Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 – original
November 8, 2018	CTO application form version 16- update • Q1.8: clarified that the Sponsor name should be entered into the sponsor contact organization field even if the contact person does not work directly with the Sponsor; • Q1.12: clarified that the question refers to any scientific reviews (independent or not)
May 1, 2019	CTO application form version 20 • Help text (in green) was added to several questions • Follow-up questions were numbered (e.g., 3.7.1; 3.7.2) • Q2.18.42: OCREB guidance text was modified to instruct applicants to include the specific questionnaire name in the document name for proper referencing in the approval letter • Question 3.7 added to capture the therapeutic area(s) of research • Question 3.7.2 added to confirm whether OCREB is the intended REB of Record. Guidance text was added • Section 5.0: expanded to include waiver of consent and criteria for waiving consent • Question 11.3 added to allow a delegate to sign off on resubmissions
August 20, 2020	CTO application form version 21 • References to the CHEER study added throughout the application • CTO helpdesk contact information (support.ctontario.ca) added throughout the document • The term “Aboriginal” revised to “Indigenous” throughout the document • Question 1.0: Instructions about the PI response letter added. • Question 1.0.1: New question about the Canadian Collaboration for Child Health (CHEER) study added • Question 1.1: Help text revised to clarify the defitions of clinical and multi-centre trials • Question 1.13: Revised to “Has any REB refused to approve this study, or has the study been withdrawn from any other REB due to that REB’s concerns?” • Question 2.4: Help text expanded to include “Study processes may include restrictions or modifications to the usual lifestyle activities and should be entered into Q2.14; justification would be part of the rationale for the study question (Q2.2); study procedures, what participants will actually complete as part of this study, should be entered into Q2.14.” • Question 2.5: New question added “Does the study include a control group?” • Question 2.6: “Neonates” added as an option • Questions 2.6.19 and 2.6.20: Added to input the age range of children and neonates included in the study • Question 2.18: Cannabis added as an option Question 2.18.44: Device based apps or wearable devices added as an option • Question 4.2: Advertisements added as an option

Version Date	Key Changes
	• Question 5.1.1: New question added “Will a written consent be obtained from all participants and/or substitute decision makers (SDMs)? ” • Question 5.3.2: New question added “Please explain why it is impossible or impracticable to conduct the research with prior consent. ” • Section 5 (consents): Reference to the OCREB consent form template added • Question 7.1: New identifiers/options added (social insurance number, device identifier, Internet protocol address, race/ethnicity, family/caregiver information). • Question 7.4: Secure file transfer added as an option • Question about data transfer agreement deleted • Question 7.13: New question added “Select the electronic tools that will be used for the research interventions like, recruiting, data collection or follow-up ” • Questions 7.14 -7.20: If ‘Web-based portal, Device based apps or Wearable devices’ are selected in 7.13, new questions 7.14 - 7.20 will appear • Question 8.10: New question added “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) ” • Section 11: Instructions revised to clarify when the attestation would be signed by the PI, Co-I or PI delegate.

Orange text *indicates an upload or action feature*

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

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

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

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

1.0 ***Is this a resubmission in response to a request from CTO 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 please select "No".

If this is a re-submission for modifications requested by CTO or the REB please 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 CTO.

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 https://cheerchildhealth.ca/

1.1 ***Is this a multi-centre 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-centre: The study will include two or more CTO participating sites. For a list of participating sites, click here.

If 'No', the following message appears

The CTO application process is for multi-centre trials only. As this is not a multi-centre trial CTO CANNOT ACCEPT your application.

If you are unsure, please go to support.ctontario.ca and submit your question in the CTO Online Helpdesk.

1.2 *Please complete the Provincial Applicant (PA)/CHEER Applicant (CA) 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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

CONTACT TYPE: PROVINCIAL APPLICANT

HELP TEXT:

Provincial Applicant refers to the individual who takes overall responsibility for submitting all study-wide (provincial) materials to the REB of Record on behalf of all participating Ontario sites. The provincial materials include the clinical trial initial application, all ongoing submissions such as proposed changes to the study amendments, reportable events and continuing review applications.

CHEER 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 in Canada. 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 *Is there a Provincial Co-Applicant/CHEER Co-Applicant?

☐Yes ☐No

Q1.3: Recommend answering "No" ; Including a Co-Applicant does not grant the individual permission to submit any REB materials on the PA's behalf. In addition, including a Co-Applicant will require the Co-Applicant to sign off on the initial submission of the PIA. Co-investigators should be noted in the study delegation log.

HELP TEXT:

Provincial Co-Applicant/CHEER Co-Applicant refers to a qualified individual who agrees to assume responsibilities of the Provincial Applicant/CHEER Applicant in his/her absence. All REB submissions remain the responsibility of the Provincial Applicant/CHEER Applicant

If 'Yes':

1.3.1 *Please complete the Provincial Co-Applicant/CHEER Co-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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

CONTACT TYPE: PROVINCIAL CO-APPLICANT

1.4 *Are the contact details for the Provincial/CHEER Administrative Study Contact different than the Provincial Applicant/CHEER Applicant named above?

