effort in which the investigator designs and implements the study protocol and the investigator or the institution acts as the study sponsor.

☐ Yes ☐ No

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.12 appears

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
☐ External not-for-profit
☐ External PI (outside of Western)

☐ Local Team Member(Western-affiliated team member other than PI on this REB application)
☐ Local Principal Investigator (PI on this REB application)

If industry sponsored is selected in Question 1.12:
If applicable, enter the Sponsor's Study ID Number: **<Single-Line Text Box>**

If any checkbox other than 'Self" is selected in Question 1.12:
***Complete the Sponsor details:**
Title:
First Name:
Last Name:
***Organization:**
Address:
City:
Province/State:
Postcode/Zip:
***Telephone:**
***Email:**

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.13 appears

1.13 ***Is this a student project?**

☐ No
☐ Yes-Resident/Fellow
☐ Yes-MD
☐ Yes-Post-doctoral Fellow
☐ Yes-PhD
☐ Yes-Masters
☐ Yes-Undergraduate
☐ Yes-Other

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

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.14 appear

1.14 ***Has the study undergone a formal scientific or peer review (i.e., internal peer review or external review (e.g., CIHR, NSERC, NIH, etc))?**

☐ Yes ☐ No

If Yes: *Describe (e.g., names of committees or individuals involved in the review, whether review is in process or completed, etc.). If no scientific review or feedback was provided, please indicate as such. If there was feedback provided, you MUST upload it in the following field: <Multi-Line Text Box>

If Yes: Upload any relevant scientific review documents or correspondence. This must include reviewer feedback (if applicable):

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

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.15 appears

1.15 ***Has the study been reviewed and approved by another REB in Canada?

☐ Yes ☐ No ☐ Pending

If Yes: ***Upload the initial and most recent approval letter(s) and/or relevant correspondence. **Upload Document (Document Name, Document Date, Version) – Document Type: Other REB approval letter

If 'Pending': ***Indicate what REB(s) is reviewing the REB application: **<Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.16 appears

1.16 ***Has the study been rejected by any other REB?

☐ Yes ☐ No

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

If Yes: Upload any relevant documents (if applicable):

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

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.17 appears

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

HELP TEXT: If your research study is supported by, conducted in collaboration with or is funded by 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.

☐ Yes ☐ No

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.18 appears

1.18 ***Is this a multi-centre study?

☐ Yes ☐ No

If Yes: ***Name the lead site and project leader for the study: **<Multi-Line Text Box>

HELP TEXT: A multi-centre study is a study being conducted at different study sites by different study teams. All data generated from the study sites are entered into one database for analyses. In comparison, a single centre study is a study being conducted by one study team (that can include both internal and external study team members) and is conducted in one or multiple locations.

If "Yes" to 1.18, then 1.19 -1.20 appear

1.19 ***Has this study started elsewhere (provincially, nationally or internationally)?

☐ Yes ☐ No

If Yes: ***Enter the approximate date the study started: **<Multi-Line Text Box>

If Yes: ***Describe any known issues (e.g., safety or recruitment related): **<Multi-Line Text Box>

1.20 ***When is overall (global) enrolment expected to end?
<Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.21 appears

1.21 ***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>

If "Box 1" or "Box 2" is selected in Question 1.2, then the 1.22 appears:

1.22 ***Are there any associated sub-studies and/or companion studies?

☐ Yes ☐ No

If Yes: *Will your site be involved in the sub-studies and/or companion studies?

☐ Yes ☐ No

If Yes*Are the sub-studies and/or companion studies mandatory or optional?

☐ Mandatory ☐ Optional

If Yes* Briefly describe the sub-studies and/or companion studies including the rationale for it.: **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.22 appears

1.23 ***Indicate how the results will be communicated to participants and other stakeholders (e.g.; advocacy groups, scientific community).

To Participants:

☐ Publication(s)

☐ End of study letter

☐ Group debriefing

☐ Other

☐ No Plan

If 'Publication(s)': ***Describe publication plan: **<Multi-Line Text Box>

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

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

HELP TEXT: An End of Study Letter can be offered to participants who have completed the study. The End of Study Letter can remind participants of the objectives of the study and how study data will be used to meet them. An End of Study Letter can also provide participants with any relevant resources.

To Other Stakeholders:

☐ Presentation(s)

☐ Publication

☐ Other

☐ No plan
**If 'Presentation(s)': ***Describe presentation plan:
**If 'Publication': ***Describe publication plan:
If 'Other': ***Specify other: **<Multi-Line Text Box>
If 'No plan': ***Justify no plan: **<Multi-Line Text Box>

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., group debriefing script, 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 'Group debriefing' is selected in 1.22, question 1.25 will appear:
Upload the group debriefing (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Group Debriefing

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., End of study letter, 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 'End of study letter' is selected in 1.22, question 1.26 will appear:
Upload the end of study letter (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: End of Study Letter

If "Box 1" or "Box 2" is selected in Question 1.2, then 1.23 appears
1.24 ***Provide a brief LAY/non-scientific summary of the study (max 250 words). Succinctly describe why and how this research will be conducted.
<Multi-Line Text Box>
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.

Section 2 - Study Description

If "Delegated L1" is selected in Question 1.7, Question 2.1 will appear

2.1 ***Does this retrospective study include the collection of (select all that apply):
☐ Chart/Record collection
☐ Biological Specimens
☐ Registry data
☐ Existing research dataset
☐ Bioarchaeological Human Remains

☐ Other

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

If charts/record collection: *How many participant charts/records will be accessed? **<Multi-Line Text Box>**

If Biological Specimens: *How many biological specimens will be retrieved? **<Multi-Line Text Box>**

If Biological Specimens: *Where and/or from whom will the biological specimens being obtained from?

If 'registry' is selected then the following appears:

*Who maintains the registry? Click here to enter text.

*Has the custodian of the registry granted access/use for research purposes?

☐Yes ☐No

*Where is the registry located? **<Multi-Line Text Box>**

*In what format is the registry currently stored? **<Multi-Line Text Box>**

If 'existing research dataset' is selected in 2.1 then the following appears:

*Who maintains the dataset? **<Multi-Line Text Box>**

*Has the custodian of the dataset granted access/use for research purposes?

☐Yes ☐No

*Where is the existing research dataset located? **<Multi-Line Text Box>**

*In what format is the existing research dataset currently stored? **<Multi-Line Text Box>**

If "Biolarchaeological Human Remains" is selected in 2.1, the following appears

***What type of bioarchaeological specimens will be used for the purpose of this study? <Multi-Line Text Box**

***How will the bioarchaeological human remains be used in this study? Multi-Line Text Box>**

***From where, and how, will the study team be accessing the bioarcheological human remains? Multi-Line Text Box>**

***Has the use of these bioarchaeological human remains (for the purpose of this study) been reviewed/approved by any regulatory body (e.g., ministry, museum, institution, committee, etc. responsible for overseeing the use/protections of these biological materials)?

☐ Yes ☐ No

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

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

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

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

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

If 'other' is selected in 2.1 then the following appears:
*Describe other: **<Multi-Line Text Box>**

If "Chart/Record collection", "Biological Specimens", "Registry data", "Existing research dataset" is selected in Q2.1, 2.2 and 2.3 appear

2.2 *Provide the Retrospective start date for study data and/or biological sample collection. NOTE: To qualify as retrospective, study data and/or biological sample(s) must have been collected prior to your application. **<Multi-Line Text Box>**

2.3 *Provide the Retrospective end date for study data and/or biological sample collection. NOTE: To qualify as retrospective, study data and/or biological sample(s) must have been collected prior to your application. **<Multi-Line Text Box>**

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Question 2.4 appears:

2.4 ***Will you collect biological specimens in this study?**

☐ Yes ☐ No

2.5 ***What are the study hypotheses or research question(s) or purpose of this study?** **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then 2.6 appears

2.6 ***What is the rationale for this study (why is it being done)? In your response, ensure to include relevant background information from previous studies that have been done. Cite references where appropriate and add as a separate attachment (do not include within your response). **<Multi-Line Text Box>**

Upload any references used above (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: References

If "Box 1" or "Box 2" is selected in Question 1.2, then 2.7 appears

2.7 *a) Please select an option that BEST describes your study design:

☐Clinical trial
☐Pilot for a clinical trial
☐Qualitative
☐Mixed methods
☐Survey
☐Secondary analysis of existing dataset
☐Cohort (prospective or retrospective)
☐Cross-sectional
☐Case-control
☐Collaborative community-based research
☐Database, registry, or biobank
☐Other study design and/or methodology

If "Pilot for clinical Trial" is selected in 2.7a:

- Pilot studies should be designed with at least one of the following objectives which should be clearly defined: i) generate initial data for the primary outcome, to determine the sample size; ii) determine the feasibility of recruitment, consent, protocol adherence, or acceptability of the intervention to the participant or clinical area; iii) delineate logistic factors for appropriate oversight, eg. number of research personnel required; iv) pilot data collection forms; v) dose-finding; vi) test the randomization and allocation process; vii) determine the most appropriate outcome measures.
- Analyses of pilot studies should be mainly descriptive or focus on confidence interval estimation.

