Clinical Trial Initial Application

Orange text *indicates an upload or action feature*

Red/italics/bold *indicates question/feature dependencies*

Red/italics/bold text highlighted yellow *indicates the logic behind why a shared question appears in this sub-form (does not appear on the online forms)*

Green text/bold *indicates the help text associated with the question*

Black/italics/bold *indicates instructional text for researchers*

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

This symbol ↕ indicates a question that appears in other clinical trial forms (e.g., a question that is shared between parent and sub-form)

SECTION 1.0 - GENERAL INFORMATION

ATTENTION:

Before you begin completing the application, please review the Observational and Clinical Trial application form templates on the Tools and Resources page to determine which set of forms are best suited to your study.

For CanReview Studies, please visit the Templates & Forms page on the CanReview website.

1.0 *Is this a resubmission in response to a request from System Administrators or the Research Ethics Board to make changes to your application?

Choose an item.

HELP TEXT:

If this is the FIRST TIME this application is being submitted select "No".

If this is a re-submission for modifications requested by System Administrators or the REB, select "Yes".

If 'Yes' to question 1.0:

If you are re-submitting this application in response to a request for changes from the REB, please ensure that you upload a response letter in question 10.1, outlining how each comment/question from the REB has been addressed in this re-submission.

A response letter is not required if re-submitting in response to a request for changes from System Administrators.

1.0.1 *Is this a Canadian Collaboration for Child Health (CHEER) study?

☐ Yes ☐No

HELP TEXT:

The Canadian Collaboration for Child Health: Efficiency and Excellence in the Ethics Review of Research (CHEER) is a cross-province streamlined ethics review process for multi-site studies to achieve a single ethics review for child health studies in Canada. For more information please visit cheerchildhealth.ca.

1.1 *Is this a multi-site clinical trial?

☐ Yes ☐No

HELP TEXT:

In a clinical trial, participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
Multi-site: The study will include two or more participating sites.

For a list of participating sites, click here.

For CanReview studies, visit canreview.ca/howitworks/participating-sites.

If 'No', the following message appears

The Stream platform application process is for multi-site trials only. As this is not a multi-site trial we are UNABLE TO ACCEPT your application.

If you are unsure, please submit a ticket via the Stream Helpdesk.

1.2 *Complete the Lead Applicant details:

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Province: Click here to enter text.
Telephone: Click here to enter text.
*Email: Click here to enter text.

CONTACT TYPE: LEAD APPLICANT

HELP TEXT:

Lead Applicant refers to the individual who takes overall responsibility for submitting all study-wide materials to the REB of Record on behalf of all participating sites. The study-wide materials include the Clinical Trial Initial Application , all ongoing submissions such as proposed changes to the study amendments, reportable events and continuing review applications.

1.3 *Are the contact details for the Lead Administrative Contact different than the Lead Applicant named above?

☐Yes ☐No

Should be YES – a Site Study contact is needed to address application queries (Q1.3.1)

HELP TEXT:

The Lead Administrative Contact is the person tasked with completing and coordinating the REB submissions for this study.

If 'Yes':

1.3.1 *Complete the Lead Administrative Contact details:

*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.

Telephone: Click here to enter text.

*Email: Click here to enter text.

CONTACT TYPE: LEAD ADMINISTRATIVE CONTACT

1.4 *Enter the complete study title (enter exactly as written in protocol): Click here to enter text.

HELP TEXT:

Enter the complete study title as written on the protocol/study plan. This information will appear as written in REB letters.

1.5 Enter the Study ID/Number (if applicable): Click here to enter text.

Q#1.5: If no Study ID available, may add study acronym here so it doesn't show up as blank in the approval letter

HELP TEXT:

This number refers to a code or short identifier used by the lead researcher/lead research group/sponsor to identify the study. If included/applicable, this information will appear in REB letters.

1.6 *Upload protocol (clean final version with no changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: PROTOCOL

1.7 *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 emails. The short title is not included in REB letters): Click here to enter text.

1.8 *Who is the study sponsor?

*Sponsor organization name: Click here to enter text.

*Contact email: Click here to enter text.

CONTACT TYPE: MAIN SPONSOR CONTACT

HELP TEXT:

The sponsor is an individual, corporate body, institution or organization that takes responsibility for the initiation and management of the study. For trials subject to the Canadian Food and Drugs Act and applicable Regulations, the sponsor is the individual/body holding the authorization with Health Canada.

1.9 *Is this an Investigator-initiated study?

☐Yes ☐No

HELP TEXT:

An investigator-initiated study typically refers to a research study in which the investigator designs and implements the study protocol including responsibility for data analysis and publication.

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

☐Yes ☐No

***If 'Yes' to question 1.10, question 1.10.1-1.10.2 appears*:**

1.10.1 ***Enter the approximate date (e.g., month/year) the study started:** Click here to enter text.

1.10.2 ***Are there any known issues (e.g., unexpected risks, slow recruitment) with the study?**

☐Yes ☐No

HELP TEXT:

"Issues" refers to any unexpected challenges facing the study. Issues may be related to participant safety, site initiation, or study design (for example).

If 'Yes' to question 1.10.2, question 1.10.3 appears:

1.10.3 ***Describe the issues with the study:** Click here to enter text.

1.11 ***When is overall (global) enrolment expected to end?** Click here to enter text.

1.12 ***Has this study undergone a scientific review?**

☐Yes ☐No

Q1.12: Based on the definition of a Scientific review, most studies should have had this review done and the response should be YES ; This review could be either an internal or external review or peer review

HELP TEXT:

Scientific review refers to a review for scientific merit and is inclusive of the following elements: background literature review, scientific design, statistical data analysis, and participant risk assessment.

If 'Yes' to question 1.12, questions 1.12.1 – 1.12.2 appear:

1.12.1 ***Describe (e.g., names of committees or individuals involved in the review, whether review is in process or completed, etc.):** Click here to enter text.

1.12.2 Upload any relevant scientific review documents or correspondence (if applicable):

Q#1.12.2 – This field is NOT mandatory

UPLOAD DOCUMENT - DOCUMENT TYPE:
SCIENTIFIC OR SCHOLARLY REVIEW

1.13 ***Has any REB refused to approve this study, or has the study been withdrawn from any other REB due to that REB's concerns?**

☐Yes ☐No

If 'Yes' to question 1.13, questions 1.13.1 – 1.13.2 appear:

1.13.1 ***Provide additional details about the rejection or withdrawal, including the reasons/concerns:**
Click here to enter text.

1.13.2 Upload any relevant documents (if applicable):

UPLOAD DOCUMENT - DOCUMENT TYPE: REB REJECTION DOCUMENTS

HELP TEXT:

Any relevant documents refer to documents which are believed to be of material importance to the review (e.g., another REB's disapproval or rejection letter).

1.14 ***How many sites do you expect will participate in this study through Stream?** Click here to enter text.

1.14.1 ***Select all provinces/territories with research sites participating on this study through Stream:**

- ☐ Alberta
- ☐ British Columbia
- ☐ Manitoba
- ☐ New Brunswick
- ☐ Newfoundland & Labrador
- ☐ Northwest Territories
- ☐ Nova Scotia
- ☐ Nunavut
- ☐ Ontario
- ☐ Prince Edward Island (P.E.I)
- ☐ Yukon

If 'Ontario' is selected in question 1.14:

1.14.2 ***Select the name of each Ontario site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

Q#1.14.2: Application should have at least 2 sites ; Please contact OCREB if this is not the case

If 'British Columbia' is selected in question 1.14:

1.14.3 ***Select the name of each British Columbia site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

If 'Quebec' is selected in question 1.14:

1.14.4 ***Select the name of each Quebec site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

If 'Manitoba' is selected in question 1.14:

1.14.5 ***Select the name of each Manitoba site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

If 'Alberta' is selected in question 1.14:

1.14.6 ***Select the name of each Alberta site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

If 'New Brunswick' is selected in question 1.14:

1.14.7 ***Select the name of each New Brunswick site participating on the study through Stream (answer question once per site):**

Choose an item.

Add Another

If 'Nova Scotia' is selected in question 1.14:

1.14.8 *Select the name of each Nova Scotia site participating on the study through Stream (answer question once per site):

Choose an item.

Add Another

If 'Newfoundland & Labrador' is selected in question 1.14:

1.14.9 *Select the name of each Newfoundland & Labrador site participating on the study through Stream (answer question once per site):

Choose an item.

Add Another

If 'P.E.I' is selected in question 1.14:

1.14.10 *Select the name of each P.E.I site participating on the study through Stream (answer question once per site):

Choose an item.

Add Another

If 'Yukon' is selected in question 1.14:

1.14.11 *Select the name of each Yukon site participating on the study through Stream (answer question once per site):

Choose an item.

Add Another

If 'Northwest Territories' is selected in question 1.14:

1.14.12 *Select the name of each Northwest Territories site participating on the study in CTO Stream (answer question once per site):

Choose an item.

Add Another

If 'Nunavut' is selected in question 1.14:

1.14.13 *Select the name of each Nunavut site participating on the study in CTO Stream (answer question once per site):

Choose an item.

Add Another

1.15 *Will a Contract Research Organization (CRO) be used for this study?

☐Yes

☐No

If 'Yes':

1.15.1 *Provide the name of the CRO Organization:

*Name of CRO organization : Click here to enter text.

*Email: Click here to enter text.

CONTACT TYPE: MAIN CRO CONTACT

1.16 *Indicate how the results will be broadly communicated to participants, substitute decision makers (SDMs) and other stakeholders (e.g., advocacy groups, scientific community):

TO PARTICIPANTS/SDMs

☐Each PI to provide debriefing at end of test session
☐Group debriefing
☐End of study letter
☐Publication(s)
☐Other
☐No Plan **[Exclusive]**

HELP TEXT:

For additional information about communicating results to participants please see the Participant Experience Toolkit.

If 'Other':

1.16.1 *Specify other: Click here to enter text.