☐Yes ☐No

HELP TEXT:

The Provincial/CHEER Administrative Study Contact is the person tasked with completing and coordinating the REB submissions for this study.

If 'Yes':

1.4.1 *Please complete the Provincial/CHEER Administrative Study Contact 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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

Q1.4 should be answered "yes" unless the PA/PI is completing the application and will be the only individual communicating with the REB. Enter the contact details for main study staff member (ethics/regulatory/start-up) assisting with the PIA. This may differ from the owner of the PIA. For example, a sponsor or CRO representative could be the "project owner" if he/she created the PIA.

CONTACT TYPE: PROVINCIAL ADMINISTRATIVE STUDY CONTACT

1.5 *Please enter the complete study title: Click here to enter text.

HELP TEXT:

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

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

HELP TEXT:

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

Q. 1.6: This can be left blank if there is no Study ID and will show up as blank in the approval letter

1.6.1 *Please Upload Protocol:

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 *Please complete the Main Sponsor Contact 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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
*Email: Click here to enter text.

Q1.8: Please list **SPONSOR Name** in the Organization field, even if the contact person does not work directly with Sponsor - e.g., use Children's Oncology Group (COG), AstraZeneca, GSK. If the sponsor contact's organization is different, - e.g., St. Jude's Hospital or a CRO, add the sponsor contact's organization name to the 'address' field instead. This ensures that the correct sponsor name appears in listings and letters.

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:

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: refers to **any scientific review** (independent or not)

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

1.12.1 ***Please 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):

UPLOAD DOCUMENT - DOCUMENT TYPE: SCIENTIFIC OR SCHOLARLY 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 research subject risk assessment.

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 centres do you expect will participate in this study through CTO Stream?** Click here to enter text.

1.14.1 Please list the name and location of each centre identified in question 1.14 (if known) Click here to enter text.

Q1.14 please include number and names of the other participating centres and the name of the Centre PI if known.

1.15 ***Please provide the Contract Research Organization (CRO) contact details if applicable:**

☐Yes – CRO contact details available

☐No – CRO contact details not available

☐No CRO

If 'Yes':

1.15.1 ***Please enter the CRO contact 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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

CONTACT TYPE: MAIN CRO CONTACT

1.16 *Please complete the Primary Institutional Representative 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.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email:

Q1.16: CTO works with each institution to identify the appropriate Institutional Rep (IR) and will provide this information to each site. The IR must be listed in the PIA but is not required to sign off on the PIA. Please check your centre's SRERS form provided by CTO or contact CTO to obtain this information.

CONTACT TYPE: PROVINCIAL INSTITUTIONAL REPRESENTATIVE

HELP TEXT:

The primary institutional representative is an administrator identified by the organization. If you are not sure who this individual is, click here to go to the CTO website and download the SRERS administration form for this institution, which contains this information.

1.17 *Is there a Secondary Institutional Representative at this Institution? (Organization listed in question 1.2)

☐Yes ☐No

Q1.17: Many institutions do not have a secondary institutional rep. Please check your centre's SRERS form provided by CTO or contact CTO to obtain this information.

HELP TEXT:

If you are unaware of whether your site has a secondary institutional representative or are unsure who this individual is, click here to go to the CTO website and download the SRERS administration form for this institution, which contains this information.

If 'Yes':

1.17.1 *Please complete the Secondary Institutional Representative 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.
*Address: Click here to enter text.
*City: Click here to enter text.

*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

CONTACT TYPE: PROVINCIAL INSTITUTIONAL REPRESENTATIVE

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 Q2.14; justification would be part of the rationale for the study question (Q2.2); study procedures, what participants will actually complete as part of this study, should be entered into Q2.14.

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.

NOTE. In the studies transferred from O2 ("legacy studies"), this question inadvertently was left blank and there is no ability to change it in an amendment. Due to the nature of the studies submitted to OCREB, having this blank in the legacy studies is fine.

☐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

If any of the categories marked with an asterisk are selected, questions related to "special populations" will appear in the Provincial Initial Application/CHEER Initial Application and the Centre Initial Application

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 are poor or from lower economic backgrounds.

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.

If 'Students':

2.6.2 *Justify inclusion of students in the research: Click here to enter text.

If 'Staff':

2.6.3 *Justify inclusion of staff in the research: Click here to enter text.

If 'People with mental health issues':

2.6.4 *Justify the inclusion of people with mental health issues in the research: Click here to enter text.

If 'Institutionalized people':

2.6.5 *Justify the inclusion of institutionalized people in the research: Click here to enter text.

If 'Prisoners/persons in detention':

2.6.6 *Justify the inclusion of prisoners/persons in detention in the research: Click here to enter text.

If 'People in poverty/economically disadvantaged':

2.6.7 *Justify the inclusion of people in poverty/economically disadvantaged people in the research: Click here to enter text.

If 'Educationally disadvantaged people':

2.6.8 *Justify the inclusion of educationally disadvantaged people in the research: Click here to enter text.

If 'People who are unable to read or write':

2.6.9 *Justify the inclusion of people who are unable to read or write in the research: Click here to enter text.

If 'Children':

2.6.10 *Justify inclusion of children in the research: Click here to enter text.