IF "Other study design and/or methodology" is selected in 2.7a:

*Provide other Study Design or Methodology: **<Single line text box>**

b) Provide a BRIEF summary of the overall study design type and methodology being employed in this study.
DO NOT include procedural details, information about objectives, inclusion/exclusion criteria, sample size calculations and data analysis here.
IF you have external collaborators, please list their name, affiliation, and role in the study**<Multi-Line Text Box>**
HELP TEXT:
Describe only the study type [the formulation of trials and experiments or other types of research (e.g., epidemiological) involving human beings.] and basic methods [i.e., name variables in the study such as data collection and measurement techniques] in this section AND find the corresponding sections for explicitly describe objectives, inclusion/exclusion criteria, study procedures, sample size calculations and data analysis elsewhere.

DO NOT include Information about objectives, inclusion/exclusion criteria, study procedures, sample size calculations and data analysis here.

If "Box 1" or "Box 2" is selected in Question 1.2, then the following appears:

Upload a flow diagram (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: Flow Diagram

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Questions 2.8- 2.13 appear

2.8 *Will this study include the following population(s): (select ALL that apply)

☐ Patients (see help text)
☐ People who are unable to consent
☐ Healthy Volunteers
☐ Caregivers/Study Partners
☐ Cognitively impaired individuals
☐ Students
☐ Adult individuals who are temporarily unable to provide consent (e.g. unconscious)
☐ Staff/Health Care providers
☐ Pregnant Women
☐ People with mental health issues
☐ Elderly people
☐ People who are institutionalized
☐ People with palliative disease
☐ Prisoners/persons in detention
☐ People in long-term care
☐ People in poverty
☐ Minors
☐ People in medical emergencies
☐ Bioarchaeological Human Remains
☐ Indigenous peoples, including First Nations, Inuit and Metis
☐ Other populations and/or distinct communities not listed

HELP TEXT:
Examples of a non-patient participant can include:

- **caregivers/study partner**
- **Employees/staff**
- **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 for this study)

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

HELP TEXT:
Research studies that have obtained or are looking to use the cadaveric material(s) through the Body Bequeathal program in the Department of Anatomy and Cell Biology, Schulich Medicine & Dentistry, Western University must be submitted for REB review to the Cadaveric Research Ethics Board (CREB) using the CREB application within WREM.
If Other: ***Specify other: **<Multi-Line Text Box>

If "Patient" is selected in 2.8, Q2.9-2.12 will appear

2.9 ***If a patient population is included, describe the procedures that are considered usual diagnostic, therapeutic "routine", or standard of care? (**Do NOT describe any STUDY specific activities here**.).**<Multi-Line Text Box>**
HELP TEXT:
Please consider prescribing patterns, visit frequency, practitioners seen and any other information relevant to contextualizing any interventions being proposed. This response should reflect what care participants would experience today outside of the research.

2.10 *** If a patient population is included, please **describe ALL of the procedures** that will be carried out in this study. Please note that all procedures, visits, data/tissue collection, study drug administration (if applicable), and protocol-specified activities must be summarized. **<Multi-Line Text Box>**

2.11 *** If a patient population is included, where are study assessments being conducted. Please consider all study procedures. (see help text)
#HELP TEXT: Note that Western/Robarts are considered off-site locations for hospital/Lawson based studies, and vice-versa. <Multi-Line Text Box>

2.12 ***Describe any additional time commitments patient participants are required to take as part of study procedures. **<Multi-Line Text Box>**

2.13 ***Will the participants be withdrawn from or denied usual therapy for any condition in order to participate in this study?
☐ Yes ☐ No ☐ N/A
If Yes: ***Explain and include the justification.<Multi-Line Text Box>**

2.14 ***Will management or treatment of the participant's condition be prolonged or delayed because of this research project?
☐ Yes ☐ No ☐ N/A
If Yes: ***Discuss the potential risks and benefits to the participants. **<Multi-Line Text Box>
If Yes: ***Describe how alternatives for future care are affected by participation in this study **<Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.15 appears:

2.15*Does this study include a non-patient group (e.g., caregiver, student, employee, etc.)- SEE HELP TEXT?

☐ Yes ☐ No

If 'Yes': * For all non-patient participants, please describe **ALL** study related procedures and any study specific testing that will be done (i.e., how are you doing it? What will participants experience?) . Ensure that if there are multiple groups you describe all study related procedures for each group: **<Multi-Line Text Box>**
HELP TEXT: Include details such as study locations, anticipated time commitments, use of audio/video-recording, if procedures are optional or mandatory, if/how your study procedures will evolve and why, etc.

If "Biolarcheological Human Remains" is selected in 2.8, Q2.16-Q2.19 will appear

2.16 *What type of bioarcheological specimens will be used for the purpose of this study? **<Multi-Line Text Box**

2.17. *How will the bioarcheological human remains be used in this study? **Multi-Line Text Box>**

2.18. *From where, and how, will the study team be accessing the bioarcheological human remains? **Multi-Line Text Box>**

2.19. *Has the use of these bioarchaeological human remains (for the purpose of this study) been reviewed/approved by any regulatory body (e.g., ministry, museum, institution, committee, etc. responsible for overseeing the use/protections of these biological materials)?

☐ Yes ☐ No

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

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

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

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

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

If 'Indigenous Peoples' selected from Q2.8 the Q2.20 appears:

2.20 *Which of the following criteria apply to this research (select ALL that apply)?

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

  If 'Other: *Please clearly describe how your research will be involving the Indigenous communities **<Multi-Line Text Box>**

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

2.21*Is this a collaborative community-based project?

HELP TEXT: Some examples of communities include but are not limited to: Indigenous, LGBTQ+, religious, ethnic, etc. Researchers have an ethical responsibility to the community during and after the research. Please refer to TCPS2 Chapter 9 for ethical principles in community engagement. (Note: These principles can be applied to all community-based research, not only in Indigenous contexts)

☐ Yes ☐ No

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

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

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

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

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

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

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

If 'Community-based': *Does the community have their own ethics or research approval process?

☐ Yes ☐ No

If 'yes':

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

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

Add another

If "Box 1" or "Box 2" is selected in Question 1.2, then 2.22 appears

2.22 *Indicate your 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)
- ☐ Case Report Form(s)
- ☐ Other (e.g., visual stimuli, participant diary, data collection forms, etc.)

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., paper survey, 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 'Paper Survey(s)/Questionnaire(s)': *Upload the paper Survey(s)/Questionnaire(s):

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

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., online survey, 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 'Online Survey(s)/Questionnaire(s)': *Upload the online Survey(s)/Questionnaire(s):

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

If 'Online Survey(s)/Questionnaire(s)': *Specify what survey platform is being used: **<Multi-Line Text Box>**

If 'Online Survey(s)/Questionnaire(s)': *Can all questions be skipped by the participant?

☐ Yes ☐ No

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

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

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

*Will the interview be audio-recorded?

☐ Yes ☐ No

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

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

If 'YES'*Is audio-recording during the interview optional or mandatory?

☐ Mandatory ☐ Optional

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

If 'Optional" *How will you accommodate participants who do not want to be audio-recorded during the interview?**<Multi-Line Text Box>**

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., focus group guide, 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 'Focus Group Guide(s)': *Upload Focus Group guide(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Focus Group(s) Guide

*Will the focus group interview be audio-recorded?

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

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

If 'YES'* Is audio-recording during the focus group optional or mandatory?
☐ Mandatory ☐ Optional

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

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

Note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., non-participant observation guide, 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 'Non-Participant Observation Guide(s)': *Upload Non-Participant Guide(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Non-Participant Observation Guide

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., participant observation guide, 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 'Participant Observation Guide(s)': *Upload Participant Observation guide(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Participant Observation Guide

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., visual stimuli, 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 'Case Report Form(s)': *Upload Case Report Form(s):
Upload Document (Document Name, Document Date, Version) – Document Type: Other Data Collection Instruments

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., visual stimuli, 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 'Other': *Upload "Other" instruments:
Upload Document (Document Name, Document Date, Version) – Document Type: Other Data Collection Instruments

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

If '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":* Of the study instruments being used, clarify which ones are not standardized instruments: **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.23 appears:

2.23 Will any technological tool(s)/platform(s)/software/device(s) be used throughout the project (e.g., for data collection, analysis, transfer, storage, etc.) that is beyond an institutional network, institutional MS Office 365, or hard drive?

☐ Yes ☐ No

If 'Yes': *Specify the tool(s)/platform(s)/software(s)/device(s) and the institution who hosts them as applicable (for example, Western Qualtrics, University of Alberta REDCap, Cryeos etc.): **<Multi-Line Text Box>**

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

- Technology Risk Assessment by Western's Technology Risk Assessment Committee (TRAC)? (Not applicable to Lawson-affiliated research)
- Authorized Technology and/or Privacy Review at LHSC or SJHC?

