CTO Provincial Initial Application Form

Orange text *indicates an upload or action feature*
Red/italics/bold *indicates question/feature dependencies*
Questions with an asterisk (*) are mandatory and must be completed prior to signatures/submission
Indicates a shared question

SECTION 1.0 - GENERAL INFORMATION

1.0 ***Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?**
Choose an item.

Always answer 'YES" to Q1.0 if the application is being re-submitted in response to a request by OCREB or by the OCREB office.

1.1 ***Is this a multi-centre clinical trial?**
☐ Yes ☐No

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 contact CTO 1-877-715-2700 or support@ctostream.ca

If 'yes' for 1.1, question 1.2 appears:
1.2 ***Please complete the Provincial Applicant (PA) 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.

1.3 ***Is there a Provincial Co-Applicant?**
☐Yes ☐No

***If 'Yes':** ***Please complete the Provincial 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.

Recommend answering "No" to Q1.3. Including a Co-Applicant does not grant the individual permissions 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-Is should be noted in the study delegation log.

Fax: Click here to enter text.
*Email: Click here to enter text.

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

☐Yes ☐No

***If 'Yes':* *Please complete the Main 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.

1.5 ***Complete Study Title: (Enter exactly as written in protocol)** Click here to enter text.

1.6 **Please enter the Sponsor's Study ID/Number:** Click here to enter text.

***Please Upload Protocol:**
Upload Document

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 REB submissions.)**
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.

1.9 ***Is this an Investigator-initiated study?**
☐Yes ☐No

1.10 ***Has this study started elsewhere (provincially, nationally or internationally)?**
☐Yes ☐No
***If 'Yes':* *Enter the approximate date (e.g., month/year) the study started:** Click here to enter text.
***If 'Yes':* *Describe any known issues (e.g., safety or recruitment related):** Click here to enter text.

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

1.12 ***Has the attached protocol(s) undergone an independent scientific review?**

☐Yes ☐No

***If 'Yes':* *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.

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

1.13 ***Has this study been rejected by any REB?**

☐Yes ☐No

***If 'Yes':* *Please describe:** Click here to enter text.
***If 'Yes'*: Upload any relevant documents (if applicable):**
Upload Document

1.14 ***How many Ontario centres do you expect will participate in this study?**
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 ***Are the Main CRO Contact details available?**

☐Yes ☐No ☐No CRO

***If 'Yes':* *Please enter the Main 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.

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: Click here to enter text.

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.

1.17 **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.

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.

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.

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.

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):**
If any of the * below are selected, questions related to "special populations" will appear in the recruitment section (section 4), consent section (section 5) and/or in the Centre Initial Application form

☐Patients
☐Healthy volunteers
☐Students*
☐Staff*
☐People with mental health issues*
☐People institutionalized*
☐Prisoners/persons in detention*
☐People in poverty/economically disadvantaged*
☐Educationally disadvantaged people*
☐People who are unable to read or write*
☐Children*
☐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
☐Aboriginal people and/or ethno-cultural minorities*
☐Other

***If 'Other': *Specify:** Click here to enter text.
***If 'Students': *Justify inclusion of students in the research:** Click here to enter text.
***If 'Staff'': *Justify inclusion of staff in the research:** Click here to enter text.
***If 'people with mental health issues': *Justify the inclusion of people with mental health issues in the research:** Click here to enter text.

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.

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

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

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

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

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

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

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

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

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

If 'individuals with physical disabilities': ***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': ***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': ***Justify the inclusion of adult individuals who are temporarily unable to provide consent in the research:** Click here to enter text.

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

If 'Aboriginal people (including First Nations, Inuit and Métis peoples) or other ethno-cultural minorities': ***Justify inclusion of Aboriginal people and/or ethno-cultural minorities 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': ***Explain and include the justification:** Click here to enter text.

If 'Yes': ***Indicate how participants will be debriefed:** Click here to enter text.

2.12 ***What is the accepted standard of care for this population in Ontario?** Click here to enter text.

2.13 ***Will the participants be withdrawn from or denied usual therapy for any condition in order to participate in this study?**

☐Yes ☐ No

If 'Yes': ***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 in Ontario?** 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 Ontario centres using CTO?**

☐Yes ☐No

If 'Yes': **Please upload sub-study or companion protocol**
Upload Document
If 'Yes': ***Describe the sub-study including the rationale for it:** Click here to enter text.

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.

2.17 ***Is this protocol directly related to a previously approved study at a CTO REB?**

☐Yes ☐No

If 'Yes': ***Please provide the CTO Stream Review Reference #:** Click here to enter text.

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

☐Drugs, Biologics (including vaccines), Genetic Therapies or Radiopharmaceuticals
☐Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))
☐Medical Devices
☐Biological specimen collection (e.g., blood/tissue for PK, biomarker, biobanking, genetic testing, etc., excluding specimens taken as part of normal care or for safety)
☐Radiation (including tests involving exposure to radiation)
☐Surveys/Questionnaires/Interviews/Focus Groups
☐Other health related interventions not listed above

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

2.18a appears only if 'Drugs, Biologics (including vaccines), Genetic Therapies 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 Application)?**

☐Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations
☐Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations
☐Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations
☐No

Drugs, Biologics (including vaccines), 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

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

If 'Investigator Brochure (IB)': ***Please upload Investigator Brochure (IB):**

Upload Document

If 'Product Monograph (PM)': ***Please upload Product Monograph (PM):**

Upload Document

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': ***Please upload document:**

Upload Document

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

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

Upload Document

If 'Product Monograph (PM)': ***Please upload Product Monograph (PM):**

Upload Document

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': ***Please upload document:**
Upload Document

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 Application (ITA) under the Medical Device 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

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': ***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': ***Drug used:** Click here to enter text.