If 'People in medical emergencies':

2.6.11 *Justify the inclusion of people with medical emergencies in the research: Click here to enter text.

If 'People who lack capacity to consent':

2.6.12 *Justify the inclusion of people who lack the capacity to consent in the research: Click here to enter text.

If 'Cognitively impaired individuals':

2.6.13 *Justify the inclusion of cognitively impaired individuals in the research: Click here to enter text.

If 'Individuals with physical disabilities':

2.6.14 *Justify the inclusion of Individuals with physical disabilities in the research: Click here to enter text.

If 'People who have trouble understanding and/or producing speech':

2.6.15 *Justify the inclusion of people who have trouble understanding and/or producing speech in the research: Click here to enter text.

If 'Adult individuals who are temporarily unable to provide consent':

2.6.16 *Justify the inclusion of adult individuals who are temporarily unable to provide consent in the research: Click here to enter text.

If 'Pregnant women':

2.6.17 *Justify inclusion of pregnant women in the research: Click here to enter text.

If 'Indigenous peoples and/or other distinct communities':

2.6.18 *Justify inclusion of Indigenous peoples and/or other distinct communities in the research: Click here to enter text.

If 'Children', questions 2.6.19 - 2.6.20 appear:

2.6.19 *Children age range (years and months):

Age Range Start: Click here to enter text.

Age Range End: Click here to enter text.

If 'Neonates':

2.6.20 *Justify the inclusion of Neonates in the research: 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 ***Does this study involve deception or partial disclosure?**

☐Yes ☐No

If 'Yes':

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

If 'Yes':

2.11.2 *Indicate how participants will be debriefed: Click here to enter text.

2.12 ***Describe the accepted Standard of Care (SOC) for this/these population(s):** Click here to enter text.

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

☐Yes ☐ No

If 'Yes':

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

2.14 ***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.

2.15 ***Please 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

2.16 ***Are there any associated sub-studies or companion studies that will be conducted at any of the centres using CTO?**

☐Yes ☐No

Q2.16: 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.

If 'Yes':

2.16.1 Please upload sub-study or companion protocol

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

If 'Yes':

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

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

☐Yes ☐No

HELP TEXT:

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

If 'Yes':

2.17.1 *Please provide the CTO Stream Project ID: Click here to enter text.

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

2.18 *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

☐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)

☐Radiation (including tests involving exposure to radiation)

Q2.18: "radiation" must be selected if there is ANY radiation use in the study, including for diagnostic purposes.

☐Surveys/Questionnaires/Interviews/Focus Groups

☐Other health related interventions not listed above

HELP TEXT:

a) 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.

b) 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.

c) Biobanking refers to a large repository of donated human DNA and/or its information collected from volunteers with or without disease which is used to identify genes that contribute to human disease.

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

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

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

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

2.18a 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' is selected in 2.18:

2.18a ***Does this submission 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 ANSWER ONLY]**

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 2.18a.

2.18.1 ***Please 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':

2.18.1.1 *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.

2.18.2 *Please 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)':

2.18.2.1 *Please upload Investigator Brochure (IB):

UPLOAD DOCUMENT - DOCUMENT TYPE: INVESTIGATOR BROCHURE

If 'Product Monograph (PM)':

2.18.2.2 *Please upload Product Monograph (PM):

UPLOAD DOCUMENT - DOCUMENT TYPE: PRODUCT MONOGRAPH

2.18.3 *Please indicate the status of Health Canada Clinical Trial Application:

☐No Objection Letter pending

☐No Objection Letter enclosed

If 'No Objection Letter Enclosed':

2.18.3.1 *Please upload document:

UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA

Q2.18.3: NOL submission is not required by OCREB ; document uploaded here will NOT be acknowledged in the approval letter

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 2.18a.

2.18.4 *Please 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':

2.18.4.1 ***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.

2.18.5 ***Please 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)':

2.18.5.1 ***Please upload Investigator Brochure (IB):**

UPLOAD DOCUMENT - DOCUMENT TYPE: INVESTIGATOR BROCHURE

If 'Product Monograph (PM)':

2.18.5.2 ***Please upload Product Monograph (PM):**

UPLOAD DOCUMENT - DOCUMENT TYPE: PRODUCT MONOGRAPH

2.18.6 ***Please indicate the status of the Health Canada Clinical Trial Application**:

☐Notice of Authorization pending

☐Notice of Authorization enclosed

If 'Notice of Authorization Enclosed':

2.18.6.1 ***Please upload document:**

UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA

Medical Devices

These questions appear only if 'Medical Devices' was selected from list in question 2.18.

2.18.7 ***Health Canada medical device classification:**

☐Class I

☐Class II

☐Class III

☐Class IV

If 'Yes – an Investigational Testing Authorization (ITA) under the Medical Devices Regulations' selected in question 2.18a, the following questions appear:

2.18.8 ***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.

2.18.9 ***Please indicate the status of the device(s) with Health Canada (select all that apply):**

☐Licensed (e.g., has Medical Device License (MDL)), but being used outside of current Health Canada authorization

☐Investigational

If 'Licensed (e.g. has Medical Device License (MDL)), but being used outside of current Health Canada authorization':

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

2.18.10 *Does this device contain a drug?