☐ Yes ☐ No ☐ Unsure

HELP TEXT: The HSREB occasionally relies on technology reviews by institutional offices to best advise around data security, privacy, and participant consent. Ultimately, these reviews are entirely separate from the REB approval process and reflect institutional requirements or guidance. Ethics approval may or may not be held pending these institutional reviews.

If 'Yes': Upload any relevant reports and/or other review/approval documentation or communications
(NO documentation is required for Lawson-hosted REDCap and WebEx or Western-hosted Qualtrics, Zoom, Office 365, and OWL):

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

If 'Yes' in 2.23 the following appears: *Specify what information/data will be collected through and/or entered into the tool(s)/platform(s)/software(s)/device(s) and for what purpose:
If personal identifiers will be entered/shared using the technology, please list them and ensure consistency with Q13.11
<Multi-Line Text Box>

If 'Yes' in 2.23 the following appears:: *Specify who will have access to this information and for what purpose (incl. third party vendors and any future use, if applicable): **<Multi-Line Text Box>**

If 'Yes' in 2.23 the following appears:: *Specify how long the information will be accessible in the tool(s)/platform(s)/software/device(s). Please note that this is not the same as overall data retention which is addressed in Q13.17. Please respond just about the technologies/platforms in question: **<Multi-Line Text Box>**

If 'Yes' in 2.23 the following appears:: * Specify how the information will be removed from the tool(s)/platform(s)/software/device(s): **<Multi-Line Text Box>**

If Yes is selected in Question 1.19, Question 2.24 will appear
2.24 ***What is the global or overall sample size? **<Multi-Line Text Box>**

If "Full Board" or "Delegated Level 2" is selected in Question 1.3, Questions 2.25 appears.
2.25 ***What is the total local sample size? If there is more than one group (e.g., patients, caregivers, students, employers, etc.), please also specify the number of participants in each group **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.26 appears:
2.26 *Is the sample size justified in the study protocol/research plan or sponsor protocol?
☐ Yes ☐ No

If Yes is selected in Question 2.26, the following appears:
*Provide the sample size justification. If there is a description of the justification in a study protocol/research plan, indicate the page number. **<Multi-Line Text Box>**

If No is selected in Question 2.26, the following appears:
***Provide the sample size justification**<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.27 appears:
2.27 * Provide the data analysis plan. <Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.28 appears:

2.28 *List all of the inclusion criteria for all participant populations. **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.29 appears:

2.29 *List all of the exclusion criteria for all participant populations. **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.30 appears:

2.30 *What is/are the primary objective(s) of the study and briefly describe how it/they will be measured. NOTE: For qualitative research studies, if this is not applicable indicate "NA" **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then the 2.31 appears:

2.31 What is/are the secondary objective(s) (if applicable) of the study and briefly describe how it/they will be measured. **<Multi-Line Text Box>**

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Questions 2.32-2.34appears

2.32 *Does this study include any use of deliberate deception or withholding of key information that may influence a participant's performance or response?

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

☐ Yes ☐ No

If "Yes" to use of deception in Q2.32: *Explain and justify the use of deception or withholding of key information. **<Multi-Line Text Box>**

If "Yes" to the use of deception in Q2.32: *Upload the Debriefing Script that will be used to inform participants of the deception and how they will be consented to use the data collected when the participants were deceived within the research study, if applicable. <**Upload Document (Document Name, Document Date, Version) – Document Type: Debriefing Script>**

2.33 *Will study participants be subject to restrictions (lifestyle) during the study?

☐ Yes ☐ No

If Yes: *Describe the restrictions for study participants. **<Multi-Line Text Box>**

2.34 *Describe the circumstances under which an INVESTIGATOR WOULD INITIATE the withdrawal of a participant/remove them from the study (please note that a participant's ability to withdraw themselves is addressed in Q13.17):<**Multi-Line Text Box>**

Section 3 - Clinical Trials Information

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Question 3.1 will appear

3.1 *Is this a clinical trial?

☐ Yes ☐ No

HELP TEXT:

A Clinical Trial is a biomedical or behavioral research study of human participants designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases:
Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects).

Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety.

Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use.

Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

If No is selected in Question 3.1, Question 3.2a will appear

3.2 *Has this study been or will this study be registered on a publicly accessible registry (e.g., OSF, clinicaltrials.gov, or other)?

☐ Yes ☐ No

If Yes: *Indicate the registry name and registration number.

If No: *Justify why not (see help text):

HELP TEXT:
Please note the HSREB strongly recommends that all studies be registered in a publicly accessible registry.

The HSREB does not mandate registration for any studies other than clinical trials. However, there are many good reasons to register any study, including

- **To fulfill ethical obligations to research participants and the research community by conducting high quality studies with low risks of bias**
- **To provide information about ongoing or completed studies to potential participants, other scientists, and referring clinicians (as applicable)**
- **To reduce publication bias (i.e., not publishing study results depending on the study's findings)**
- **To help readers to understand the context of study results**
- **To facilitate systematic reviews and other analyses of the research literature (a societal benefit)**

The HSREB has published a guidance document on study registration.

Many places exist for study registration. One recommendation is OSF.io (Open Science Framework), where it is possible to upload protocols, statistical analysis plans, and any other type of study-related document. Registration is fast and free.

Note that, if OSF is chosen as the registry, please ensure your protocol/documents get "Registered" rather than simply uploaded. These are two distinct options at OSF. It is well-explained on their website.

If 'No' selected in Q3.1, Question 3.3 will appear

3.3 *Is this study primarily investigating a medical device?

☐ Yes

☐ No

If 'Yes' selected in Q3.3, Questions 3.4-3.8 will appear

3.4 *****Enter the name of the device components, parts and/or accessories as per product label: **<Multi-Line Text Box>**

3.5 *****Health Canada medical device classification:

HELP TEXT: A Class II or higher medical device requires Health Canada authorization for investigational use.

☐ Class I (Note: does not require Health Canada Authorization for investigational use.

☐ Class II

☐ Class III

☐ Class IV

If 'Class II; Class III; or Class IV' is selected in question 3.5, question 3.5a-3.5b appears

3.5a *****Enter the device license number/model or catalogue number: **<Multi-Line Text Box>**

3.5b *****Indicate the status of the 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' is selected in question 3.5b, question 3.5b1 appears

3.5b1*****Describe how the 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>**

If 'Investigational Testing Application (ITA) under the Medical Device Regulations' is selected in question 3.5, question 6.9 appears

3.5b2 For each device covered under the ITA, upload the ITA or equivalent if received:

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

3.6 ***Is the device commercially available or licensed outside of Canada?**

☐ Yes ☐ No

If Yes: *Where is it commercially available or licensed? <Multi-Line Text Box>

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

☐ Yes ☐ No ☐ N/A

If Yes: *Provide: IDE # or PMA #: <Multi-Line Text Box>

3.8 ***Has the device been evaluated in previous human trials?**

☐ Yes
☐ No
☐ N/A

If No Questions 3.8a-3.8d will appear:

3.8a ***Describe any animal or other studies that have led to this study. (Cite references where applicable and attach the references in the question below): <Multi-Line Text Box>**

3.8b ***Describe any additional safety monitoring that will be implemented for a first in human study: <Multi-Line Text Box>**

3.8c *Has this study already started elsewhere?

☐ Yes ☐ No

If 'Yes': *How many humans have received the device or therapy as of today and provide any available data (including adverse events): <Multi-Line Text Box>

3.8d Upload any references used above (if applicable):

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

Add Another

If Yes is selected in Question 3.1, Question 3.9-3.19 will appear

3.9 ***What is the proposed type of clinical trial (select all that apply):**

☐ Pilot

☐ Phase I
☐ Phase I/II
☐ Phase II
☐ Phase II/III
☐ Phase III
☐ Phase III/IV
☐ Phase IV
☐ Other
If Other: ***Specify Other **<Multi-Line Text Box>

3.10 If this is a multi-phase or combination phase trial (e.g., Phase I/II), specify whether this application is for REB review of one phase only or for both (e.g., for REB review of Phase II only when Phase I of a Phase I/II study has been completed): **<Multi-Line Text Box>**

3.11 ***Does this study involve any of the following (select all that apply):
☐Drugs, Biologics (including vaccines), Genetic Therapies or Radiopharmaceuticals
☐Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))
☐Medical Devices
☐Biological specimen collection (e.g., blood/tissue for PK, biomarker, biobanking, genetic testing, etc., excluding biological specimens taken as part of normal care or for safety)
☐Radiation (including tests involving exposure to radiation)
☐Other health related interventions not listed above

If 'Drugs', 'NHP', or 'Medical Devices' is selected in Question 3.11, Question 3.12 will appear

3.12 ***Does this submission require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)?
☐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

3.13 ***Has this study been submitted to the USA 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
If Yes: ***Provide: IND #, IDE # or PMA #: **<Multi-Line Text Box>

3.14 ***Has this study been or will this study be registered on a publicly accessible clinical trial registry? (e.g., www.clinicaltrials.gov, www.controlled-trials.com/isrctn/)