If 'No plan':

1.16.2 *Justify no plan: Click here to enter text.

TO OTHER STAKEHOLDERS

☐Presentation(s)
☐Publication
☐Other
☐No plan

If 'Other':

1.16.3 *Specify other: Click here to enter text.

If 'No plan':

1.16.4 *Justify no plan: Click here to enter text.

SECTION 2.0 - STUDY DESCRIPTION

2.1 *Explain this study in lay or non-scientific language (e.g., language suitable for a media release): (max 300 words) Click here to enter text.

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.

2.2 *What is the rationale for this study (i.e., why is this study being done)? (max 300 words) Click here to enter text.

2.3 *What is the overall anticipated public and/or scientific benefit of the study? Click here to enter text.

2.4 *Summarize the study design/methodology: Click here to enter text.

HELP TEXT:

Study design/methodology refers to the type of study and the processes and tools by which the study objectives will be reached. Study processes may include restrictions or modifications to the usual lifestyle activities and should be entered into question 2.13; justification would be part of the rationale for the study question (question 2.2); study procedures, what participants will actually complete as part of this study, should be entered into question 2.13.

2.4.1 *Does the study include a control group?

☐Yes ☐No

HELP TEXT:

Members of a control group receive a standard of care, a placebo or no treatment. There may be multiple control groups as part of your clinical trial.

If 'Yes':

2.4.1.1 *Provide a rationale for including a control group: Click here to enter text.

2.5 *How many participants will be enrolled in the overall study (i.e., what is the sample size)? Click here to enter text.

2.6 *This study will target the following population(s) (select all that apply):

☐Patients
☐Healthy volunteers
☐Students
☐Staff
☐People with mental health issues
☐Institutionalized people
☐Prisoners/persons in detention
☐People in poverty/economically disadvantaged
☐Educationally disadvantaged people
☐People who are unable to read or write

Q2.6: for most new oncology studies, the response will be 'patients' for adult studies and 'patients and children' for paediatric studies.

☐Children
☐Neonates
☐People in medical emergencies
☐People who lack capacity to consent
☐Cognitively impaired individuals
☐Individuals with physical disabilities
☐People who have trouble understanding and/or producing speech (e.g., require special support including the use of assistive devices)
☐Adult individuals who are temporarily unable to provide consent (e.g. unconscious)
☐Pregnant women
☐Elderly people
☐People in palliative care
☐People in long-term care
☐Indigenous peoples and/or other distinct communities
☐Other

HELP TEXT:

Target means the study is designed to include individuals from selected populations (e.g., does not refer to incidental inclusion of these populations and in the event of incidental inclusion of Indigenous peoples, Indigenous identity or membership in an Indigenous community will not be used as a variable for the purpose of analysis of the research data).

People in poverty/economically disadvantaged refers to individuals who lack sufficient resources to meet basic needs like food, shelter and clothing and also those who experience limitations on opportunities, choices, and participation in society as a result of their financial status.

Children or the term "child" refers to individuals who have not yet reached the age of majority

Indigenous peoples refers to persons of First Nations, Inuit, or Métis descent, regardless of where they reside and whether or not their names appear on an official register.

Other communities are those distinguishable by a combination of their ethnic, racial, faith-based and cultural make-up or orientations, as well as those communities that may self-identify as a visible minority.

If 'Other':

2.6.1 *Specify other: Click here to enter text.

2.7 *Provide the inclusion criteria: Click here to enter text.

2.8 *Provide the exclusion criteria: Click here to enter text.

2.9 *What are the primary objectives of this study? Click here to enter text.

2.10 *What are the secondary objectives of this study? Click here to enter text.

2.11 ***Describe the accepted Standard of Care (SOC) for study participants:** Click here to enter text.

2.12 ***Will management/treatment/usual therapy of a participant's condition be prolonged, delayed, withdrawn or denied because of this study?**

☐Yes ☐ No

If 'Yes':

2.12.1 ***Explain and include the justification:** Click here to enter text.

2.13 ***What study related procedures will be carried out that are not considered part of the diagnostic, therapeutic "routine" or standard of care?** Click here to enter text.

2.14 ***Provide the section and page number in the protocol that describes how the study data will be analyzed.**

Section: Click here to enter text.

Page Number: Click here to enter text.

Add Another

2.15 ***Are there any associated sub-studies or companion studies not already included in the main protocol that will be conducted at any of the sites using Stream?**

☐Yes ☐No

Q2.15: a sub-study or companion involves an investigation into a research question that is associated with the main trial. It is usually undertaken in the same population or sub-population of participants, and it may involve additional measurements, or data collection. If you are unsure, please contact OCREB for guidance.

HELP TEXT:

"Not already included in the main protocol" refers to associated sub-studies or companion studies which are outside of the current application.

If 'Yes':

2.15.1 Upload sub-study or companion protocol

UPLOAD DOCUMENT - DOCUMENT TYPE: SUB-STUDY OR COMPANION PROTOCOL

If 'Yes':

2.15.2 ***Describe the sub-study including the rationale for it:** Click here to enter text.

2.16 ***Is this protocol directly related to a study previously approved through Stream?**

☐Yes ☐No

HELP TEXT:

Directly related refers to a different study that was previously submitted and reviewed through Stream and that is connected in some way to the currently submitted study.

If 'Yes':

2.16.1 ***Provide the Stream Project ID:** Click here to enter text.

2.16.2 ***How does this protocol relate to the previously submitted protocol?** Click here to enter text.

2.17 ***This study will involve the following (select all that apply):***

☐Drugs, Biologics (including vaccines), Genetic Therapies, Cannabis or Radiopharmaceuticals
☐Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))
☐Medical Devices or Software as Medical Devices (may include Mobile Applications, Artificial-Intelligence/Machine Learning-based medical devices as per the Medical Device Directorate)
☐Biological specimen collection (e.g., blood/tissue for pharmacokinetic (PK), biomarker, biobanking, genetic testing, etc., excluding specimens taken as part of normal care or for safety)
☐ Stem cell research
☐Radiation (including tests involving exposure to radiation)
☐Surveys/Questionnaires/Interviews/Focus Groups
☐Other health related interventions not listed above

Q2.17: "radiation" must be selected if there is ANY radiation used in the study, including for diagnostic purposes.

HELP TEXT:

Cannabis refers to any part of a cannabis plant, including phytocannabinoids, other than a non-viable seed of a cannabis plant, a mature stalk, without any leaf, flower, seed or branch, of such a plant, or fibre derived from a stalk or the root or any part of the root of such a plant.

Natural Health Product refers to substances such as vitamins and minerals, herbal medicines, homeopathic preparations, energy drinks, probiotics, amino and other essential fatty acids and many alternative and traditional medicines.

Biobanking refers to a large repository of donated biospecimens/human DNA and/or its information collected from volunteers with or without disease which is used to identify genes that contribute to human disease. The biobank could be leveraged for future research that may or may not be related to the study and a separate REB application may be required

Survey refers to the action of asking a question or series of questions in order to gather information.

Questionnaires refer to a set of questions that are given to participants in order to collect facts or opinions.

Interviews refer to a meeting at which information is obtained from a person.

Focus group refers to a meeting at which information is obtained from multiple people.

Software as Medical Device refers to active software that is intended to acquire, process, or analyze a medical image, or information from an in vitro diagnostic device or a measurement/signal from a monitoring device or imaging device, and/or intended for the purpose of supporting or providing recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition.

2.17a appears only if 'Drugs, Biologics (including vaccines), Genetic Therapies, Cannabis or Radiopharmaceuticals' AND/OR 'Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))' AND/OR 'Medical Devices or Software as Medical Device (SaMD)' is selected in 2.17:

2.17a *Does this study require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Authorization)?

☐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 Authorization (ITA) under the Medical Devices Regulations

☐No **[EXCLUSIVE]**

Drugs, Biologics, Genetic Therapies or Radiopharmaceuticals

This section appears only if 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in 2.17a.

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

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

☐Investigational

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

2.17.1.1 *Describe how the product(s) is/are being used in the study outside the conditions of use approved by Health Canada: Click here to enter text.

2.17.2 *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)

HELP TEXT:

Clinical Trial Application (CTA) refers to 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 'Investigator Brochure (IB)':

2.17.2.1 *Upload Investigator Brochure (IB) and/or Product Monograph (PM):

UPLOAD DOCUMENT - DOCUMENT TYPE: IB, PM, OR DEVICE IFU

2.17.3 *Indicate the status of Health Canada Clinical Trial Application:

☐No Objection Letter pending

☐No Objection Letter enclosed

Q2.17.3: NOL submission is not required by OCREB ; document uploaded here will NOT be acknowledged in the

If 'No Objection Letter Enclosed':

2.17.3.1 *Upload document:

UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA

Health Products

This section appears only if 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' was selected from list in question 2.17a.

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

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

☐Investigational

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).

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

2.17.4.1 *Describe how the Health Product is being used in the study outside of the parameters of the conditions of use approved by Health Canada: Click here to enter text.

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

☐Investigator Brochure (IB)

☐Product Monograph (PM)

If 'Investigator Brochure (IB)':

2.17.5.1 *Upload Investigator Brochure (IB) and/or Product Monograph (PM):

UPLOAD DOCUMENT - DOCUMENT TYPE: INVESTIGATOR BROCHURE

2.17.6 *Indicate the status of the Health Canada Clinical Trial Application:

☐Notice of Authorization pending

☐Notice of Authorization enclosed

If 'Notice of Authorization Enclosed':

2.17.6.1 *Upload document:

UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA

Medical Devices

These questions appear only if 'Medical Devices' was selected from list in question 2.17.

2.17.7 *Health Canada medical device classification for the intended use of the device(s) in this study (select all that apply):

☐Class I

☐Class II

☐Class III

☐Class IV

HELPTEXT:

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.

If 'Yes – an Investigational Testing Authorization (ITA) under the Medical Devices Regulations' selected in question 2.17a, the following question appears:

2.17.8 *Name of all device components, parts and/or accessories as per product label for devices covered under the ITA with Health Canada: Click here to enter text.