☐Yes ☐No

If 'Yes':

2.18.10.1 *Drug used: Click here to enter text.

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

UPLOAD DOCUMENT - DOCUMENT TYPE: INSTRUCTIONS FOR USE

US Regulatory Requirements

2.18.12 *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

2.18.13 *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 an United States government agency (such as NCI, DHHS, DOJ) that is subject to the Common Rule or that is subject to the Food and Drug Administration (FDA) review and approval you must indicate 'Yes'.

Biological Specimen Collection

This section appears only if "Biological Specimen Collection" was selected from list in question 2.18.

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

2.18.15 *Will stem cells be collected or used in this study?

☐Yes ☐No

If 'Yes':

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

2.18.16 *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:

2.18.16.1 *Specify details: Click here to enter text.

2.18.17 *Does the sponsor plan to put a material transfer agreement (MTA) or similar contract in place with each participating centre to ensure secure transfer and storage of specimens?

☐Yes ☐No ☐N/A (specimens will not be transferred out of the centres)

If 'No':

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

2.18.18 *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 any future testing

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 any future testing 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 2.18.18, questions 2.18.19-2.18.24 appear:

2.18.19 *Please indicate whether the specimen collection for the purposes of this study is (select all that apply):

☐Optional

☐Mandatory

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

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

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

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

Click here to enter text.

2.18.24 ***Please indicate to what extent the study participant is able to withdraw specimens collected for the purposes of the study after the specimens have been shipped offsite, and any limitations to the withdrawal:** Click here to enter text.

If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 2.18.18, questions 2.18.25-2.18.31 appear:

2.18.25 ***Please indicate whether the sample collection for genetic testing is (select all that apply):**

☐Optional

☐Mandatory

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

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

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

2.18.29 ***Describe what will happen to the specimens at the end of that period (e.g., destroyed, returned):**
Click here to enter text.

2.18.30 ***Please indicate to what extent the study participant is able to withdraw specimens collected for genetic testing after the specimens have been shipped offsite, and any limitations to the withdrawal:**
Click here to enter text.

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

☐Yes ☐No

If 'Yes':

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

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

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

If 'No':

2.18.31.4 ***Please explain/justify:** Click here to enter text.

If 'Stored or retained or banked for any future testing' is selected in 2.18.18, questions 2.18.32-2.18.38 appears:

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

☐Optional

☐Mandatory

2.18.33 ***Where will the biobank(s)/repositories be located (e.g., name of bank & address including country)?**
Click here to enter text.

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

2.18.35 ***Who will be the custodian of the specimens that will be stored or retained or banked for any future testing?** Click here to enter text.

HELP TEXT:

Custodian refers to a person or organization/institution who has responsibility for taking care of or protecting something.

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

2.18.37 ***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.

2.18.38 ***Please indicate to what extent the study participant is able to withdraw banked specimens, and any limitations to the withdrawal:** Click here to enter text.

Radiation

This section appears only if "Radiation" was selected from list in question 2.18.

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

☐Diagnostic

☐Radiation therapy

☐Other

If 'Diagnostic':

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

If 'Other':

2.18.39.2 ***Specify other:** Click here to enter text.

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

☐Yes ☐No

If 'Yes':

2.18.40.1 ***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 2.18; questions 2.18.41 – 2.18.43 appear:

2.18.41 ***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).

2.18.42 *Please upload all surveys/questionnaires, screen shots and/or interviews/focus group scripts:
UPLOAD DOCUMENT - DOCUMENT TYPE: SURVEYS OR INTERVIEW/FOCUS GROUP SCRIPTS

Q2.18.42: 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

2.18.43 Please 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 2.18.43.

Other Health Related Interventions

If ''Other Health Related Interventions' selected in questions 2.18:

2.18.44 *Other Health Related Interventions

☐Cognitive behavioural therapy
☐Surgery
☐Exercise
☐Device based apps or wearable devices
☐Other:

If 'Other':

2.18.44.1 *Specify other: Click here to enter text.

If 'Device based apps or wearable devices':

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

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

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 ***Please 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 ***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: 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.

Note: results from standard clinical tests and/or adverse events are not considered to be incidental findings.

3.7 ***Please 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

- For any clinical trial involving cancer patients, the answer to Q3.7.2 should be "Yes".
- If unsure, contact OCREB.

SECTION 4.0 – RECRUITMENT

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

☐Yes ☐No

If 'Yes':

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

4.2 ***What recruitment materials/methods are being used (select all that apply)?**

☐None

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

☐Recruitment database

☐Third-party organization or recruitment company

☐Telephone call scripts

☐Website

☐Social Media

☐Video (recordings will not be reviewed without scripts)

☐Email Script

☐Other

If 'Other':

4.2.1*Specify other: Click here to enter text.

4.3 ***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':

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

4.4 ***Describe the overall strategies for minimizing coercion or undue influence for the population(s) included in the study:** Click or tap here to enter text.

HELP TEXT:

Undue influence refers to the impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student, employer/employee).