☐ Yes ☐ No
If Yes: ***Indicate the registry name and registration number. **NOTE: REB approval will not be issued until this is received. <Multi-Line Text Box>
If No: *Justify why not: **<Multi-Line Text Box>**

3.15 ***Has the drug or other therapy been evaluated in previous human trials?
- ☐ Yes
- ☐ No
- ☐ Not applicable

If No to Q3.15, then Questions 3.15a-3.15d will appear:
3.15a ***Describe any animal or other studies that have led to this study. (Cite references where applicable and attach the references in the question below) **<Multi-Line Text Box>**

3.15b *Describe any additional safety monitoring that will be implemented for a first in human study. **<Multi-Line Text Box>**

3.15c *Has this study already started elsewhere?
☐ Yes ☐ No
If 'Yes': ***How many humans have received the drug, device or therapy as of today and provide any available data (including adverse events). **<Multi-Line Text Box>

3.15d Upload any references used above (if applicable):
Upload Document (Document Name, Document Date, Version) – Document Type: References
Add Another

3.16 ***Which of the following will be used in this study (select all that apply):
- ☐ placebo
- ☐ sham procedure(s)
- ☐ washout
- ☐ withholding treatment
- ☐ no-treatment arm
- ☐ None

If 'placebo': ***Justify placebo: **<Multi-Line Text Box>
If 'sham procedure(s)': ***Justify sham procedure(s): **<Multi-Line Text Box>
If 'washout': ***Justify washout: **<Multi-Line Text Box>
If 'withholding treatment': ***Justify withholding treatment: **<Multi-Line Text Box>
If 'no-treatment arm': ***Justify no-treatment arm: **<Multi-Line Text Box>

3.17 If applicable, describe the provisions made to break the code of a double-blind study in an emergency situation: **<Multi-Line Text Box>**

3.18 ***Are there any prohibited medications while participants are in this study?
☐ Yes ☐ No

If Yes: *How will participants be informed of these prohibited medications

- ☐ They will be listed in the letter of information.;
- ☐ Participants will receive a separate list of prohibited medications that they can then give to their other health care providers

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., prohibited medication list, 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 'Participants will receive a list of prohibited medications that they can then give to their other health care providers':
*Upload the list of prohibited medications.
Upload Document (Document Name, Document Date, Version) – Document Type: Prohibited Medications

3.19 *Are there any other participant-facing material(s) (e.g., wallet card, instructions, etc.)?.
NOTE: This does not include recruitment materials.
☐ Yes ☐ No

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., wallet card, 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 Yes: *Upload the other participant material(s). **Upload Document (Document Name, Document Date, Version) – Document Type: Other Participant Materials**
Add Another

Section 4 - Drugs, Biologics (including vaccines), Genetic Therapies or Radiopharmaceuticals

If 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in question 3.12, question 4.1 appears
4.1 *Indicate the status of the product(s) covered under the CTA with Health Canada (select all that apply):
☐ Approved (marketed) drug(s), biologic(s), Radiopharmaceutical or Vaccine(s) used outside the parameters of the Health Canada NOC or DIN)
☐ Investigational drug(s), biologic(s), Radiopharmaceutical or Vaccine(s) (not approved/marketed by Health Canada)
HELP TEXT: Approved drug refers to marketed drugs, with conditions of use identified in the Notice of Compliance (NOC), Notice of Compliance with Conditions (NOC/c) or Drug Identification Number (DIN).

Conditions of use refers to the parameters under which the agent (e.g., drug, natural health product) has been approved for use in Canada. Includes the indication(s) and clinical use; target patient populations(s); route(s) of administration; and dosage regimen(s).
Drug Identification Number (DIN) refers to a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.
Investigational product(s) refers to a drug that has not been marketed in Canada and does not have a Drug Identification Number (DIN)
Clinical Trial Application (CTA) – an application made to Health Canada requesting authorization to conduct a clinical trial involving a drug, biologic, genetic therapy, radiopharmaceutical or natural or non-medicinal health product in Canada.

If 'Drugs, Biologics (including vaccines), Genetic Therapies or Radiopharmaceuticals' is selected in 3.4.
4.2 *Provide the name(s) of all the drug(s), biologic(s), radiopharmaceutical(s) or vaccine(s): (include the generic name and trade name): **<Multi-Line Text Box>**

If 'Approved (marketed) drug(s), biologic(s), Radiopharmaceutical or Vaccine(s) used outside the parameters of the Health Canada NOC or DIN)' is selected in question 4.1, question 4.3 appears
4.3 *Describe how the product(s) is/are being used in the study outside the conditions of use approved by Health Canada: **<Multi-Line Text Box>**

If 'Investigational drug(s), biologic(s), Radiopharmaceutical or Vaccine(s) (not approved/marketed by Health Canada))' is selected in question 4.1, question 4.4 appears
4.4 *Describe how the product(s) is/are being used in the study: **<Multi-Line Text Box>**

If 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in question 3.5, question 4.5 and 4.6 appears
4.5 *Indicate which of the following document(s) were submitted to Health Canada for the product(s) covered under the Clinical Trial Application (CTA) (select all that apply)?
☐Investigator Brochure (IB)
☐Product Monograph (PM)

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., IB-Drug name, ed.#, 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

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., PM-drug name, 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

4.6 *Indicate the status of Health Canada Clinical Trial Application (NOL) NOTE: REB approval will not be issued until this is received:
☐ No Objection Letter enclosed
☐ No Objection Letter pending

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 'No Objection Letter Enclosed':
***Upload Health Canada NOL document:**
Upload Document (Document Name, Document Date, Version): Document Type: NOL

If 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in question 3.12, question 4.7 appears
4.7 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: NOL/ITA/CTA> <Add Another>

Section 5 - Natural Health Products or non-prescription or disinfectant drugs

This section appears only if 'Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))' is selected in 3.4.

If 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' is selected in question 3.12, question 5.1 appears
5.1 *Indicate the status of the product(s) covered under the CTA with Health Canada (select all that apply):
☐ Natural Health Product (NHP) used outside the parameters of the product license or recommended conditions of use:
☐ Investigational Natural Health Product (NHP) not licensed by Health Canada
Help Text:

Approved health product refers to licensed natural or non-prescription health products, with a Natural Product Number (NPN) or homeopathic medicine number (DIN-HM).
Conditions of use refers to the parameters under which the agent (e.g., drug, natural health product) has been approved for use in Canada. Includes the indication(s) and clinical use; target patient populations(s); route(s) of administration; and dosage regimen(s).
Natural Product Number refers to an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the Natural Health Products Regulations.
Homeopathic Medicine Number (DIN-HM) refers to an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the Natural Health Products Regulations.
Investigational refers to a natural or non-prescription health product that has not been licensed in Canada and does not have a natural product number (NPN) or homeopathic medicine number (DIN-HM).

5.2 *****Provide the name(s) of the Natural Health Product(s): **<Multi-Line Text Box>**

If 'Natural Health Product (NHP) used outside the parameters of the product license or recommended conditions of use:' is selected in question 5.1, question 5.3 appears
5.3 ***** Describe how the Natural Health Product is being used in the study outside of the parameters of the product license or recommended conditions of use: **<Multi-Line Text Box>**

If 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' is selected in question 3.5, question 5.4 and 5.5 appears
5.4 *****Indicate which of the following document(s) were submitted to Health Canada for the product(s) covered under the Clinical Trial Application (CTA) (select all that apply)?
☐Investigator Brochure (IB)
☐Product Monograph (PM)

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., IB-drug name, ed.#, 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

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., PM-drug name, 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

5.5 *Indicate the status of Health Canada Clinical Trial Application:
NOTE: REB approval will not be issued until this is received
☐ Notice of Authorization enclosed
☐ Notice of Authorization pending

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 'Approval received':
* Upload the Health Canada Notice of Authorization document:
Upload Document (Document Name, Document Date, Version) – Document Type: NOA

If 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' is selected in question 3.12, question 5.6 appears
5.6 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: NOL/ITA/CTA

Section 6 – Medical Devices

This section appears only if 'Medical Devices' is selected in 3.4.