Add Another

HELP TEXT:

Investigational Testing Authorization (ITA) refers to an application made to Health Canada requesting authorization to conduct a clinical trial involving a medical device in Canada. If the study involves

multiple medical devices, press "Add Another" to answer the question once for each device used in the study.

If 'Yes – an Investigational Testing Authorization (ITA) under the Medical Devices Regulations' selected in question 2.17a, questions 2.17.9-2.17.12 appear:

2.17.9 *Indicate the status of the investigational 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':

2.17.9.1 *Describe how the investigational device component(s), parts and/or accessories is/are being used in the study outside of the parameters of the conditions of use approved by Health Canada: Click here to enter text.

2.17.10 *Does the investigational device(s) contain a drug?

☐Yes ☐No

If 'Yes':

2.17.10.1 *Drug used: Click here to enter text.

2.17.11 *For each investigational device covered under the ITA, upload the Instructions for Use (IFU) or equivalent:

UPLOAD DOCUMENT - DOCUMENT TYPE: INSTRUCTIONS FOR USE

2.17.12 For each investigational device covered under the ITA, upload the Health Canada Letter of Authorization, if available:

UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA

US Regulatory Requirements

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

☐Yes ☐No

2.17.14 *Is this research supported by the United States federal government?

☐Yes ☐No

HELP TEXT:

If your research study is supported by, conducted in collaboration with or is funded by a United States government agency (such as the National Cancer Institute (NCI), Department of Health and Human Services (DHHS), Department of Justice (DOJ)) that is subject to the Common Rule.

Biological Specimen Collection

This section appears only if 'Biological Specimen Collection' was selected from list in question 2.17.

2.17.15 *What type of specimen(s) will be collected from the study participants? Click here to enter text.

If 'Stem cell research' selected in question 2.17, questions 2.17.16 and 2.17.17 appear:

2.17.16 *Describe the stem cell component of the study: Click here to enter text.

2.17.17 Upload the Stem Cell Oversight Committee (SCOC) approval letter (if applicable):

UPLOAD DOCUMENT – DOCUMENT TYPE: SCOC APPROVAL LETTER

HELP TEXT:

As per TCPS 2 Article 12.10: Research involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source, and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by SCOC and an REB. The researcher shall provide evidence of SCOC approval to the REB.

2.17.18 *How will the 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

HELP TEXT:

Prospectively refers to collection which will be done in the future.

If Other:

2.17.18.1 *Specify details: Click here to enter text.

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

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

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

☐Stored or retained or banked for future unspecified research

HELP TEXT:

Purposes of this study means collection of specimens is necessary to achieve the objectives of the study.

Genetic testing involves examining a person's DNA (the chemical database that carries instructions for the body's functions). Genetic testing can reveal changes or alterations in a person's genes that may cause illness or disease including inherited diseases. Genetic testing also can be used to determine a person's biological relationship (e.g., parent), or a person's ancestry.

Stored or retained or banked for future unspecified research refers to the retention of samples and/or data as part of a study that potentially will be used at a later date for a defined purpose or for an as yet undefined purpose.

If 'For the purposes of this study (excluding specimens taken as part of normal care or for safety)' is selected in 2.17.19, questions 2.17.20-2.17.25 appear:

You have indicated samples are collected 'for the purposes of this study'. Answer questions 2.17.20-2.17.25 for these samples only.

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

☐Optional

☐Mandatory

2.17.21 *Describe how the specimens will be used in this study: Click here to enter text.

2.17.22 *Where will the specimens be sent (e.g., name & address including country)? Click here to enter text.

2.17.23 *Indicate how long the specimens will be retained: Click here to enter text.

2.17.24 *Describe what will happen to the specimens at the end of that period (e.g., destroyed, returned):

Click here to enter text.

2.17.25 *Will study participants be provided the opportunity to withdraw specimens collected for the purpose of the research study?

☐Yes ☐No

If 'Yes':

2.17.25.1 *Are there any limitations to the withdrawal? Click here to enter text.

If 'No':

2.17.25.2 *Explain why not: Click here to enter text.

If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 2.17.19, questions 2.17.26 – 2.17.32 appear:

You have indicated samples are collected 'for genetic testing'. Answer questions 2.17.26-2.17.32 for the genetic testing only.

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

☐Optional

☐Mandatory

2.17.27 *Describe the planned genetic testing: Click here to enter text.

2.17.28 *Where will specimens be sent (e.g. name & address including country)? Click here to enter text.

2.17.29 *Indicate how long the specimens will be retained: Click here to enter text.

2.17.30 *Describe what will happen to the specimens at the end of that period (e.g., destroyed, returned):

Click here to enter text.

2.17.31 *Will study participants be provided the opportunity to withdraw specimens collected for the purpose of genetic testing?

☐Yes ☐No

If 'Yes':

2.17.31.1 *Describe any limitations to the withdrawal: Click here to enter text.

If 'No':

2.17.31.2 *Explain why not: Click here to enter text.

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

☐Yes ☐No

If 'Yes':

2.17.32.1 *Describe what information will be shared and with whom? Click here to enter text.

2.17.32.2 *How will consent be obtained to release this information? Click here to enter text.

2.17.32.3 *Describe whether participants will be given the option of not receiving information about themselves: Click here to enter text.

If 'No':

2.17.32.4 *Explain/justify: Click here to enter text.

If 'Stored or retained or banked for future unspecified research' is selected in 2.17.19, questions 2.17.33-2.17.44 appears:

You have indicated samples are 'stored or retained or banked for future unspecified research'. Answer questions 2.17.33-2.17.44 for this use only.

2.17.33 *Indicate whether the sample storage/retention/banking for future unspecified research (and collection of any additional samples for this purpose, if applicable) is optional:

☐Yes – this is optional

☐No - this application is strictly for establishing a repository

HELP TEXT:

Please note as per TCPS 2 2022 the sample storage/retention/banking for future unspecified must be optional.

2.17.34 *Where will the samples be stored? For example, where is the biobank(s)/repositories located (e.g., name of bank & address including country) or where will the lead researcher/research group be storing the samples (e.g., name of the institution and address including country)? Click here to enter text.

2.17.35 *Where will the associated data be located (e.g., name & address including country)? Click here to enter text.

2.17.36 *Who will be the custodian of the specimens that will be stored or retained or banked for future unspecified research? Click here to enter text.

HELP TEXT:

Custodian refers to a person or organization/institution who is overall responsible for the specimens.

2.17.37 *Provide a general description of the nature and types of future research that may be conducted: Click here to enter text.

2.17.38 *Could specimens be shared with researchers outside of Canada?

☐Yes ☐No

2.17.39 *Who will have access to the banked specimens? Click here to enter text.

2.17.40 *Could banked samples be used for whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant?

☐Yes ☐No

2.17.41 *Could future research include sequencing or technologies that might result in identification of material incidental findings?

☐Yes ☐No

2.17.42 *Is it anticipated that data derived from the samples could be linked with other data about participants, either in public (for example, social media, public registries) or personal records (for example, medical records, administrative databases)?

☐Yes ☐No

2.17.43 *Describe what will happen to the 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): Click here to enter text.

2.17.44 *Will study participants be provided the opportunity to withdraw banked specimens?

☐Yes ☐No

If 'Yes':

2.17.44.1 *Describe any limitations to the withdrawal: Click here to enter text.

If 'No':

2.17.44.2 *Explain why not: Click here to enter text.

Radiation

This section appears only if 'Radiation' was selected from list in question 2.17.

2.17.45 *Indicate the sources of radiation/radiopharmaceutical exposure (select all that apply):

☐Diagnostic

☐Radiation therapy

☐Other

If 'Diagnostic':

2.17.45.1 ***Specify diagnostic:** Click here to enter text.

If 'Other':

2.17.45.2*Specify other: Click here to enter text.

2.17.46 ***Will research participants be exposed to radiation/radiopharmaceuticals over and above what they would receive with standard of care?**

☐Yes ☐No

If 'Yes':

2.17.46.1*Describe the radiation exposure that is above standard of care: Click here to enter text.

Surveys/Questionnaires/Interviews/Focus Groups

If 'Surveys/Questionnaires/Interviews/Focus Groups' selected in question 2.17; questions 2.17.47 - 2.17.49 appear:

2.17.47 ***How will the surveys/questionnaires/interviews/focus groups be administered (e.g., paper, electronic)?** Click here to enter text.

HELP TEXT:

For electronic means list the name of the tool being used to administer and/or collect the data (e.g. emails, videoconferencing, smartphone application, portal developed by sponsor, web-based surveys such as Survey Monkey or REDcap).

2.17.48 ***Upload all surveys/questionnaires, screen shots and/or interviews/focus group scripts:**

UPLOAD DOCUMENT - DOCUMENT TYPE: SURVEYS OR INTERVIEW/FOCUS GROUP SCRIPTS

Q2.17.48: Please include the Questionnaire names as part of the document name (e.g., EQ-5D-5L; QLQ-C30; FACT-G, etc.) for proper referencing in the approval letter

2.17.49 Provide the URL for any electronic materials (as applicable): Click here to enter text.

Add Another

HELP TEXT:

Please ensure that a copy of each of these materials is uploaded in question 2.17.48.

Other Health Related Interventions

If 'Other Health Related Interventions' selected in questions 2.17:

2.17.50 ***Other Health Related Interventions**

☐Cognitive behavioural therapy

☐Surgery

☐Exercise

☐Device based apps or wearable devices

☐Other:

HELP TEXT:

Device based applications or wearable devices are tools that collects real-time information such as heart-rate, heart rhythm, blood pressure, location (e.g. Fitbit).

If 'Other':

2.17.50.1 *Specify other: Click here to enter text.

If 'Device based apps or wearable devices':

2.17.50.2 *Specify the name(s) of the device based apps or wearable devices: Click here to enter text.