If any option other than 'none' is selected in Q4.2, then Q4.5 appears:

4.5 ***Upload all recruitment materials that will be used during the study:**

UPLOAD DOCUMENT - DOCUMENT TYPE: RECRUITMENT MATERIALS

4.6 ***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:

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

☐Yes ☐No

If 'Yes':

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

If 'Yes':

Provide the following as applicable:

4.6.1.2 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:

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.

4.6.1.3 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

4.6.1.4 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':

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

SECTION 5.0 - INFORMED CONSENT INFORMATION

5.1 ***Is a waiver of the requirement to obtain informed consent being requested for this study?**

☐**Yes** ☐**No**

HELP TEXT:

A waiver of consent implies that no consent process is required; there is no information and consent form or verbal review of study information with participants.

If 'Yes':

5.1.0 * Provide Justification: Click here to enter text.

If 'No' to question 5.1, question 5.1.1 will appear:

5.1.1 ***Will a written consent be obtained from all participants and/or substitute decision makers (SDMs)?**

☐Yes ☐No

HELP TEXT:

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

If 'No':

5.1.2 * Describe why a written consent will not be obtained: Click here to enter text.

5.1.3 * Describe any alternative methods that will be used to obtain non-written consent: Click here to enter text.

If 'Yes' to question 5.1: Question 5.2 - 5.4 will appear:

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

☐All participants

☐Some participants

If 'Some participants':

5.2.1 *Describe the participant population for whom you are seeking a waiver and justify why the REB should consider a waiver of consent: Click here to enter text.

5.3 ***Do the following criteria apply to this study (select all that apply)?**

☐ The research involves no more than minimal risk to the participants

☐ The waiver of informed consent is unlikely to adversely affect the welfare of participants

☐ It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required

☐ Research relies exclusively on secondary use of non-identifiable data/specimens

If 'The waiver of informed consent is unlikely to adversely affect the welfare of participants':

5.3.1 *Please explain why there is unlikely to be an adverse effect: Click here to enter text.

If 'It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required':

5.3.2 *Please explain why it is impossible or impracticable to conduct the research with prior consent:

Click here to enter text.

HELP TEXT:

Minimal risk research is defined by the Tri-Council Policy Statement (TCPS 2) as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

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

Secondary use refers to the use in research of data or originally collected for a purpose other than the current research purpose.

If 'The research involves no more than minimal risk to the participants', 'The waiver of informed consent is unlikely to adversely affect the welfare of participants' OR 'It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required' is selected in 5.3, question 5.4 appears:

5.4 ***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

If 'Yes':

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

If 'Yes':

5.4.2 Attach copy of debriefing materials (e.g., script and/or form):

UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'No':

5.4.3 ***Please justify why participants will not be debriefed:** Click here to enter text.

HELP TEXT:

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

If 'Some participants' is selected in question 5.2:

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

UPLOAD DOCUMENT - DOCUMENT TYPE: PROVINCIAL CONSENT FORM

HELP TEXT:

The CTO informed consent form template must be used to create the main Provincial consent form (Except for studies which will be reviewed by OCREB which require the use of the OCREB consent template - https://ocreb.ca/about-ocreb/guidelines-templates-and-sops/). Refer to the CTO website for further details. If you have questions, go to support.ctontario.ca and submit a ticket within the CTO Stream online Helpdesk.

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

5.5.1 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

If 'No' to question 5.1, question 5.6 will appear:

5.6 *Is there any proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)?

☐Yes ☐No

HELP TEXT:

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.

If 'Yes' to question 5.6: questions 5.7-5.8 will appear:

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

HELP TEXT:

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.

5.8 *Do the following criteria apply to this study (select all that apply)?

☐ The research involves no more than minimal risk to the participants

☐ The alteration to consent requirements is unlikely to adversely affect the welfare of participants

☐ It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, without the alteration in consent procedures

☐ Participants will be provided an opportunity to refuse consent and/or withdraw data/specimens

If 'The alteration to consent requirements is unlikely to adversely affect the welfare of participants' selected:

5.8.1 *Please explain why there is unlikely to be an adverse effect:

If 'It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, without the alteration in consent procedures':

5.8.2 *Please explain why it is impossible or impracticable to conduct the research without the alteration: Click here to enter text.

HELP TEXT:

Minimal risk research is defined by the Tri-Council Policy Statement (TCPS 2) as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

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

If 'No' to question 5.1: then question 5.9 will appear:

5.9 ***Upload clean versions of all proposed debriefing material(s):**
UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'No' to question 5.1, question 5.10 will appear:

5.10 ***Upload clean versions of all proposed consent forms (e.g., screening, main, optional, parent, participant, etc.):**
UPLOAD DOCUMENT - DOCUMENT TYPE: PROVINCIAL CONSENT FORM
HELP TEXT:
The CTO informed consent form template must be used to create the main Provincial consent form. (Except for studies which will be reviewed by OCREB which require the use of the OCREB consent template - https://ocreb.ca/about-ocreb/guidelines-templates-and-sops/). Refer to the CTO website for further details. If you have questions, go to support.ctontario.ca and submit a ticket within the CTO Stream online Helpdesk

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

A screening consent form refers to a separate consent to allow the researcher to carry out a smaller number of select test procedures in order to make a preliminary eligibility determination. Screening tests may be used in situations where the absence or presence of a specific biomarker precludes participation in the study. Screening procedures for research eligibility are considered part of the participant selection and recruitment process and therefore require REB review.