6.1 *Enter the name of the device components, parts and/or accessories as per product label:
<Multi-Line Text Box>

6.2 *Health Canada medical device classification:
HELP TEXT: A Class II or higher medical device requires Health Canada authorization for investigational use.
The manufacturer or trial sponsor should refer to "The Keyword Index to Assist Manufacturers in Verifying the Class of Medical Devices" released by Health Canada to confirm the classification of medical device products after application of the Classification Rules for Medical Devices set out in Schedule 1 of the Medical Devices Regulations.
For Software as Medical Devices, the manufacturer or trial sponsor should refer to "Guidance Document: Software as a Medical Device (SaMD) – Classification Examples" released by Health Canada to confirm the classification of Software as Medical Device.
☐ Class I (Note: does not require Health Canada Authorization for investigational use.
☐ Class II
☐ Class III

☐ Class IV

If 'Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations' is selected in question 3.12, question 6.3 appears
6.3 *Indicate the status of the 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' is selected in question 6.3, question 6.4 appears
6.4 *Describe how the 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>**

If 'Class II; Class III; or Class IV' is selected in question 6.2, question 6.5 appears
6.5 *Enter the device license number/model or catalogue number: **<Multi-Line Text Box>**

6.6 *Is the device commercially available or licenced outside of Canada?
☐ Yes ☐ No
If Yes: *Where is it commercially available or licenced? <Multi-Line Text Box>

6.7 *Does this device contain a drug?
☐ Yes ☐ No
HELP TEXT: If the investigational testing of a device is in conjunction with a drug in a clinical trial then the sponsor must obtain authorization for the clinical trial and authorization for the use of the investigational medical device
If Yes: ***Drug Used: **<Multi-Line Text Box>

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-ITA, reference#, 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 'Yes' is selected in question 6.7, 6.8 appears
6.8 * For each device that includes a drug(s) covered under the ITA, upload the Product Monograph (PM) or equivalent::
Upload Document (Document Name, Document Date, Version) – Document Type: Product Monograph

If 'Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations' is selected in question 3.12, question 6.9 appears
6.9 For each device covered under the ITA, upload the ITA or equivalent:
Upload Document (Document Name, Document Date, Version) – Document Type: NOL/NOA/ITA

If 'Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations' is selected in question 3.12, question 6.3 appears
6.10 IF this is an investigator-initiated study, please upload the ITA application 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 7 - Radiation

This section appears only if 'Radiation' is selected in 3.4.

7.1 *Indicate the sources of radiation/radiopharmaceutical exposure (select all that apply):
☐Diagnostic
☐Radiation therapy
☐Other
If 'Diagnostic': ***Specify diagnostic: **<Multi-Line Text Box>
If 'Other': ***Specify other: **<Multi-Line Text Box>

7.2 *Will research participants be exposed to radiation/radiopharmaceuticals over and above what they would receive with standard of care?
☐Yes ☐No
If 'Yes': *Describe the radiation exposure that is above standard of care: <Multi-Line Text Box>

7.3 *Are you using a radionuclide?
☐Yes ☐No

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., HRSSRC approval letter, 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 'Yes': ***All human radionuclide research requires approval from the Human Radionuclide Safety and Scientific Review (HRSSRC). **The HSREB requires this approval before REB approval can be issued. HRSSRC Terms of Reference (see Appendix 1) are available on the LHSC Radiation Safety Website.
Upload Document (Document Name, Document Date, Version) – Document Type: Human Radionuclide Safety and Scientific Review Approval

Section 8 – Other Interventions

This section appears only if 'Other' is selected in 3.4.

8.1 *Other Health Related Interventions
☐Cognitive behavioural therapy
☐Surgery
☐Exercise

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

Section 9 - Phase I Trial

This section appears only if 'Phase 1' or Phase I/II is selected in 3.2.

9.1 ***Indicate type of Phase I trial.**

- ☐ First-in-human, first-in-kind (e.g. the first compound ever evaluated in humans against a new molecular target), single-agent
- ☐ First-in-human, but not first-in-kind (i.e. other agents of the same class have entered human testing), single-agent
- ☐ Investigational agent (e.g. in phase II testing) + investigational agent
- ☐ Investigational agent + approved agent (molecular or chemotherapy)
- ☐ Approved agent + approved agent
- ☐ Other

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

9.2 ***What is the starting dose and describe how this concentration was chosen. **<Multi-Line Text Box>**

9.3 ***Describe the waiting period in-between patients within cohort(s) and in-between dose levels. **<Multi-Line Text Box>**

If 'First-in-human, first-in-kind (e.g. the first compound ever evaluated in humans against a new molecular target), single-agent' is selected in question 9.1, question 9.4 appears

9.4 ***For "first-in-kind" and "first–in-humans" trials, if the study suggests dosing up to 3 patients in the initial cohort without waiting period in-between patients, provide sufficient justifications. **<Multi-Line Text Box>**

9.5 ***Has this study already started?**

☐ Yes ☐ No

If 'Yes': ***How many humans have received the drug as of today and provide any available data (including toxicities observed to date). **<Multi-Line Text Box>

9.6 ***Provide information on communication between investigators and the sponsor (i.e. - how, when and by whom is the determination made to enter the next dose level). **<Multi-Line Text Box>**

9.7 ***Will a pocket card with emergency contact information and important information on the drug and its side effects be given to participants?**

☐ Yes ☐ No

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., pocket card, 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 'Yes': ***Upload the pocket card:
Upload Document (Document Name, Document Date, Version) – Document Type: Pocket Card
If 'No': ***Justify: **<Multi-Line Text Box>

9.8 ***Will the patient be hospitalized and observed overnight for the first dose?
☐ Yes ☐ No
If 'No': ***Describe why the patient will not be hospitalized and observed overnight for the first dose. **<Multi-Line Text Box>

Section 10 - Biospecimen Collection

If yes is selected in 2.4 this section will appear

10.1 ***What type of biological specimen(s) will be collected from the study participants (excluding samples taken as part of normal care)? **<Multi-Line Text Box>**

10.2 *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>**

10.3 *How will the 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>**.

10.4 ***Select the purpose(s) for which the biological specimens will be collected (select all that apply):
☐For the purposes of this study (excluding biological 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 biological specimens taken as part of normal care or for safety)' is selected in 10.4, questions 10.5 – 10.10 appear:

10.5 ***Indicate whether the Biological Specimen Collection for the purposes of this study is (select all that apply):
☐Mandatory

☐ Optional (separate LOI/C required)

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

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

☐ Yes ☐ No

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

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

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

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

If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 10.4, questions 10.11 – 10.17 appear:

10.11 *Indicate whether the sample collection for Genetic Testing is (select all that apply):

☐Mandatory

☐Optional (separate LOI/C required)

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

10.13 *Will the biological specimens, collection for genetic testing, 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>

10.14 *For the samples being used for genetic testing, indicate how long they will be retained:**<Multi-Line Text Box>**

10.15 *For the samples being used for genetic testing, describe what will happen to them after they will no longer be used for genetic testing (e.g., destroyed, returned): **<Multi-Line Text Box>**

10.16 *For the samples being used for genetic testing, indicate to what extent the study participant is able to withdraw the biological specimens, and any limitations to the withdrawal:: **<Multi-Line Text Box>**

10.17 *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 'Yes': *Describe any genetic counseling that will be provided when communicating the results. <Multi-Line Text Box>
If 'No': *Explain/justify why family members or their health care providers will not be informed of any genetic testing results: <Multi-Line Text Box>

If 'Stored or retained or banked for any future testing' is selected in 10.4, questions 10.18 – 10.24 appear:

10.18 *Indicate whether the biological specimens to be Stored or Retained or Banked for any future testing is (select all that apply):
☐Mandatory
☐Optional (separate LOI/C required)

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

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

10.21 *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>**

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

10.23 *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>**

10.24 *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 10.25- 10.30 appears

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

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

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

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

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

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

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

Section 11 - Risks, Benefits and Safety

If "Box 1" or "Box 2" is selected in Question 1.2, then 11.1 appears

11.1 *Describe any direct benefits to the study participants. If there are no direct benefits to the participants themselves, please state as such:**<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.6, then 11.2 appears:

11.2 ***What is the overall anticipated public and scientific benefits of the study? **<Multi-Line Text Box>**

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Question 11.3 will appear

11.3 ***a) List and describe the known risks, harms, and inconveniences of any tests, procedures or other protocol-mandated activities that are conducted for research purposes. This information must be included in the informed consent documentation. **Include the estimated frequencies of these risks,** severity, and reversibility**, as applicable.** **<Multi-Line Text Box>**

b) *Have you provided incidence rates for all risks?
☐ N/A, no physical or mental health risks have been identified
☐ YES

☐ NO, please justify If "NO" **<Multi-Line Text Box>**

If "placebo", "sham" "procedure", "washout" or "withholding" treated is selected in Question 3.9, Question 11.4 will appear

11.4 ***For studies involving placebo, washout or withholding treatment, list any risks related to withdrawal or absence of treatment. **<Multi-Line Text Box>**

If "Full Board" or "Delegated Level 2" is selected in Question 1.7, Question 11.5 – 11.12 will appear

11.5 For the study risks listed above, describe the monitoring to be undertaken during and following the study conclusion. **<Multi-Line Text Box>**

11.6 ***Are there any reproductive risks associated with participation in the study?

☐ Yes ☐ No

If 'Yes': * Provide a **SUMMARY** of the relevant data (e.g., teratogenicity or embryotoxicity, risks to female partners of male participants, risks related to male participant fathering a child) and indicate what monitoring will be undertaken during the study and following the study conclusion? **<Multi-Line Text Box>**
HELP TEXT: If there is a sponsored protocol DO NOT CUT AND PASTE. Provide only a summary.