SECTION 3.0 - CLINICAL TRIAL INFORMATION

3.1 *Phase of trial (select all that apply):

☐Pilot
☐Phase I
☐Phase II
☐Phase III
☐Phase IV
☐Other:

If 'Other':

3.1.1 *Specify other: Click here to enter text.

3.2 If this is a multi-phase or combination phase trial (e.g., phase I/II), specify whether this submission is for REB review of one phase only or of both (e.g., for REB review of phase II only when phase I of a phase I/II study has been completed): Click here to enter text.

3.3 *Will the study be registered in a public registry?

☐Yes ☐No

If 'Yes':

3.3.1 Provide the name of the registry (e.g., clinicaltrials.gov): Click here to enter text.

3.3.2 Provide the registration #: Click here to enter text.

Or,

☐Pending

If 'No':

3.3.3 *Justify: Click here to enter text.

3.4 *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':

3.4.1 *Justify placebo: Click here to enter text.

If 'Sham procedure(s)':

3.4.2 *Justify sham procedure(s): Click here to enter text.

If 'Washout':

3.4.3 *Justify washout: Click here to enter text.

If 'Withholding treatment':

3.4.4 *Justify withholding treatment: Click here to enter text.

If 'No-treatment arm':

3.4.5 *Justify no-treatment arm: Click here to enter text.

3.5 If applicable, describe the provisions made to break the code of a double-blind study in an emergency situation: Click here to enter text.

3.6 *Is there a potential for incidental findings in the research?

☐Yes ☐No

HELP TEXT:

Incidental findings refers to unanticipated discoveries made in the course of research that are outside the scope of the research. The following link can be used as a resource: Panel on Research Ethics: How to Address Material Incidental Findings.

If 'Yes':

3.6.1 *Describe how incidental findings will be managed and under what circumstances they would be disclosed to study participants: Click here to enter text.

Q3.6.1 : for most OCREB studies, there will not be any expected return of incidental findings. If this is the case, indicate it as such. If this changes during the conduct of the study, an amendment must be submitted.

If actionable/material incidental findings are anticipated or possible for this study (e.g. WGS being done), describe the findings and the plan for disclosure to participants (with consent), or provide the rationale for non-disclosure.

3.7 *Identify the research area (select all that apply):

- ☐ Bacterial and Fungal Diseases
- ☐ Behaviors and Mental Disorders
- ☐ Blood and Lymph Conditions
- ☐ Cancers and Other Neoplasms
- ☐ Digestive System Diseases
- ☐ Diseases and Abnormalities at or Before Birth
- ☐ Disorders of Environmental Origin
- ☐ Ear, Nose, and Throat Diseases
- ☐ Eye Diseases
- ☐ Gland and Hormone Related Diseases
- ☐ Heart and Blood Diseases
- ☐ Immune System Diseases
- ☐ Mouth and Tooth Diseases
- ☐ Muscle, Bone, and Cartilage Diseases
- ☐ Nervous System Diseases
- ☐ Nutritional and Metabolic Diseases
- ☐ Occupational Diseases
- ☐ Parasitic Diseases
- ☐ Respiratory Tract (Lung and Bronchial) Diseases
- ☐ Skin and Connective Tissue Diseases
- ☐ Substance Related Disorders
- ☐ Symptoms and General Pathology

☐ Urinary Tract, Sexual Organs, and Pregnancy Conditions

☐ Viral Diseases

☐ Wounds and Injuries

☐ Determinants of Health

☐ Other

If 'Other':

3.7.1 *Specify other: Click here to enter text.

If 'Cancers and Other Neoplasms':

3.7.2 *Is this study being submitted to the Ontario Cancer Research Ethics Board (OCREB) for review?

☐Yes ☐No

SECTION 4.0 – RECRUITMENT

4.1 *How will potential participants learn/find out about the study? (Select all that apply):

☐Referral from healthcare providers *

***Please select this option if it is anticipated that patients will be referred to the oncologist /Study Investigator**

☐ Introduction from community partner (including health charity, advocacy organization, community group, etc.) or other groups

☐Advertisements, including brochures, newspaper, radio, flyers, posters, and/or web-based recruitment tools (participants will self-refer) **

****Please select this option if any recruitment materials are being submitted in the application**

☐Recruitment database

☐Third-party organization or recruitment company

☐Website

☐Social media

☐Video (recordings will not be reviewed without scripts)

☐Survey panel (e.g., Mechanical Turk)

☐Snowball sampling

☐From the investigator or other study team member(s) (e.g., for research involving colleagues, where potential participants are identified through the use of public information, or for institutions that have a permission to contact framework)*

***This should be selected for most if not all studies**

☐Other

If 'Other':

4.1.1*Specify other: Click here to enter text.

4.2 *How will participants initially be contacted by the research team? (Select all that apply):

☐Telephone

☐Email

☐In-person

☐Letter

☐Participants will contact the study team

☐Materials not ready at this time (to be submitted later)

☐Other

If 'Other' is selected in 4.2:

4.2.1 *Describe other methods of contact: Click here to enter text.

4.3 Upload all advertising/recruitment materials that will be used during the study, as applicable (e.g., telephone/email scripts, letters, posters, social media, website, etc.):

UPLOAD DOCUMENT - DOCUMENT TYPE: RECRUITMENT MATERIALS

All recruitment materials such as POSTERs, Brochures, etc. should be uploaded here. Note that OCREB <u>does not allow</u> inclusion of study drug name or Sponsor name and logos in recruitment materials so these should be removed before uploading the materials here

HELPTEXT:

Upload all materials associated with questions 4.1 and 4.2.

4.4 *Does the study exclude any participants based on culture, language, religion, race, disability, sexual orientation, ethnicity, linguistic proficiency, competency/capacity, sex, gender, age or other criteria?

☐Yes ☐No

If 'Yes':

This should be YES if inclusion criteria has age requirements or studies only apply to a specific sex (e.g. Prostate ca; Ovarian ca)

4.4.1 *Describe and justify: Click here to enter text.

4.5 *Which of the following criteria apply to this research (select all that apply)?

☐ The research conducted on First Nations, Inuit or Métis lands

☐ Recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup 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 Indigenous communities, peoples, language, history or culture

☐ None of the above

HELP TEXT:

Additional information and guidance on the ethical conduct of research involving the First Nations, Inuit and Métis peoples of Canada can be found in Chapter 9 of the Tri-Council Policy Statement (TCPS 2).

If any option other than 'none of the above' is selected, the following appears:

4.5.1*Is there a plan to engage the relevant community or communities?

☐Yes ☐No

If 'Yes':

4.5.1.1*Describe how the relevant communities have been or will be engaged: Click here to enter text.

If 'Yes':

Provide the following as applicable:

4.5.1.2 A preliminary or formal research agreement between the researcher and the responsible body at the research site:

UPLOAD DOCUMENT - DOCUMENT TYPE: PRELIMINARY OR FORMAL RESEARCH AGREEMENT

HELP TEXT:

A preliminary or formal research agreement refers to a document that serves as a primary means of clarifying and confirming mutual expectations and, where appropriate, commitments between researchers and communities.

Research site refers to the location(s) where research-related activities are actually conducted.

4.5.1.3 A written decision or documentation of an oral decision taken in a group setting to approve the proposed research or to decline further participation:

UPLOAD DOCUMENT - DOCUMENT TYPE: COMMUNITY ENGAGEMENT DECISION

4.5.1.4 A written summary of advice received from a culturally informed advisory group or ad hoc committee (e.g., an urban community of interest):

UPLOAD DOCUMENT - DOCUMENT TYPE: WRITTEN SUMMARY OF ADVICE

If 'No':

4.5.1.5 *Provide the rationale: Click here to enter text.

SECTION 5.0 - INFORMED CONSENT INFORMATION

5.1 *Will informed consent be obtained from potential participants (select all that apply)?

☐ Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)

☐ Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)

Note: The use of remote consent, use of a substitute decision maker (SDM) or different methods of documenting informed consent (e.g., written, verbal, implied) are NOT considered alterations

☐ Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)

☐ This study involves incapacitated patients experiencing a medical emergency and we are seeking authorization to proceed with the research intervention without the prior consent of participants/SDM (if this is your entire study population, select only this option – you do not need to separately select the 'alteration' and 'waiver' options above)

HELP TEXT:

A substitute decision maker (SDM) is the term used for the person who would make health and personal care decisions on participants' behalf when they are unable to do so. See the Health Care Consent Act for more information.

An alteration in consent means that there is a departure from the general principles of consent as described in Chapter 3 of TCPS 2. Alterations to consent requirements may include providing prospective participants with only partial disclosure about the purpose of the study, deceiving prospective participants entirely about the purpose of the study, and obtaining informed consent at a later time in the study. Alterations to consent should only be proposed to the extent necessary, i.e., to the minimal extent required in order to achieve the aims of the research.

A waiver of consent means that researchers do not propose to obtain informed consent in any way from participants or their substitute decision maker (SDM); there is no written or verbal study information provided to or discussed with participants. Review TCPS 2 Article 3.7A for prospective research, 5.5A for secondary use of identifiable information/data and/or 12.3A for secondary use of identifiable specimens to see if the research meets the criteria for a waiver of consent. Review PHIPA section 44 for research involving personal health information.

If 'Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)' is selected in 5.1, then question 5.2 will appear:

5.2 *A waiver of the requirement to obtain informed consent is being requested for:

☐ All participants/substitute decision makers (SDMs) **[Exclusive]**

☐ Some participants/SDMs **[Exclusive]**

If 'Some participants/SDMs':

5.2.1 *Describe the circumstances/participant population for whom you are seeking a waiver: Click here to enter text.

If 'Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)' is selected in 5.1, questions 5.3 and 5.4 appear:

Questions 5.3 and 5.4 below appear because you have indicated informed consent will not be obtained from some or all participants/SDMs:

5.3 *Explain why the waiver of consent is unlikely to have an adverse effect: Click here to enter text.