5.10.1 **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

5.11 ***Does this study include assent form(s)?**
☐Yes ☐No
If 'Yes':
5.11.1 ***Upload all proposed assent forms:**
UPLOAD DOCUMENT - DOCUMENT TYPE: PROVINCIAL ASSENT FORM

If 'Optional' is selected in question 2.18.25;, question 5.12 will appear:

5.12 ***Describe the processes used for obtaining and documenting informed consent for genetic testing:**
Click here to enter text.

Q5.12: applicant may note: "*This has been addressed in the consent form(s).*"

5.13 ***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

If 'Publication(s)':

5.13.1 *Describe publication plan: Click here to enter text.

If 'Other':

5.13.2 *Specify other: Click here to enter text.

If 'No plan':

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

TO OTHER STAKEHOLDERS

☐Presentation(s)

☐Publication

☐Other

☐No plan

If 'Presentation(s)':

5.13.4 *Describe presentation plan: Click here to enter text.

If 'Publication':

5.13.5 *Describe publication plan: Click here to enter text.

If 'Other':

5.13.6 *Specify other: Click here to enter text.

If 'No plan':

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

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.

6.2.2 ***Describe if and when the withdrawal or absence of treatment/intervention will be disclosed to the participant:** 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 or embryotoxicity, risks related to breastfeeding or birth defects, risks to female partners of male participants, risks related to male participant fathering a child):** 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 *Please Justify:

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':

6.8.4 *Please upload DSMB/C charter

UPLOAD DOCUMENT - DOCUMENT TYPE: DSMB/C CHARTER

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

6.8.3 * Please provide the additional information that is not covered in the DSMB/C Charter

6.8.4 * Please upload DSMB/C charter Click here to enter text.

UPLOAD DOCUMENT - DOCUMENT TYPE: DSMB/C CHARTER

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

6.8.5 *Please 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.

6.8.6 *Is it independent?

☐Yes ☐No

If 'No':

6.8.7 *Justify: Click here to enter text.

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

☐Lead Researcher/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.

Q6.10: relates to the overall study and any rules or criteria for stopping the study – e.g., futility as per the protocol.

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)?

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☐Full date of birth
- ☐Partial date of birth
- ☐Full date of death
- ☐Partial date of death
- ☐Age
- ☐Sex and/or gender
- ☐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
- ☐Full face photograph
- ☐Voice/audio 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

Q7.1: All identifiers disclosed/provided to the sponsor, must be selected.

***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.

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 '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 and/or gender':* **7.1.11 *Justify sex and/or gender:** Click here to enter text.
- *If 'Full postal code':* **7.1.12 *Justify full postal code:** Click here to enter text.
- *If 'First 3 digits of postal code':* **7.1.13 *Justify first 3 digits of postal code:** Click here to enter text.
- *If 'Pathology specimen number':* **7.1.14 *Justify pathology specimen number:** Click here to enter text.
- *If 'Medical device identifier':* **7.1.15 *Justify medical device identifier:** Click here to enter text.
- *If 'Admission date':* **7.1.16 *Justify admission date:** Click here to enter text.
- *If 'Discharge date':* **7.1.17 *Justify discharge date:** Click here to enter text.
- *If 'Medical record number':* **7.1.18 *Justify medical record number:** Click here to enter text.
- *If 'Health card number':* **7.1.19 *Justify health card number:** Click here to enter text.
- *If 'Driver's license number':* **7.1.20 *Justify driver's license number:** Click here to enter text.
- *If 'Address':* **7.1.21 *Justify address:** Click here to enter text.
- *If 'Telephone number':* **7.1.22 *Justify telephone number:** Click here to enter text.
- *If 'Fax number':* **7.1.23 *Justify fax number:** Click here to enter text.
- *If 'E-Mail address':* **7.1.24 *Justify E-mail address:** Click here to enter text.
- *If 'Full face photograph':* **7.1.25 *Justify full face photograph:** Click here to enter text.
- *If 'Voice/audio recording':* **7.1.26 *Justify voice/audio recording:** Click here to enter text.
- *If 'SIN number':* **7.1.27 *Justify SIN number:** Click here to enter text.
- *If 'Device Identifier':* **7.1.28 *Justify device identifier:** Click here to enter text.
- *If 'Internet Protocol address (IP address)':* **7.1.29 *Justify internet protocol address (IP address):** Click here to enter text.
- *If 'Race and/or ethnicity':* **7.1.30 *Justify race and/or ethnicity:** Click here to enter text.
- *If 'Family/caregiver names and/or contact information':* **7.1.31 *Justify family/caregiver names and/or contact information:** Click here to enter text.

HELP TEXT:

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

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

UPLOAD DOCUMENT - DOCUMENT TYPE: DATA COLLECTION DEMOGRAPHIC PAGES

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 the lead researcher/group/sponsor collect/receive the study data? (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 25 years

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

7.8 ***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

Q7.8: refers to databases that are separate from/external to the Sponsor's database (e.g., ICES; CCO etc.).