11.7 ***If a research participant fathers a child while in the study, will access to the health records of the pregnant partner and/or their child be required and/or will the pregnant partner and/or child be monitored by this study during and/or after the pregnancy?

☐ Yes ☐ No

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., Preliminary Partner LOI/C, 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 'Yes': * Upload a copy of the Preliminary Pregnant Partner Letter of Information AND the Pregnant Partner Information Letter/Consent Form
Upload Document (Document Name, Document Date, Version) – Document Type: Preliminary and Pregnant Partner Information Letter/Consent Form

11.8 ***Does participation in this study affect alternatives for future care or eligibility for future research?

☐ Yes ☐ No

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

11.9 ***Is there a data and safety monitoring board (DSMB) or committee (DSMC)?

☐ Yes ☐ No

If 'Yes': * Is the DSMB/DSMC independent of the sponsor?

☐ Yes ☐ No

If 'Yes': Provide a copy of the charter or describe the DSMB including its purpose, membership, relationship to the sponsor, how often they meet and whether the committee will review unblinded data: **<Multi-Line Text Box>**
IF "No" to "Is the DSMB/DSMC independent of the sponsor?": Justify why the DSMB is not independent of the sponsor. **<Multi-Line Text Box>**

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., DSMB/DSMC charter, 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 'Yes': Upload DSMB/DSMC charter:
Upload Document (Document Name, Document Date, Version) – Document Type: DSMB/C Charter
If 'Yes': Describe the clinical criteria for stopping the study protocol due to safety concerns? **<Multi-Line Text Box>**
If 'No': ***Provide justification. **<Multi-Line Text Box>

11.10 *****Are there any plans to perform an interim analysis?
☐ Yes ☐ No
If 'Yes': ***Describe: **<Multi-Line Text Box>
If 'No': ***Justify: **<Multi-Line Text Box>

11.11 If you are using imaging or sample testing in your study procedures, how will incidental findings be disclosed to participants (if applicable)? **<Multi-Line Text Box>**
HELP TEXT-Imaging, Genetic testing, etc.)

Section 12 - Recruitment and Consent

If "Box 1" or "Box 2" is selected in Question 1.2, then 12.1 appears:
12.1 *****Will Personal Information (PI) and/or Personal Health Information (PHI) be used to pre-screen and/or identify potential participants ?
☐ Yes ☐ No
If 'Yes': * Who is accessing the PI and/or PHI for pre-screening/identification and under whose authorization?
<Multi-Line Text Box>
If 'Yes': ***Describe what PI and/or PHI will be used or accessed to pre-screen and/or identify potential participants? **<Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.6, then 12.2 appears:

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

☐ No I am not requesting a waiver of consent

If 'Yes' *Specify for what type of data the waiver is being requested? (checkbox)

☐ Prospective data collection

☐ Secondary use of identifiable information

☐ Secondary use of non-identifiable information

HELP TEXT: This question refers to the source of the data being used for this study. For example. If data is being extracted for a study from a database that is linked to a Master List with identifiable information, secondary use of identifiable information will be used for this new project (even if the new study team intends to extract and use only de-identified information).

If 'Prospective data collection'

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

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

☐ I confirm

If 'I confirm' is selected:

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

*Explain why it is impossible or impracticable to conduct the research without prior consent, or a modified consent model (e.g., verbal consent)?:

If 'I confirm' is selected: *Is there a plan to debrief participants about this research?

☐Yes ☐No

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

Note that 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). 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 "Yes" *Attach copy of debriefing material(s), script, and/or form:

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

Add Another

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

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

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

☐ I confirm

If "I confirm" is selected then:
***Explain why identifiable information is essential to the research: <Multi-Line Text Box>**

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

If "I confirm" is selected then:
***Explain what measures will be taken to protect the privacy of individuals, and to safeguard the identifiable information: <Multi-Line Text Box>**

If "I confirm" is selected then:
***Is your use of information/samples such that broad consent was previously obtained for future secondary research use?**
☐Yes ☐No
If "Yes:" *Please attach copy of the letter of information and consent and any other relevant documentation that was used to obtain consent for future use.

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

If "I confirm" is selected then:
*Explain why it is impossible or impracticable to obtain consent: **<Multi-Line Text Box>**

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

If 'Secondary use of non-identifiable information' then:

***Is your use of information/samples such that broad consent was previously obtained for future secondary research use?

☐Yes ☐No

If "Yes:" *Please attach copy of the letter of information and consent and any other relevant documentation that was used to obtain consent for future use.

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

If 'No' is selected in 12.2, questions 12.3 and 12.4 appear:

12.3 *Is there a broad recruitment plan (e.g., recruitment database, call centre, advertising)?

☐Yes ☐No

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

12.4 * How will you recruit potential participants?

- ☐ Investigator or other study member who is part of the circle of care will approach patients
- ☐ Investigator or other study member who is part of the circle of care will approach the substitute decision maker
- ☐ Investigators will receive referrals from other healthcare providers
- ☐ Investigators will recruit a non-patient group (e.g., caregiver, students, employees, etc.)
- ☐ Advertising (e.g., brochures, flyers, poster, newspaper ad, or web-based)
- ☐ Existing database
- ☐ Social media
- ☐ Recruitment database
- ☐ Third-party organization or recruitment company
- ☐ Other

If 'Other': * Specify "Other" type(s) of recruitment material(s): **<Multi-Line Text Box>**

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., poster, 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 'Advertisement' is selected in 12.4, questions 12.5a will appear:

12.5 a *Upload all advertisement material(s):

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

If 'Social Media' is selected in 12.4, questions 12.5b will appear:

b *Upload all Social Media material(s):

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

If 'Existing Database' is selected in 12.4, questions 12.6 – 12.7 appear:

12.6 *Is the database maintained by the Principal Investigator?

☐ Yes ☐ No

If 'No': ***Specify who is the custodian of the database and clarify if you have permission from the custodian to access/use this data for research purposes? **<Multi-Line Text Box>

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

12.7 *If this database has been approved by the HSREB provide the HSREB number to which this existing database is approved for use in research studies. **<Multi-Line Text Box>**

If 'No' is selected in 12.2, questions 12.8 and 12.9 appear:

12.8 *Who will make initial contact with potential participants? For studies recruiting in clinical settings, is this person/are these people within circle of care? Please name: **<Multi-Line Text Box>**

12.9 *How will initial contact be made with potential participants?

#HELP TEXT: for hospital based investigators please see the hospital "Electronic Mail (E-mail) Use" policy (INT006) for hospital requirements

- ☐ In person
- ☐ Email (include: If email communication will be used please ensure that participants understand that email communication is not a secure form of communication)
- ☐ Letter
- ☐ Telephone
- ☐ No contact (advertisement and online data collection only)
- ☐ Other

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

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., email script, 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 'Email' selected in 12.9:

Upload Email script(s): **(Document Name, Document Date, Version) – Document Type: Email script**

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., communication letter, 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 'Letter':
Upload Letter Document(s) (other then LOI/C): **(Document Name, Document Date, Version) – Document Type: Letter Document**

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., telephone script, 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 'Telephone':
Upload Telephone script**(s): (Document Name, Document Date, Version) – Document Type: Telephone script**

If 'Investigators will recruit a non-patient group' is selected in 12.4 (box 4), question 12.10 appears:

12.10 ***If recruiting non-patients (e.g., caregivers, students, employees, etc.), describe the method(s) for recruiting **<Multi-Line Text Box>**

If 'No' selected in 12.2 then questions 12.11-12.21 appear:

12.11 ***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>**

12.12 Who will be obtaining consent? Please Name: **<Multi-Line Text Box>**

12.13 ***Which of the following will be used (select all that apply):
☐Assent form(s)
☐Letter of Information/Consent form(s)

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., Main-LOI, Caregiver-LOI, Genetic substudy-LOI, etc., 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 'Letter of Information/Consent form(s)': *Upload clean versions of all proposed consent forms (e.g., screening, main, optional):
Upload Document

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., Assent, 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 'Assent form(s)': *Upload clean versions of all proposed assent form(s): Upload Document

12.14 *Is there a relationship between the participant and the person obtaining consent?

☐ Yes ☐ No

If 'Yes': ***Explain the nature of the relationship (e.g., physician, employer, student) and what steps will be taken to avoid undue influence (actual, apparent, perceived, or potential). **<Multi-Line Text Box>

12.15 *Does this study have competitive enrollment

☐ Yes ☐ No

12.16 *Will persons not capable to consent for themselves be included in the study?

HELP TEXT: there is no age of consent. It is based on capacity to understand.

☐ Yes ☐ No

If 'Yes': ***Describe how capacity will be assessed for any individuals noted above. If participants are incapable of providing consent, provide information on how substitute decision makers will be identified and how their consent will be obtained to contact them for use of the participant's information for research. Note, discuss what safeguards will be employed to ensure the rights of the research participant are protected. **<Multi-Line Text Box>

12.17 When the inability to provide an informed consent is expected to be temporary, describe what procedures that will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent. Alternatively, if diminished capacity is anticipated for the study population, describe the procedure used to assess capacity and obtain ongoing consent. **<Multi-Line Text Box>**

12.18 *How much time will be given to participants to review the information before being asked to give consent? **<Multi-Line Text Box>**

12.19 *Does the study exclude any participants based on culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, sex or age, etc.?