HELP TEXT:

Researchers seeking a waiver of the requirement to seek prior informed consent must justify that this will not have an adverse impact on the welfare of participants, including direct indirect or societal risks.

5.4 *Why/how it is impossible or impracticable to seek informed consent? Click here to enter text.

HELP TEXT:

Impracticable refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience.

If 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' is selected in 5.1, questions 5.5-5.7 appear:

Questions 5.5-5.7 below appear because you have indicated there will be a proposed alteration in the consent procedures:

5.5 *Describe the proposed consent procedures, including an explanation of the nature and extent of the proposed alteration: Click here to enter text.

HELP TEXT:

Alterations in consent refer to deferred or partial consent, or deception. Alterations to consent should only be proposed to the extent necessary, i.e., to the minimal extent required in order to achieve the aims of the research.

Please refer to the Tri-Council Policy Statement (TCPS 2) Chapter 3 for more information on the general principles of consent and alterations to these procedures.

5.6 *Explain why the alteration is unlikely to have an adverse effect: Click here to enter text.

HELP TEXT:

Researchers seeking an alteration in consent procedures must justify that this will not have an adverse impact on the welfare of participants, including direct indirect or societal risks.

5.7 *Why/how is it impossible or impracticable to conduct the research without the alteration? Click here to enter text.

HELP TEXT:

Impracticable refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience.

If 'Informed consent/assent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' OR 'Informed consent/assent will not be obtained from some or all participants/substitute decision makers…'is selected in 5.1, question 5.8 appears:

5.8 *Is there a plan to provide a debriefing to participants which may also offer participants the possibility of refusing consent and/or withdrawing data/specimens?

☐Yes ☐No

HELP TEXT:

Debriefing must be a part of all research involving waiver of consent or another alteration to consent requirements whenever it is possible, practicable and appropriate. The lack of prior consent, or of fully informed consent, may be addressed through debriefing conducted as soon as possible following participants' involvement in the research, and within a timeframe that allows participants to withdraw their data or human biological materials (where possible, practicable and appropriate).

Guidance on debriefing can be found in the Tri-Council Policy Statement, Article 3.7 (A and B).

If 'Yes' to 5.8:

5.8.1 *Describe the debriefing plan: Click here to enter text.

If 'No':

5.8.2 *Justify why participants will not be debriefed: Click here to enter text.

If 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)' or 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' is selected in 5.1, or 'Some participants/SDMs' in 5.2 then questions 5.9-5.10 appear:

5.9 *How will the informed consent discussion be held? (Select all that apply):

☐ In person
☐ Remote
☐ No discussion proposed

HELP TEXT:

For the purposes of this application, remote consent refers to situations where informed consent is obtained when the participant and the person conducting the consent discussion/obtaining informed consent are not physically in the same room (e.g., consent discussion held by phone, tele/videoconference).

If 'No discussion proposed':

5.9.1 *Justify why no discussion proposed: Click here to enter text.

5.10 *Indicate how informed consent from participants/substitute decision makers (SDMs) will be documented (select all that apply):

☐ Written
☐ Verbally
☐ Implied consent
☐ Other

HELP TEXT:

Written consent: a process where the participant personally signs and dates the informed consent form (ICF).

Verbal consent: a consent process where the participant does not personally sign or date the ICF; instead, their consent is documented by the person conducting the consent discussion.

Implied consent: The research team concludes that the participant has given informed consent based on their action or inaction in particular factual circumstances. For example, when an individual completes a survey after being provided with written information about the study, the research team may reasonably infer that the participant consents to provide this information for research purposes. Implied consent does not require the participant to clearly state/affirm their consent (e.g., by signing a consent, a verbal consent process, or selecting 'I agree' on an online survey).

Reminder: Not all methods of documentation are appropriate/permissible for all studies. There may be restrictions based on funders, privacy legislation, and government regulations. Researchers must not propose methods of documentation that are not permitted for their study.

If 'Other' is selected in 5.10, 5.10.1 will appear:

5.10.1 *Describe the proposed documentation process: Click here to enter text.

If 'Written' is selected in 5.10, 5.10.2 will appear:

5.10.2 *Is there a proposal to use a central e-consent platform/consent repository for this study (i.e., will electronic consent forms be stored outside of the site where informed consent is obtained?):

☐Yes ☐No

If 'Yes', 5.10.2.1 - 5.10.2.2 will appear:

5.10.2.1 *What organization/institution is hosting the e-consent platform? Click here to enter text.

5.10.2.2 *Where will the consent forms be stored? (Location of data storage including country): Click here to enter text.

If 'This study involves incapacitated patients experiencing a medical emergency…' is selected in 5.1, questions 5.11-5.18 appear'

Questions 5.11-5.18 below appear because you have indicated This study involves incapacitated patients experiencing a medical emergency:

5.11 *Is there any standard efficacious care for this medical condition?

☐Yes ☐No

If 'Yes':

5.11.1 *Describe/explain: Click here to enter text.

5.12 *Does the research offer a realistic possibility of direct benefit to the participant in comparison with standard care?

☐Yes ☐No

If 'Yes':

5.12.1 *Describe/explain: Click here to enter text.

5.13 *Is the study population limited to patients who require immediate intervention due to a serious threat?

☐Yes ☐No

If 'Yes':

5.13.1 *Describe/explain why immediate intervention is required/cannot wait until the participant regains capacity or SDM is located: Click here to enter text.

5.14 *With respect to obtaining consent from the SDM prior to proceeding with the research:

How will this informed consent discussion be held? (Select all that apply):

☐ In person
☐ Remote
☐ No discussion proposed

HELP TEXT:

For the purposes of this application, remote consent refers to situations where informed consent is obtained when the participant and the person conducting the consent discussion/obtaining informed consent are not physically in the same room (e.g., consent discussion held by phone, tele/videoconference, etc.).

If 'No discussion proposed':

5.14.1 *Justify why no discussion proposed: Click here to enter text.

5.15 *With respect to obtaining consent from the SDM prior to proceeding with the research:

How will informed consent from substitute decision makers (SDMs) be documented? (Select all that apply):

☐ Written
☐ Verbally
☐ Other

HELP TEXT:

Written consent: a process where the participant personally signs and dates the informed consent form (ICF). This includes scenarios where the participants signs via electronic signature applications and/or e-consent tools/platforms, as well as original/wet-ink signature participant signatures and/or scanned/faxed copies of handwritten participant signature. For clarity, the key is that the participant is personally providing their signature/dating their signature, regardless of the method (e.g., wet-ink, electronic) or tool (e.g., paper, platform, etc.) used to obtain the signature.

Verbal consent: a consent process where the participant does not personally sign or date the ICF; instead, their consent is documented by the person conducting the consent discussion.

Reminder: Not all methods of documentation are appropriate/permissible for all studies. There may be restrictions based on funders, privacy legislation, and government regulations. Researchers must not propose methods of documentation that are not permitted for their study.

If 'Other' is selected in 5.15:

5.15.1 *Describe the proposed documentation process: Click here to enter text.

5.16 *When the previously incapacitated participant regains decision-making capacity, or when the SDM is found, consent needs to be obtained for the continuation of the project (including continued use of the data) and subsequent research procedures (if applicable):

How will this informed consent discussion be held? (Select all that apply):

☐ In person
☐ Remote
☐ No discussion proposed

HELP TEXT:

For the purposes of this application, remote consent refers to situations where informed consent is obtained when the participant and the person conducting the consent discussion/obtaining informed consent are not physically in the same room (e.g., consent discussion held by phone, tele/videoconference, etc.).

If 'No discussion proposed':

5.16.1 *Justify why no discussion proposed:

5.17 *When the previously incapacitated participant regains decision-making capacity, or when the SDM is found, consent needs to be obtained for the continuation of the project (including continued use of the data) and subsequent research procedures (if applicable).

How will this informed consent be documented? (Select all that apply):

☐ Written
☐ Verbally
☐ Other

HELP TEXT:

Written consent: a process where the participant personally signs and dates the informed consent form (ICF). This includes scenarios where the participants signs via electronic signature applications and/or e-consent tools/platforms, as well as original/wet-ink signature participant signatures and/or scanned/faxed copies of handwritten participant signature. For clarity, the key is that the participant is personally providing their signature/dating their signature, regardless of the method (e.g., wet-ink, electronic) or tool (e.g., paper, platform, etc.) used to obtain the signature.

Verbal consent: a consent process where the participant does not personally sign or date the ICF; instead, their consent is documented by the person conducting the consent discussion.

Reminder: Not all methods of documentation are appropriate/permissible for all studies. There may be restrictions based on funders, privacy legislation, and government regulations. Researchers must not propose methods of documentation that are not permitted for their study.

If 'Other' is selected in 5.17:

5.17.1 *Describe the proposed documentation process: Click here to enter text.

5.18 *Is a waiver of the requirement to obtain consent being sought in order to use the data collected if an SDM cannot be found and the participant expires prior to providing consent?

☐Yes ☐No

If 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)' or 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' is selected in 5.1, OR 'Some participants/SDMs' is selected in 5.2, questions 5.19-5.21 appear:

5.19 *Does this study permit/require the enrollment of participants who lack capacity to consent (either temporarily or permanently)?

☐Yes ☐No

If 'Yes', 5.19.1 and 5.19.2 appear:

5.19.1 *Will assent be obtained from these study participants?

☐Yes ☐No

If 'No':

5.19.1.1 *Why not? Click or tap here to enter text.

5.19.2 *Considering the study population and study timelines, is it reasonably foreseeable/expected that participants may achieve or regain capacity during the course of the study?

☐Yes ☐No

5.20 *Is it foreseeable that participant(s) may lose decision-making capacity during the study?