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':

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

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

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

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

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

7.9 *Will any of the study data be entered into a database for future use?

☐Yes ☐No

If 'Yes':

7.9.1 *Please specify: Click here to enter text.

7.9.2 *Where will it be stored? Click here to enter text.

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

HELP TEXT:

Custodian refers to a person or organization/institution who has responsibility for taking care of or protecting something.

7.9.4 *Who will have access to the database? 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 *Please indicate to what extent the study participant is able to withdraw their data after the data have been shipped/sent offsite (such as part of an e-CRF) and any limitations on the withdrawal:
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 2.18, questions 7.12-7.13 will appear:

7.11 *Will the specimens be coded to enable them to be linked back to identifying information if required. [e.g., for withdrawal of the sample or to return unused samples]?

☐Yes ☐No

If 'Yes':

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

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

If 'Surveys/Questionnaires/Interviews/Focus Groups' is selected in 2.18 or 'Device based apps or wearable devices' is selected in 2.18.44 question 7.14 will appear:

7.13 *Select the electronic tools that will be used for the research interventions like, recruiting, data collection or follow-up:

Q7.13: Do NOT select Email if it will only be used for communicating with participants

☐Email
☐Electronic messaging (e.g. text message, WhatsApp)
☐Video conferencing

☐Web-based (online) portal
☐Device based apps (downloaded or installed to a smartphone or other device)
☐Wearable devices
☐Other

If 'Email' is selected in question 7.13:
EMAIL:
7.13.1 *Justify purpose: Click here to enter text.
7.13.2 *Please confirm disclaimer related to email risks will be included in informed consent form: Click here to enter text.

If 'Electronic messaging' is selected in question 7.13:
ELECTRONIC MESSAGING (E.G. TEXT MESSAGE, WHATSAPP)
7.13.3 *Specify the name: Click here to enter text.
7.13.4 *Justify purpose: Click here to enter text.
7.13.5 *Please confirm disclaimer related to electronic messaging will be included in the informed consent form: Click here to enter text.

If 'Video conferencing' is selected in question 7.13:
VIDEO CONFERENCING
7.13.6 *Specify the name: Click here to enter text.
7.13.7 *Justify purpose: Click here to enter text.
7.13.8 *Please confirm that a video conferencing tool approved by the privacy Office of the institution (lead or local) will be used for the research: Click here to enter text.

If 'Web-based (online) portal' is selected in question 7.13:
WEB-BASED (ONLINE) PORTAL
7.13.9 *Specify the name: Click here to enter text.
7.13.10 *Justify purpose: Click here to enter text.

If 'Device based apps' is selected in question 7.13:
DEVICE BASED APPS (DOWNLOADED OR INSTALLED TO A SMARTPHONE OR OTHER DEVICE)
7.13.11 *Specify the name: Click here to enter text.
7.13.12 *Justify purpose: Click here to enter text.

If 'Wearable devices' is selected in question 7.13:
WEARABLE DEVICES
7.13.13 *Specify the name: Click here to enter text.
7.13.14 *Justify purpose: Click here to enter text.

If 'Other' is selected in question 7.13:
7.13.15 *Specify other: Click here to enter text.
7.13.16 *Justify purpose: Click here to enter text.

If 'Web-based portal, Device based apps or Wearable devices' are selected in 7.13 questions 7.14 - 7.20 will appear:

7.14 *Please list what identifiable information would be collected about the participants for the purpose of registering or operating the tool? Click here to enter text.

HELP TEXT:
Most electronic tools developed by third parties require personal identifiers of participants to operate (e.g., registration, data collection). Some examples of identifiable information collected by app or device include email address, participant name, study ID, date of birth, device identifier, global positioning system (GPS) coordinates, internet protocol address (IP address, permission to access the camera).

7.15 ***Please justify the collection and use of each of the identifiers listed above.** Click here to enter text.
HELP TEXT:
Wherever possible, anonymous data should be used instead of identifiable data. For example, using participant ID or study number instead of first and last name, providing a pseudo email address (e.g. participant@hospital.ca) instead of the participant using their personal email address, standardizing the input of day and month of birth if full date of birth is required to register but not needed for the study.

7.16 ***Please list the name of the third party or vendor that owns or stores the data in the tool:** Click here to enter text.

7.17 ***Please list what participant information would be collected by the researchers from the tool for the study:** Click here to enter text.

7.18 ***Please identify if data will be encrypted while stored ("at rest") in the tool:**
☐Yes - Data is encrypted while stored ("at rest")
☐No - Data is not encrypted while stored ("at rest"). This information will need to be included in the consent form (ICF)

7.19 ***Please identify if data will be encrypted when moving ("in transit") between the tool and the researcher's institutional storage:**
☐ Yes - Data is encrypted when moving ("in transit")
☐*No - Data is not encrypted when moving ("in transit"). This information will need to be included in the consent form (ICF)*

7.20 ***Please upload all documents indicating that the tool(s) has been approved by a privacy expert after undergoing a privacy and/or security review.**
Upload Document - Document Type: Privacy Documents

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):

If 'Charitable foundation':

Charitable foundation

8.1.5 *Name(s):

If 'Granting agency':

Granting agency

8.1.6 *Name(s):

If 'Internal funding':

Internal funding

8.1.7 *Name(s):

If 'US federal funds':

US federal funds

8.1.8 *Name(s):

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

8.1.9 *Name of funding agency/ies

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.