Ensure consistency with Q2.29 (exclusion criteria).

☐ Yes ☐ No

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

12.20 *List any anticipated communication difficulties when conducting this study:

☐ None

- ☐ Individuals who may require translation
- ☐ Individuals who are illiterate
- ☐ Individuals unable to communicate

If any answer other than 'None' is selected in 12.20, the following appears:

*****Describe the procedures to address any communication difficulties (ensure this is congruent with your inclusion/exclusion criteria): **<Multi-Line Text Box>**

HELP TEXT. Ensure the applicable signature lines (for a translator and/or a witness) have been added to the Informed Consent Form(s)

12.21 *****Are potential participants allowed to enroll in other studies while in the current study?

- ☐ Yes
- ☐ No

If 'No': ***Justify or explain why participation in additional studies would not be appropriate: **<Multi-Line Text Box>

If 'No' is selected in 12.2, questions 12.22 appears:

12.22 *****Does your study design and letter of information and consent address any of the following:

- ☐ Open Access Data Sharing
- ☐ Contact for future research (must be optional)
- ☐ Broad consent for future secondary use of data/samples without further contact (must be optional)
- ☐ None of the Above

HELP TEXT: Please see letter of information and consent guidance documents for requirements when explaining open access data sharing, future contact, and future unspecified research to participants. Please note that future unspecified use of data or biological specimens MUST be optional as per TCPS2 Article 3.13).

Section 13 - Confidentiality and Data Security

If "Box 1" or "Box 2" is selected in Question 1.2, then 13.1 appears:

13.1 (For patient orientated research studies.) Do you plan now or in the future to link your study data to the large healthcare databases held at ICES? For example, this would allow you to follow patients passively life-long, determine their healthcare costs, assess how similar your patients are compared to Ontario citizens, and help identify control groups.
Help Text: If yes, you must collect the 5 key identifiers used to link your study data with ICES data: Ontario provincial health card (OHIP) number (version code not required), last name, first name, gender and full date of birth. It is extremely important that the health card number is collected accurately; this is the key identifier used for linkage. Note: patients who do not have an OHIP number can't be linked to ICES data. For more information, please see the linking your study data with the large healthcare databases held at ICES guidance document.

☐ Yes ☐ No ☐ N/A

If "Box 1" or "Box 2" is selected in Question 1.2, then 13.2 appears:

13.2 *Are you collecting personal identifiers for this study?

☐ Yes ☐ No

If 'Yes' is selected in 13.2, question 13.3 and 13.4 appear:

13.3 *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
☐ Ontario 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
☐ Age
☐ Biological Sex
☐ Gender Identity
☐ Hospital Patient Identification Number (PIN)
☐ 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 'Biological Sex: * * *Explain and justify sex and if it will be stored on paper or electronically**<Multi-Line Text Box>**
If 'Gender Identity': * ***Explain and justify gender 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 'Hospital PI': ***Explain and justify hospital PIN and if it will be stored on paper or electronically **<Multi-Line Text Box>
If 'Medical Device identifier: ***Explain and justify medical device identifier 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>

13.4 *Will there be a master list linking identifiers/identifiable information (e.g., name, contact information) to the unique participant code (e.g., study number, pseudonym)?

☐Yes ☐No

If 'Yes': ***Who will have access to the Master list? **<Multi-Line Text Box>

If 'No'* Explain why the study data must remain identifiable. **<Multi-Line Text Box>**

If "Box 1" or "Box 2" is selected in Question 1.2, then 13.5 appears:

13.5 ***Where will information collected as part of this study be stored (applies to both paper copy and electronic copy)? (select all that apply)

☐ University or Hospital network drive
☐ University or Hospital local hard-drive
☐ Laptop (only de-identified study data should be retained on an external device)
☐ Memory Stick
☐ Cloud Storage (Includes institutional Office 365 storage such as OneDrive)
☐ Off-site
☐ Other

If 'University or Hospital network drive': *Specify the university or hospital network drive: <Multi-Line Text Box>

If 'Laptop": *Specify who owns the laptop: <Multi-Line Text Box>If 'Laptop": *Where will the laptop be stored for the duration of this study: <Multi-Line Text Box>If 'Laptop": *Who will have access to the laptop? <Multi-Line Text Box>

If 'Memory Stick":*Who will have access to the memory stick? <Multi-Line TextBox>

If 'Cloud Storage":*What is the name of the Cloud Storage? <Multi-Line Text Box>

If 'Cloud Storage":*What are the security details of the Cloud Storage? <Multi-Line Text Box>

If 'Off-site":*Specify where off-site the data will be stored: <Multi-Line Text Box>If 'Off-site":*Who will have access to the data that is stored off-site? <Multi-Line Text Box>

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

If "Box 1" or "Box 2" is selected in Question 1.2, then 13.6 appears:

13.6 *Indicate the measures in place to protect the confidentiality and security of any study data including Personal Information (PI) or Personal Health Information (PHI) that is accessed, collected and used (select all that apply):

☐ Access to study data and/or medical records will be limited to authorized personnel
☐ Access to electronic data will, at least, be password protected (if not password protected AND encrypted)
☐ Electronic data will be stored on a Western, hospital or other institutional server with firewalls and other security and back-up measures in place
☐ Study data stored on a laptop, external hard drive, and/or portable device(s) will be encrypted
☐ Paper copies of study data will be stored in locked filing cabinets in a secure location
☐ A master log with identifiers will be stored separately from the study data
☐ Other

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

If box 3-5 in Q13.6 is selected then Q13.7 appears

13.7 *Describe where study data/database, source data (including completed surveys), and Letters of Information and Consent, whether electronic or paper, will be kept: **<Multi-Line Text Box>**

.

If box 4 in Q13.6 is selected then Q13.8 appears

13.8 *If participant information is stored on an external hard drive, laptop(s) and/or portable device(s), the device must be encrypted. Describe (name) the encryption type and software being used. **<Multi-Line Text Box>**

Dependent on 1.2 (FB and DL2)

13.9 *If someone other than the local PI is the study data custodian (who is responsible for maintaining the study data) explain below (otherwise just indicate local PI):**<Multi-Line Text Box>**

If 'Yes' is selected in 13.2, questions 13.10-appears:

13.10 *Are you transporting materials (paper, devices and/or media) that include Personal Information (PI) and/or Personal Health Information (PHI) between sites? (See Confidentiality and Data Security guidelines)

☐ Yes ☐ No

If 'Yes': ***Describe what safeguards you will have in place to ensure the safety of information being transported. **<Multi-Line Text Box>

If "Box 1" or "Box 2" is selected in Question 1.6, then 13.11 appears:

13.11 *Will you be sending/sharing data off-site for this study?

☐ Yes ☐ No

If "Yes" 13.11a *Describe where/to whom the data will go: **<Multi-Line Text Box>**

If "Yes" 13.11b *Specify what data is going off-site? **<Multi-Line Text Box>**

If "Yes" 13.11c *Does the data to be transferred include any of the following? Select all that apply.

☐ Full Name
☐ Initials
☐ Ontario 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
☐ Age
☐ Biological Sex
☐Gender Identity

☐ Hospital Personal Identification Number (PIN)
☐ Medical Device identifier
☐ Full face photograph
☐Voice/audio/Video recording
☐ Other
☐ N/A

If 'Other" is selected: *List what other personal identifiers will be included with the data sent off-site. **<Multi-Line Text Box>**

If 'Yes to 13.11':
13.11d. ***How will the data be transmitted?
HELP TEXT: Will there be any web-based data entry? Should be a secure socket (using SSL) connection to ensure data is entered over a secure tunnel from workstation to web server
☐ Secured Fax
☐ Electronic (online) data collection
☐ Secure file transfer
☐ Registered Mail (Private Courier or Canada Post)
☐ Other

If 'Electronic (Online) data collection': ***Provide details of the Electronic (online) data collection: **<Multi-Line Text Box>

If 'Secure File Transfer': ***Describe the details of the secure file transfer: **<Multi-Line Text Box>

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

If 'Yes to 13.11':
13.11e. ***If applicable, specify any additional details on data transmission (otherwise leave answer blank). **<Multi-Line Text Box>**

If 'Yes' is selected in 13.2, questions 13.12 appears:
13.12 ***Who will have access to the identifiable data? **<Multi-Line Text Box>**

If 'Yes' is selected in 13.2, questions 13.13 appears:
13.13 ***How long will you retain identifiable data?
☐ 7 years as per UWO policy
☐ 15 years as per Lawson policy
☐ 15 years as per Health Canada policy
☐ Other
If 'Other': ***Specify Other: **<Multi-Line Text Box>

If 'Other': If you plan on retaining identifiable data for longer then institutional policy or Health Canada policy, how will you ensure the confidentiality of the identifiable information during the extended retention period?