☐Yes ☐No

5.21 *Which of the following will be used? (Select all that apply):

☐Consent form(s)

☐Assent form(s)

☐ Debriefing material(s) (e.g., script and/or form)

☐ Other consent/assent material(s) *

***This should be selected if participant materials such as Wallet card or Drug Diaries are being submitted**

If 'Consent form(s)':

5.21.1 *Upload clean versions of all proposed consent forms (e.g., screening, main, optional, parent, participant, etc.):

Please note that the use of the OCREB Consent template is MANDATORY for OCREB submissions; link available on our website: https://ocreb.ca/applicants/guidelines-templates/

UPLOAD DOCUMENT - DOCUMENT TYPE: STUDY-WIDE CONSENT FORM

HELP TEXT:

The correct informed consent form template must be used to create the main study-wide consent form (Except for studies which will be reviewed by OCREB which require the use of the OCREB consent template

CHEER Studies must use the CHEER informed consent form template to create the study-wide consent form.

Refer to the CTO website for further details (for CanReview studies, please refer to the CanReview website).

If you have questions, submit a ticket via the Stream Helpdesk.

If 'Assent form(s)':

5.21.2 *Upload clean versions of all proposed assent form(s):

UPLOAD DOCUMENT – DOCUMENT TYPE: STUDY-WIDE ASSENT FORMS

If 'Debriefing materials (e.g., script and/or form):

5.21.3 *Upload clean versions of all proposed debriefing material(s):

UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'Other consent/assent material(s):

5.21.4 *Upload clean versions of any other materials that will be distributed to study participants (e.g., diaries, wallet cards):

UPLOAD DOCUMENT - DOCUMENT TYPE: STUDY MATERIALS

SECTION 6.0 - SAFETY

6.1 *List the known short-term and long-term risks or discomforts associated with study participation, including approximate rates of occurrence, severity and reversibility: Click here to enter text.

HELP TEXT:

Risks and discomforts should consider and address physical, emotional/psychological and social/legal factors.

If 'Placebo', 'Sham procedures', 'Washout', 'Withholding treatment', or 'No-treatment arm' is selected in 3.4, question 6.2 appears:

6.2 *For studies involving placebo, sham procedure(s), washout, withholding treatment/intervention or no-treatment/no-intervention arm, list any risks related to withdrawal or absence of treatment/intervention: Click here to enter text.

6.2.1 *Describe the provisions to minimize risks to participants: Click here to enter text.

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

☐Yes ☐No

If 'Yes':

6.3.1 *Provide summary of the relevant data (e.g., teratogenicity (birth defects) or embryotoxicity, risks related to breastfeeding, risks to eggs, sperm, or ability to reproduce in the future): Click here to enter text.

6.4 *Does participation in this study positively or negatively affect participants' current or future care or eligibility for future research?

☐Yes ☐No

If 'Yes':

6.4.1 *Describe the impact: Click here to enter text.

6.5 *Will participants receive any direct benefits from participating in this study?

☐Yes ☐No

If 'Yes':

6.5.1 *Describe: Click here to enter text.

6.6 *Describe the safety monitoring plan for the study: Click here to enter text.

6.7 *Are there any plans to perform an interim analysis?

☐Yes ☐No

If 'Yes':

6.7.1 ***Describe:** Click here to enter text.

If 'No':

6.7.2 ***Justify:** Click here to enter text.

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

☐Yes ☐No

HELP TEXT:

DSMB/DSMC is an acronym for Data and Safety Monitoring Board and Data and Safety Monitoring Committee. The DSMB/DSMC is an independent group of experts that on a periodic basis, reviews and evaluates the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and makes recommendations to the study sponsor concerning the continuation, modification, or termination of the study.

If 'No':

6.8.1 ***Justify:** Click here to enter text.

If 'Yes':

6.8.2 ***Does the DSMB/C charter describe the DSMB/C, including its purpose, membership, relationship to the sponsor, how often they meet and whether the committee will review unblinded data?**

☐All information is in the DSMB/C charter

☐the DSMB/C charter contains some of this information

☐the DSMB/C charter does not contain any of this information

If 'All information is in the DSMB/C charter', or The DSMB/C charter contains some of this information':

6.8.2.1 ***Upload DSMB/C charter**

UPLOAD DOCUMENT - DOCUMENT TYPE: DSMB/C CHARTER

Draft version is acceptable for initial submission; FINAL copy can be submitted as an amendment

If 'The DSMB/C charter contains some of this information':

6.8.2.2 ***Provide the additional information that is not covered in the DSMB/C Charter:** Click here to enter text.

If 'The DSMB/C charter does not contain any of this information':

6.8.2.3 ***Describe the DSMB/C, including its purpose, membership, relationship to the sponsor, how often they meet and whether the committee will review unblinded data:** Click here to enter text.

6.8.3 ***Is it independent?**

☐Yes ☐No

If 'No':

6.8.3.1 ***Justify:** Click here to enter text.

6.9 ***Who will conduct the onsite monitoring of the study at the sites?**

☐Lead Researcher/Lead research group/Sponsor

☐Outside agency (e.g., CRO)

☐Other:

HELP TEXT:

Monitoring refers to reviewing a clinical study, ensuring conduct, proper records and reports are performed as stated in the clinical protocol, standard operating procedures, GCP and by regulatory requirements.

If 'Outside Agency (e.g., CRO)':

6.9.1 *Specify outside agency: Click here to enter text.

If 'Other':

6.9.2 *Specify other: Click here to enter text.

6.10 If applicable, describe the criteria for stopping the study early due to safety concerns or other reasons:

Click here to enter text.

Please list the Protocol criteria here; DO NOT refer to pages of the Protocol where the information can be found ; please note that this should include safety criteria related to AEs ; criteria for futility, etc.

SECTION 7.0 - PRIVACY AND CONFIDENTIALITY

7.1 *What (if any) Personal Information or Personal Health Information will be sent to or collected by the lead researcher/research group/sponsor for the purposes of this study (this includes specimens, questionnaires, diaries, registration forms, case report forms, etc.) (select all that apply)?

Q7.1: All identifiers disclosed/provided to the sponsor must be selected. Direct identifiers must NOT be selected ; Identifiers provided to Third party vendors should NOT be included here

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials (e.g. first/last only)
- ☐Full date of birth
- ☐Partial date of birth (e.g., year/month only)
- ☐Full date of death
- ☐Partial date of death (e.g., year/month only)
- ☐Age
- ☐Sex
- ☐Gender identity
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-Mail address
- ☐Identifiable photographs (e.g., full face photos, or other photos containing identifiable information)
- ☐Voice/audio recording
- ☐Video recording
- ☐Social Insurance Number (SIN) number
- ☐Device identifier
- ☐Internet Protocol address (IP address)
- ☐Race and/or ethnicity
- ☐Family/caregiver names and/or contact information
- ☐Other

HELP TEXT (7.1):

Gender identity refers to the socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender-diverse people. It influences how people perceive themselves and each other, how they act and interact, and the distribution of power and resources in society. There is considerable diversity in how individuals and groups understand, experience, and express gender.

Sex refers to a set of biological attributes in humans. It is primarily associated with physical and physiological features including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy. It may also refer to a person's legal sex, i.e., the sex that is recognized under the law

Q7.1: justification for each identifier disclosed to the sponsor should relate to study objectives and outcomes. In other words, why is it necessary to collect the identifier for this study?

- ***If 'Other':*** **7.1.1 *Specify other information:** Click here to enter text.
- ***If 'Other':*** **7.1.2 *Justify other information:** Click here to enter text.
- ***If 'Full name':*** **7.1.3 *Justify full name:** Click here to enter text.
- ***If 'Full initials':*** **7.1.4 *Justify full initials:** Click here to enter text.
- ***If 'Partial initials':*** **7.1.5 *Justify partial initials:** Click here to enter text.
- ***If 'Full date of birth':*** **7.1.6 *Justify full date of birth:** Click here to enter text.
- ***If 'Partial date of birth':*** **7.1.7 *Justify partial date of birth:** Click here to enter text.
- ***If 'Full date of death':*** **7.1.8 *Justify full date of death:** Click here to enter text.
- ***If 'Partial date of death':*** **7.1.9 *Justify partial date of death:** Click here to enter text.
- ***If 'Age':*** **7.1.10 *Justify age:** Click here to enter text.
- ***If 'Sex':*** **7.1.11 *Justify sex:** Click here to enter text.
- ***If 'Gender identity':*** **7.1.12 *Justify gender identity:** Click here to enter text.
- ***If 'Full postal code':*** **7.1.13 *Justify full postal code:** Click here to enter text.
- ***If 'First 3 digits of postal code':*** **7.1.14 *Justify first 3 digits of postal code:** Click here to enter text.
- ***If 'Pathology specimen number':*** **7.1.15 *Justify pathology specimen number:** Click here to enter text.
- ***If 'Medical device identifier':*** **7.1.16 *Justify medical device identifier:** Click here to enter text.
- ***If 'Admission date':*** **7.1.17 *Justify admission date:** Click here to enter text.
- ***If 'Discharge date':*** **7.1.18 *Justify discharge date:** Click here to enter text.
- ***If 'Medical record number':*** **7.1.19 *Justify medical record number:** Click here to enter text.
- ***If 'Health card number':*** **7.1.20 *Justify health card number:** Click here to enter text.
- ***If 'Driver's license number':*** **7.1.21 *Justify driver's license number:** Click here to enter text.
- ***If 'Address':*** **7.1.22 *Justify address:** Click here to enter text.
- ***If 'Telephone number':*** **7.1.23 *Justify telephone number:** Click here to enter text.
- ***If 'Fax number':*** **7.1.24 *Justify fax number:** Click here to enter text.
- ***If 'E-Mail address':*** **7.1.25 *Justify E-mail address:** Click here to enter text.
- ***If 'Identifiable photographs':*** **7.1.26 *Justify identifiable photographs:** Click here to enter text.
- ***If 'Voice/audio recording':*** **7.1.27 *Justify voice/audio recording:** Click here to enter text.
- ***If 'SIN number':*** **7.1.28 *Justify SIN number:**
- ***If 'Device Identifier':*** **7.1.29 *Justify device identifier:** Click here to enter text.
- ***If 'Internet Protocol address (IP address)':*** **7.1.30 *Justify internet protocol address (IP address):** Click here to enter text.
- ***If 'Race and/or ethnicity':*** **7.1.31 *Justify race and/or ethnicity:** Click here to enter text.
- ***If 'Family/caregiver names and/or contact information':***
- **7.1.32 *Justify family/caregiver names and/or contact information:** Click here to enter text.