If 'Yes':

8.2.1 *Select all that apply:

☐Unrestricted grant

☐Restricted grant drug

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

☐Other

If 'Restricted grant drug' or 'Other' is selected:

8.2.2 *Describe:

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

Q8.3: upload the sponsor's proposed budget for the study, NOT the centre-specific budget.

UPLOAD DOCUMENT - DOCUMENT TYPE: SPONSORS STUDY 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 CTO Stream apply to all industry-sponsored/supported studies and are invoiced upon receipt of the submission)

☐Yes ☐No

If 'Yes':

CTO 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 BY CTO.

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

☐Yes ☐No

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

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 the cost of the investigational intervention(s) used in the study be covered for study participants for the duration of the study?

☐Yes ☐No

If 'No':

8.6.1 *Justify: Click here to enter text.

8.7 *Will the cost of comparator intervention(s) used in the study be covered for study participants for the duration of the study?

☐Yes ☐No

If 'No':

8.7.1 *Justify: Click here to enter text.

8.8 *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

If 'No':

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

If 'Yes':

8.8.2 *Please explain how participants will obtain access and any associated cost: Click here to enter text.

8.9 *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':

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

8.10 *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':

8.10.1 *Please 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: answer "Yes" only if the translated materials are available for uploading to the current application. If they are not available, submit them later with a Provincial Amendment (PAM).

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

NOTE. Translation certificates/supporting documentation are not required for Questionnaires that are validated in the translated language(s)

SECTION 10.0 - RE-SUBMISSION INFORMATION

If 'Is this a resubmission in response to a request from CTO 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 CTO.

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

10.1 **Upload Provincial Applicant/CHEER Applicant Response to REB request for modification letter (if applicable)**:

Q10.1: a response letter is required each time the applicant re-submits the PIA 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.

UPLOAD DOCUMENT - DOCUMENT TYPE: RESPONSE TO REB LETTER

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

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

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

10.3 **Upload any additional materials requested by the REB (if applicable):**
UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS

10.4 **Please 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/PIA, if applicable.

SECTION 11.0 – ATTESTATIONS AND SIGNATURES

If 'No' to question 1.0, the Provincial Applicant/CHEER Applicant signature appears:

11.1 Provincial Applicant/CHEER 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 Provincial Applicant/CHEER 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 Provincial Applicant/CHEER Applicant:
  - I attest that this application is and all subsequent trial-related applications will be completed and submitted in compliance with TCPS2 (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 Provincial Co-Applicant/CHEER Co-Applicant listed in this application (if applicable) is appropriately qualified to assume my responsibilities as Provincial Applicant/CHEER Applicant in the event that I am unable to do so;
  - I acknowledge that I am responsible for promptly reporting to the REB, through the Clinical Trials Ontario Streamlined Research Ethics Review System, 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 provincial initial application/CHEER initial application is approved, I am aware that if I also am a centre PI on this trial, I must submit, through the Clinical Trials Ontario Streamlined Research Ethics Review System, a Centre Initial Application Form for approval to conduct the trial at my centre;
  - I am aware that the REB review materials (e.g., provincial/CHEER forms including attachments, review letters, other correspondence, approval letters, etc.) will be shared with all sites participating in this trial through the Clinical Trials Ontario Streamlined Research Ethics Review System;
  - I am aware that CTO will make the following trial information available to all Ontario sites participating in this trial: CTO Project I.D. #, Sponsor Name, Sponsor Protocol I.D. #, Trial Title, REB review status, name of Provincial Applicant/CHEER Applicant, and the names of the participating centres and PIs.

  SIGNATURE TYPE: PROVINCIAL APPLICANT

If 'Yes' to question 1.3 AND 'No' to question 1.0; the Provincial Co-Applicant/CHEER C0-Applicant signature appears:

11.2 Provincial Co-Applicant/CHEER Co-Applicant

- I agree to assume the role of Provincial Co-Applicant/CHEER Co-Applicant;
- As Provincial Co-Applicant/CHEER Co-Applicant, I agree to assume the Provincial Applicant/CHEER Applicant responsibilities (as noted above) in the event that Provincial Applicant/CHEER Applicant is unable to do so.
- I attest that I am appropriately qualified to assume the responsibilities of Provincial Applicant/CHEER Applicant in the event that he/she is unable to do so;

  SIGNATURE TYPE: PROVINCIAL CO-APPLICANT

If 'Yes' to question 1.0; the Provincial Applicant/CHEER Applicant or Delegate signature will appear:

11.3 Provincial Applicant/CHEER Applicant or Delegate

PI response can be signed by DELEGATE to submit ; ensure Q#1.0 response is 'YES" for this Section to appear

- 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 Provincial Applicant/CHEER Applicant, I attest that the delegation of this responsibility has been documented.

  SIGNATURE TYPE: PA OR DELEGATE