If 'Yes' is selected in 13.2, questions 13.14 appears:

13.14 * Please confirm that you will destroy (locally kept) identifiable data according to institutional guidelines at the time of data destruction (If applicable) ☐ Yes ☐ No

#HELP TEXT: Should be using a method (software) that destroys data to DoD standards or physically destroys the drive/disk and provides a certificate of destruction (3rd party company).

If "Box 1" or "Box 2" is selected in Question 1.6, then 13.15 appears:

13.15 *Will you link the locally collected data with any other datasets, databases or registries (e.g., health registries, Statistics Canada)?

☐ Yes ☐ No

If 'Yes': ***Identify the dataset, 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': ***Explain how the linkage 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

If "Box 1" or "Box 2" is selected in Question 1.6, then 13.16 appears:

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

☐ Yes ☐ No

**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 'No" to 12.2 then 13.17 appears

13.17 ***Indicate the extent the study participant is able to withdraw their data from the research study and any limitations on the withdrawal**<Multi-Line Text Box>**

If "Biological specimens" is selected in Question 2.1, Questions 13.18-13.23 appears

13.18 ***Will the biological specimens be linked to any study participant identifying information, directly or indirectly via a code or link (for example, to a Master List)?

☐ Yes ☐ No

If 'Yes': ***Who will have access to the code or link? **<Multi-Line Text Box>

13.19 *Describe the security measures to protect the confidentiality of the biological specimen(s): **<Multi-Line Text Box>**

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

13.21 *Will the biological specimen(s) 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 anasis of biological specimens will take place for each type of sample. <Multi-Line Text Box>

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

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

If Biological specimen collection is selected in Q2.4 (prospective), Q13.24-13.29 will appear

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

☐ Yes ☐ No

If 'Yes': *Who will have access to the code or link? <Multi-Line Text Box>

13.25 *Describe the security measures to protect the confidentiality of the biological specimen(s): **<Multi-Line Text Box>**

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

If 'video/audio recordings' is selected in question 13.3, question 13.30 appears

13.27 *Which of the following privacy protection methods will be implemented with respect to the video/audio recordings:

☐Access to original recordings will be restricted to study personnel only

☐Transcription of recordings will not include information that can identify participants (e.g., participant names and/or other identifying information will be redacted)

☐Recordings will be confidentially destroyed as soon as possible

☐Recordings will be coded

☐Recordings will not capture date and time

☐None of the above

If 'None of the above': *Justify: Click here to enter text.

Section 14 - Funding

If "Box 1" or "Box 2" is selected in Question 1.6, then 14.1 appears:

14.1 *Is this study funded?

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

☐ Yes ☐ No

If 'Yes' to Q14.1, then Q14.2-14.4 will appear:

14.2 *How is the study funded?

☐ Industry

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

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

☐ Other

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

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

Title
First Name
Last Name
Organization
Address
City
Country
Postcode
Telephone
Email

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

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

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

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

- o Lawson
- o Western University
- o No

If 'Western University' is selected,

*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 University' is selected,

*Confirm the research award(s) are held by you

☐ Yes ☐ No

If 'No'

*Provide the name(s) of the individual holding each specific research award supporting this study (if there is more than one person, ensure to include who is holding which award(s): **<Single-Line Text Box>**

If 'Western University' is selected,

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

14.4 *What is the status of funding from this source?

- Obtained
- Awarded but not received

If 'Awarded but not received' is selected above:

*Will you be able to proceed with the study?

14.5 *Indicate what compensation, if any, will be provided to participants and include a justification for compensation. If this question is N/A indicate so: **<Multi-Line Text Box>**

If "No" in 12.2 then 14.6 appear

14.6 ***Will participants be reimbursed for out of pocket expenses (e.g., parking, travel, food, etc.) incurred as a result of participation

☐ Yes ☐ No

If 'No': ***Provide justification why participants should be financially responsible for direct expenses as a result of participation in this study. **<Multi-Line Text Box>

If 'Box 1 and/or 2' is selected in Question 4.1, Question 14.7-14.9 will appear

14.7 *Will the sponsor and/or institution and/or funder cover the cost of the investigational agent(s) used in the study for the duration of the study?

- Yes
- No
- N/A

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

14.8 ***Will the sponsor and/or funder cover the cost of comparator drugs used in the study for the duration of the study?

☐ Yes ☐ No ☐ N/A

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

14.9 *Are there mechanisms in place to provide ongoing access to the investigational agent post study if participant is benefiting from treatment?

☐ Yes ☐ No ☐ N/A

**If 'No': ***Explain why not (and include this information in the consent form): <Multi-Line Text Box>

If 'Yes': Describe any restrictions, if applicable (and include this information in the consent form): **<Multi-Line Text Box>**

14.10 Attach an itemized study budget. The budget should reflect all costs to complete the study (e.g., REB fees for industry sponsored studies, database extraction, student payments, participant reimbursements, etc.).

Section 15 - Translations

If "Box 1" or "Box 2" is selected in Question 1.6, then section 15 appears

15.1*Are any participant-facing study documents being provided in a language other than English? (e.g., letter of information and consent/assent forms, recruitment materials, participant materials such as questionnaires, etc.)

☐Yes ☐No

If 'Yes' is selected in Q15.1 then 15.2 appears

15.2 *Are the translated materials available for REB review?

☐Yes ☐No

If 'No': Confirm when the translated materials will be submitted:

☐ Once available, prior to initial approval (pending REB confirmation of English versions).

☐ As an amendment, once available.

Note that your document name will appear on the approval notices. Ensure you name your document something that reflects what the document is (e.g., translated:Main-LOI, 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 'Yes' is selected in Q15.2 then 15.3 and 15.4 appear:

15.3 *Upload all translated materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.): Upload Document

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., translation certificate, 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.

15.4 Upload all translation certificates:
Document

Section 16 - Conflict of Interest (actual, apparent, perceived, or potential)

If "Box 1" or "Box 2" is selected in Question 1.6, then section 16 appears:

16.1 ***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>

16.2 ***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>

16.3 ***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>

16.4 *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>**

16.5 *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>

16.6 *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>**

If 'Yes' is selected in question 1.11, then 16.7 appears

16.7 *Is the Principal Investigator listed on this application or their institution the sponsor of this investigator-initiated 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>

16.8 *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 17 - Industry Sponsored Protocols

This section appears only if 'Industry Sponsored (e.g. Pharmaceuticals)' is selected in 1.12.

17.1 *Do you wish to apply for a REB Administration Fee Adjustment/Waiver?

☐ Yes ☐ No

If 'Yes' Justify why you are requesting a fee adjustment/waiver: **<Multi-Line Text Box>**

If No is selected in 16.1, 17.2-17.4 appear

17.2 *Enter the Billing Information - Company Institution: **<Multi-Line Text Box>**

17.3 *Enter the contract and/or protocol reference number: **<Multi-Line Text Box>**

17.4 Enter any additional Sponsor Reference or contact information: **<Multi-Line Text Box>**

Section 18 – Resubmission Information

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

Although the REB requests that you delete previous version documents and replace them with updated, revised documents please DO NOT delete any of the response letters. They can all stay attached. Ensure you have different version date and/or number for each response letter.

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 If changes have been made to ANY previously submitted Letters of Information and Consent and/or Assent Forms, please upload new versions of these documents showing the changes you have implemented using MS Word "Track Changes" feature (not any manual highlighting or colour changes).:

Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES DOCUMENT

18.3 If changes have been made to a previously submitted study instruments/stimuli (e.g., survey, questionnaire, interview guide, focus group guide, observation guide, etc.) at the request of the REB, upload the track-changes version(s):

Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES DOCUMENT

18.4 If changes have been made to a previously submitted protocol, research plan, research outline please upload the track-changes version(s):

Upload Document (Document Name, Document Date, Version) VARIABLE NAME: TRACKED CHANGES DOCUMENT

18.5 Please provide any additional comments for the REB to consider (if applicable): **<Multi-Line Text Box>**

Section 19-Confirmation of Responsibility

19.1
*Confirm that all study team members have received a certificate for completion of human research ethics training through one of the following (select ALL that apply):

- ☐ Tri-Council Policy Statement (TCPS2) Core Tutorial
- ☐ Collaborative Institutional Training Initiative (CITI Program)
- ☐ Other

If "Other" is selected in 19.1 *Indicate where the human research ethics training certificate(s) was obtained: **<Multi-Line Text Box>**

If "Initial Application" is selected in Question 1.1, then question 19.2 appears:

19.2***Principal Investigator (PI) 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, if applicable, 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., if applicable, 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 accordancewith the Personal Health Information Protection Act (PHIPA) and/or the Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.

If "Response to REB recommendations" is selected in Question 1.1, then question 19.3 appears:

19.3 ***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, if applicable, 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., if applicable, Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);

- 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/or Freedom of Information Protection of Privacy Act (FIPPA), its accompanying regulations, and the Tri-Council Policy Statement.