HELP TEXT (7.1.32):

Identifiers being disclosed to the Sponsor/Lead PI and does not reflect administrative purposes

If 'Video recording': **7.1.33 *Justify video recording:** Click here to enter text.

7.2 Upload the demographic pages of the data collection form or tools:

UPLOAD DOCUMENT - DOCUMENT TYPE: DATA COLLECTION DEMOGRAPHIC PAGES

Q7.2: Demographic Form CRF is mandatory for OCREB submissions ; Please ensure Race and ethnicity options are relevant to Canadian Population (e.g. CIHI based options)

7.3 *Will there be a code linking identifiers to the study participant?

☐Yes ☐No

HELP TEXT:

Code linking identifiers refers to any information (e.g. name, address, etc.) that permits specimens or data to be linked to individually identifiable living individuals and perhaps also to associated medical information which may allow the re-identification of the participant.

If 'Yes':

7.3.1 *Who will have access to the code? Click here to enter text.

7.4 *How will study data be sent to and/or shared with the lead researcher/research group/sponsor? (select all that apply):

☐Fax

☐Electronic (online) data collection/submission

☐Private courier

☐Canada Post registered mail (e.g., Priority, or other secure shipping method)

☐Secure File Transfer

☐Other

HELP TEXT:

Study Data refers to data collected in the course of a clinical trial or any existing information from both study sources and external sources that may need to be accessed in order to conduct this study.

Electronic (online) data collection refers to a process (conducted over the internet) of gathering and measuring information on variables of interest, in an established systematic fashion that enables one to answer stated research questions, test hypotheses, and evaluate outcomes.

If 'Other':

7.4.1 *Specify: Click here to enter text.

7.5 *Who will have access to the study data? Click here to enter text.

HELP TEXT:

Study data refers to data collected in the course of a clinical trial or any existing information from both study sources and external sources that may need to be accessed in order to conduct this study.

7.6 *How long will information collected for the study be retained/kept? Click here to enter text.

HELP TEXT:

For example, as per Division 5 of the Food and Drug Regulations all record must be retained/kept for 15 years

7.7 *How will the study data be disposed of after this period? Click here to enter text.

7.8 *Will any of the study data be sent, shared and/or stored outside of Canada (select all that apply)?

☐No

☐Yes – anonymized or anonymous data

☐Yes – de-identified data

☐Yes - identifiable data

HELP TEXT:

"Yes - identifiable data" should be selected for studies using a third-party app (i.e., ePROs) associated with a patient' email address.

If 'Yes- identifiable data', 'Yes – de-identified data', or 'Yes-anonymous data' is selected:

7.8.1 *Where will the data be sent? Click here to enter text.

If 'Yes- identifiable data', 'Yes – de-identified data' is selected:

7.8.2 *Specify the data that will be sent: Click here to enter text.

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

☐Yes ☐No

HELP TEXT:

Data linkage refers to the merging or analysis of two or more separate data sets (e.g. health information and education information about the same individuals) for research purposes.

If 'Yes':

7.9.1*Identify the data sets, databases or registries to which study data will be linked: Click here to enter text.

Q7.9.1: refers to databases that are separate from/external to the Sponsor's database (e.g., ICES; CCO etc.).

7.9.2 *Explain the purpose for the linking: Click here to enter text.

7.9.3 *Describe how the linking will be done: Click here to enter text.

7.9.4 *Describe the likelihood that identifiable data will be created through the linkage: Click here to enter text.

7.9.5 *Describe the security measures that will be in place to protect the confidentiality of the data: Click here to enter text.

7.10 *Will any of the study data be kept by the lead researcher/lead research group/sponsor for future use?

☐Yes ☐No

If 'Yes':

7.10.1 *Provide a general description of the nature and types of future research that may be conducted: Click here to enter text.

7.10.2 *Where will the study data be stored? Click here to enter text.

7.10.3 ***Who will be the custodian?** Click here to enter text.

HELP TEXT:

Custodian refers to a person or organization/institution who is overall responsible for the specimens.

7.10.4 ***Provide a general description of the repository and its governance (or a link to this information if available online):** Click here to enter text.

7.10.5 ***Could this study data be shared with researchers outside of Canada in the future?**

☐Yes ☐No

7.10.6 ***Is it anticipated that the study data may be linked with other data about participants, either in public (for example, social media, public registries) or personal records (for example, medical records, administrative databases)?**

☐Yes ☐No

7.10.7 ***Could future research include use of technologies or linkage of data that might pose a substantial risk of re-identification of the participant?** Click here to enter text.

7.10.8 ***Could future research include technology or methods that might result in identification of material incidental findings?** Click here to enter text.

7.10.9 ***Will study participants be provided the opportunity to withdraw study data collected for future research?**

☐Yes ☐No

If 'Yes':

7.10.9.1*Describe any limitations to the withdrawal: Click here to enter text.

If 'No':

7.10.9.2*Explain why not? Click here to enter text.

7.11 ***Will study participants be provided the opportunity to withdraw data after the data has been shipped/sent offsite (such as part of an e-CRF)?**

☐Yes ☐No

If 'Yes':

7.11.1 ***Describe any limitations to the withdrawal:** Click here to enter text.

If 'No':

7.11.2 ***Explain why not?** Click here to enter text.

If 'Biological Specimen Collection (e.g., blood/tissue for PK, biomarker, biobanking, genetic testing, etc., excluding specimens taken as part of normal care or for safety)' is selected in 2.17, question 7.12 -7.13 will appear:

7.12 ***In question 2.17 it was indicated that this study involves biological specimen collection. How are these samples identified/labelled?**

☐Non-identifiable – samples do not identify an individual, for all practical purposes, when used alone or combined with other available information

☐De-identified/Coded – samples are labelled or stored with a code only

☐Directly identifiable – samples are labelled or stored with directly identifiable participant information (e.g., name, initials, DOB)

If 'directly identifiable':

7.12.1 *Why is it necessary to include directly identifiable participant information/Why can't the samples be de-identified or coded? Click here to enter text.

7.12.2 *Describe the security measures to protect the confidentiality of the specimens: Click here to enter text.

If 'de-identified/coded':

7.12.3 *Who will have access to the code or link? Click here to enter text.

7.13 *Will this study involve the use of online data collection tools (including surveys), apps, wearables or other technology?

☐Yes ☐No

If 'Yes' is selected in 7.13 questions 7.14 – 7.17 will appear:

7.14 *Name the company/corporation who created/owns the online data collection tool, app, wearable or other technology used in this study: Click here to enter text.

7.15 *List study data that would be collected from the tool: Click here to enter text.

HELPTEXT:

Most electronic tools developed by third parties require the disclosure of personal identifiers for the purpose of, for example, registration, data collection (e.g., email address, participant name, date of birth, global positioning system (GPS) coordinates, internet protocol address (IP address)).

7.16 *Which of the following privacy protection methods will be implemented with respect to the online data collection tools (including surveys), apps, wearables or other technology:

☐ Metadata (location, time, date) will not be collected

☐ Agreement(s) will be in place with the service/tool provider (e.g., the company/corporation who created/owns the online data collection tool, app, wearable or other technology)

☐ Information will not be retained by the service/tool provider and cannot be independently used by the provider

☐ Apps will not collect data unless the app is actively in use by the participant

☐ Other

If 'Other':

7.16.1 *Describe: Click here to enter text.

7.17 *Is any identifiable information collected or used by the online data collection tools (including surveys), apps, wearables or other technology? This includes information collected to create accounts or profiles, collected passively, or actively entered by the participant, etc.:

☐Yes ☐No

If 'Yes':

7.17.1 *Describe the identifiable data to be collected/used: Click here to enter text.

7.17.2 *Describe how the identifiable information will be used (suggest the purpose of the collection/use): Click here to enter text.

7.17.3 *Where will the identifiable information be stored? Click here to enter text.

If 'Voice/audio recordings' or 'Video Recordings' is selected in question 7.1, question 7.18-7.19 appears

7.18 *Will the video/audio recordings be transcribed?

☐Yes ☐No

If 'Yes':

7.18.1 *Describe the transcription process, including who will conduct the transcription: Click here to enter text.

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

☐Access to original video/audio recordings will be restricted to study personnel only

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

☐ Video/audio recordings will be confidentially destroyed as soon as possible

☐Video/audio recordings will be coded

☐Video/audio recordings will not capture date and time

☐Agreement will be in place with external transcription services

☐None of the above **[EXCLUSIVE]**

If 'None of the above':

7.19.1 *Justify: Click here to enter text.

If 'Identifiable photographs…' is selected in question 7.1, question 7.20-7.22 appears

7.20 *Describe the identifiable information contained within the photographs: Click here to enter text.

7.21 *Who will take the photographs? Click here to enter text.

7.22 *With respect to the photographs, which of the following privacy protection methods will be implemented? (Select all that apply):

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

☐ Photographs sent off-site will not include information that can identify participants (e.g., identifying information will be obscured)

☐ Photographs will be confidentially destroyed as soon as possible

☐Photographs will not capture date and time

☐Agreement will be in place with external photographers

☐None of the above **[EXCLUSIVE]**

If 'None of the above':

7.22.1 *Justify: Click here to enter text.

SECTION 8.0– FUNDING

8.1 *Study funder(s) and/or material support providers (select all that apply):

☐Industry (e.g. pharmaceutical or biotech company)
☐ Government
☐Charitable foundation
☐Tri- Council (e.g., CIHR, SSHRC, NSERC, NCE)
☐ Granting agency
☐Internal funding
☐US federal funds
☐Other
☐None

If 'Other':

8.1.1 *Specify other funder(s): Click here to enter text.

If 'None'

8.1.2 *Justify: Click here to enter text.

If 'Industry (e.g. pharmaceutical or biotech company)':

Industry (e.g., pharmaceutical or biotech company)

8.1.3 *Name(s): Click here to enter text.

If 'Government':

Government

8.1.4 *Name(s): Click here to enter text.

If 'Charitable foundation':

Charitable foundation

8.1.5 *Name(s): Click here to enter text.

If 'Granting agency':

Granting agency

8.1.6 *Name(s): Click here to enter text.

If 'Internal funding':

Internal funding

8.1.7 *Name(s): Click here to enter text.

If 'US federal funds':

US federal funds

8.1.8 *Name(s): Click here to enter text.

If 'Tri-Council (e.g., CIHR, NSERC, NCE)':

8.1.9 *Name of funding agency/ies: Click here to enter text.

8.2 *Does the study involve any industry support?

☐Yes ☐No

Q8.2: should be 'Yes' for industry-sponsored studies and for studies where support is provided by industry.

HELPTEXT:

Industry support refers to financial or material resources that will be provided to the investigator(s) by an Industry sponsor.

If 'Yes':

8.2.1 *Select all that apply:

☐Unrestricted funding

☐Restricted funding **

**Select this for Industry studies that are funded based on a study-specific budget

☐In-kind (e.g., supply of drug, device, NHP or biologic)

☐Other

HELPTEXT:

Unrestricted funding refers to financial support where the recipient (the investigator or institution) has complete discretion and autonomy over how the funds are used. There are no predefined conditions, specific deliverables, or limitations imposed by the funder regarding the research project, budget line items, or timeline.

***If 'Restricted grant funding'* or 'Other' is selected:**

8.2.1.1 *Describe: Click here to enter text.

8.3 *Upload the proposed study budget (Note: This should be a non-site-specific budget; This document will be visible to all users in Stream):

UPLOAD DOCUMENT - DOCUMENT TYPE: SPONSORS STUDY BUDGET

Q8.3: upload the sponsor's generic proposed study budget for ALL Canadian sites, NOT your site-specific negotiated budget.

HELP TEXT:

Proposed study budget refers to the estimate of the foreseeable costs associated with conducting the clinical trial and the amounts proposed for payment to each study site (e.g., per visit, per patient, total). The proposed budget may be in the form of a spreadsheet and should provide sufficient detail on the proposed amounts to be paid to the site for study visits, tests, procedures and other activities associated with conducting the study.

8.3.1 *Does the funding for this trial include review fees? (Fees for submitting through Stream apply to all industry-sponsored/supported studies and are invoiced upon receipt of the submission)

☐Yes ☐No

If 'Yes':

WE WILL BE CONTACTING THE INDIVIDUAL LISTED IN QUESTION 1.8 TO INITIATE THE BILLING PROCESS. IF THIS INDIVIDUAL IS NOT THE CORRECT PERSON THE STUDY TEAM, SPONSOR AND, CRO (IF APPLICABLE) WILL BE CONTACTED.

8.4 *Will study participants or substitute decision makers be compensated for study participation (e.g., money for time or gifts, etc.)?

☐Yes ☐No

HELP TEXT:

The following link can be used as a resource: Participant Experience Toolkit.

If 'Yes':

8.4.1 *Describe the compensation, including value, type, schedule, to whom it is provided (participant or substitute decision maker) and the justification: Click here to enter text.

8.5 *Will participants or substitute decision makers be reimbursed for expenses they incur as a result of study participation?

☐Yes ☐No

HELP TEXT:

The following link can be used as a resource: Participant Experience Toolkit.

If 'Yes':

8.5.1 *Describe the nature of the expenses that will be reimbursed, to whom it will be provided, and any reimbursement limits or requirements (i.e., providing receipts): Click here to enter text.

If 'No':

8.5.2 *Justify: Click here to enter text.

8.6 *Will there be a cost to participants for the intervention(s) used in the study?

☐Yes ☐No

If 'Yes':

8.6.1 *Justify: Click here to enter text.

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

☐Yes ☐No

Q8.7: Note that this is referring to access POST Study or AFTER study is completed and there are participants still on treatment and benefitting from it

If 'No':

8.7.1 *Explain and justify: Click here to enter text.

If 'Yes':

8.7.2 *Explain how participants will obtain access and any associated cost: Click here to enter text.

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

☐Yes ☐No

If 'Yes':

8.8.1 *Describe the management plan: Click here to enter text.

8.9 *Are there any contractual or funding restrictions on publication of findings (e.g., timing or approval of manuscripts) or on reporting of interim results?

☐Yes ☐No

If 'Yes':

8.9.1 *Explain the restrictions: Click here to enter text.

SECTION 9.0 – TRANSLATIONS

9.1 *Are translated participant materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.) included in this study?

☐Yes ☐No

Q9.1: Respond "Yes" only if the translated materials are available for uploading to the application. If they are not available, submit them later as a Study -wide amendment (SWAM) and respond 'NO' to this Question

If 'Yes' to question 9.1, question 9.2 will appear:

9.2 *Are the translated materials available for REB submission at this time?

☐Yes ☐No

If 'No' to question 9.2:

Please submit the translated materials for REB review as soon as possible.

9.3 If applicable, upload all translated materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.):

UPLOAD DOCUMENT – DOCUMENT TYPE: TRANSLATED MATERIALS

9.4 If applicable, upload all translation certificates/supporting documentation for authenticity of the translation:

UPLOAD DOCUMENT – DOCUMENT TYPE: TRANSLATION CERTIFICATE

Q9.4: NOTE. Translation certificates/supporting documentation are not required for Questionnaires that are validated in the translated language(s); All other materials require a Translation Certificate

SECTION 10.0 - RE-SUBMISSION INFORMATION

If 'Is this a resubmission in response to a request from System Administrators or the Research Ethics Board to make changes to your application?

This re-submission information section is not required to be completed when the resubmission is in response to changes requested by System Administrators during pre-screening.

Any revised documents should be deleted and re-uploaded into the appropriate section(s) of the application.

10.1 Upload Lead Applicant Response to REB request for modification letter (if applicable):

UPLOAD DOCUMENT - DOCUMENT TYPE: RESPONSE TO REB LETTER

Q10.1: a response letter is required each time the applicant re-submits the CTIA unless the changes are only to the consent form(s). Always include the OCREB requirements and recommendations in the response, as applicable. The letter should have PI or sponsor input, but does not need to be signed by the PA/PI. *For multiple re-submissions, please retain ALL PA/PI response letters previously uploaded in this section.

10.2 If changes have been made to a previously submitted consent/assent form at the request of the REB, upload track-changes versions of all proposed consent and/or assent form(e.g. screening, main, optional), if applicable:

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

Q10.2: when there are multiple re-submissions, remove the previous/outdated tracked change versions of consent documents.

10.3 Upload any additional materials requested by the REB (if applicable):

UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS

10.4 Provide any additional comments for the REB to consider (if applicable): Click here to enter text.

Q10.4: this is a free text field. Please provide any additional information to assist OCREB with the review and approval of the study/CTIA, if applicable.

SECTION 11.0 – ATTESTATIONS AND SIGNATURES

If 'No' to question 1.0, the Lead Applicant signature appears:

11.1 Lead Applicant

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I agree to assume the role of Lead Applicant for this trial;
- Following the initial submission of this application form, a member of the research team may submit edits to this application on my behalf. I acknowledge that I remain ultimately responsible for REB submissions and the overall conduct of the study in accordance with the currently approved documents. I attest that, should a designate sign on my behalf, the responsibility for corresponding with the REB has been appropriately delegated, and the delegation has been documented.
- As the Lead Applicant:
  - I attest that this application is and all subsequent trial-related applications will be completed and submitted in compliance with TCPS 2 (2nd edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND in accordance with all applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice; PIPEDA or provincial privacy laws (including health related) declared substantially similar);
  - I attest that the Lead Co-Applicant listed in this application (if applicable) is appropriately qualified to assume my responsibilities as Lead Applicant in the event that I am unable to do so;
  - I acknowledge that I am responsible for promptly reporting to the REB, through Stream, all trial wide:
  - proposed modifications or amendments, including but not limited to, changes to the protocol, to the consent form, to the participant materials, to the recruitment materials, or to the Investigator Brochures or Product Monographs;
  - reportable events that meet the REB reporting criteria, including but not limited to DSMB/C reports, interim analysis reports and any new information that might adversely affect the safety of the participants or significantly affect the conduct of the trial;
  - trial progress report (renewal/ continuing review form), annually or as often as requested by the REB;
  - Trial completion or termination
  - Once the Clinical Trial Initial Application is approved, I am aware that if I also am a site PI on this trial, I must submit, through Stream, a Participating Site Initial Application Form for approval to conduct the trial at my site;
  - I am aware that the REB review materials (e.g., study-wide forms including attachments, review letters, other correspondence, approval letters, etc.) will be shared with all sites participating in this trial through the Stream;
  - I am aware that the following trial information will be made available to all sites participating in this trial: Project I.D. #, Sponsor Name, Sponsor Protocol I.D. #, Trial Title, REB review status, name of Lead Applicant, and the names of the participating sites and PIs.

SIGNATURE TYPE: LEAD APPLICANT

Study PI/Lead applicant MUST Sign the Initial submission of the CTIA

If 'Yes' to question 1.0; the Lead Applicant or Delegate signature will appear:

Q 11.2: PI response and/or resubmissions can be signed by PI Delegate or Study staff. Please ensure Q#1.0 response is 'YES" for this Section to appear

11.2 Lead Applicant or Delegate

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I confirm that I have obtained any authorizations as applicable to make changes to this application. If signing on behalf of the Lead Applicant, I attest that the delegation of this responsibility has been documented.

  SIGNATURE TYPE: LA OR DELEGATE