2.18.11 *For each device covered under the ITA, upload the Product Monograph (PM) or equivalent:

***Please upload PM or equivalent:**
Upload Document

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

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'*: *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

***If Other:* *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':* *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

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':

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

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

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

If 'No':

***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 2.18.32-2.18.37 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.

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': *Specify diagnostic: Click here to enter text.
If 'Other': *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': *Describe the radiation exposure that is above standard of care: Click here to enter text.

Surveys/Questionnaires/Interviews/Focus Groups

This section appears only if "Surveys/Questionnaires/Interviews/Focus Groups" was selected from list in question 2.18.

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

2.18.42 *Please upload all surveys/questionnaires, screen shots and/or interviews/focus group scripts:

Upload Document

2.18.43 Please provide the URL for any electronic materials (as applicable):

Click here to enter text.

Add Another

Q2.18.43: if electronic surveys or questionnaires will be provided, describe the security of the electronic device and associated data, and the process for the confidential/secure transfer of the data.

Other Health Related Interventions

This section appears only if "Other Health Related Interventions" was selected from list in question 2.18a.

2.18.44 *Other Health Related Interventions

☐Cognitive behavioural therapy
☐Surgery
☐Exercise
☐Other:

If 'Other': *Specify other: Click here to enter text.

SECTION 3.0 - CLINICAL TRIAL INFORMATION

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

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

If 'Other': *Please specify: 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':* Provide the name of the registry (e.g., www.clinicaltrials.gov):** Click here to enter text.
Provide the registration #: Click here to enter text.
Or,
☐Pending

If 'No': *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': *Justify placebo: Click here to enter text.
If 'sham procedure(s)': *Justify sham procedure(s): Click here to enter text.
If 'washout': *Justify washout: Click here to enter text.
If 'withholding treatment': *Justify withholding treatment: Click here to enter text.
If 'no-treatment arm': *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. (Note: results from standard clinical tests and/or adverse events are not considered to be incidental findings). If applicable, indicate whether incidental (actionable/material) findings are anticipated for this study. If yes, describe the plan for disclosure to participants (with consent), or provide the rationale for non-disclosure. If the response changes during the conduct of the study, an amendment must be submitted.

SECTION 4.0 – RECRUITMENT

4.1 *Has the sponsor proposed a broad recruitment plan (e.g., recruitment database, call centre, advertising)?

☐Yes ☐No

If 'Yes': *Describe: Click here to enter text.

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

☐None
☐Brochures, flyers, poster
☐Recruitment database
☐Third-party recruitment company
☐Newspaper ad
☐Telephone call scripts
☐Website
☐Video (recordings will not be reviewed without scripts)
☐Other

If 'Other': *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 or age?

☐Yes ☐No

If 'Yes': *Describe and justify: Click here to enter text.

If special populations (indicated by a *) are selected in 2.6, question 4.4 will appear:

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

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

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 Aboriginal identity as a factor for the entire study or for a subgroup in the study
☐Research that seeks input from participants regarding an Aboriginal community's cultural heritage, artefacts, traditional knowledge or unique characteristics
☐Research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data
☐Interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture
☐None of the above

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

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

☐Yes ☐No

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

'If Yes': Provide the following as applicable:

a) **a preliminary or formal research agreement between the researcher and the responsible body at the research site:**

Upload Document

b) **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

c) **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

If 'No': ***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

If 'Yes': ***Provide justification:** Click here to enter text.

Q5.1: answer "No" unless a waiver is being requested for **ALL** participants.

If 'No': Question 5.2 and 5.3 will appear:

5.2 ***Upload clean versions of all proposed consent forms (e.g., screening, main, optional):**

Upload Document

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

Upload Document

5.3 ***Does this study include assent form(s)?**

☐Yes ☐No

If 'Yes': ***Upload all proposed assent forms:**

Upload Document

If 2.18.25 = 'optional', question 5.4 will appear:

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

Q5.4: applicant may note: "*This has been addressed in the consent form(s).*"

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

TO PARTICIPANTS

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

***If 'Each PI to provide debriefing at end of test session'*: Attach copy of debriefing script, if available:**

Upload Document

If 'group debriefing': **Attach copy of group debriefing, if available:**

Upload Document

If ' end of study letter': **Attach letter, if available:**

Upload Document

If 'publication(s)': ***Describe publication plan:** Click here to enter text.

If 'Other': ***Specify other:** Click here to enter text.

If 'No plan': ***Justify no plan:** Click here to enter text.

TO OTHER STAKEHOLDERS

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

If 'Presentation(s)': ***Describe presentation plan:** Click here to enter text.

If 'Publication': ***Describe publication plan:** Click here to enter text.
If 'Other': ***Specify other:** Click here to enter text.
If 'No plan': ***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.

If 'placebo', 'sham procedures', 'washout', 'withholding treatment', or 'no-treatment arm' are selected in 3.4, question 6.2 appears:

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

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

***Describe if and when the withdrawal or absence of treatment 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':** ***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 affect alternatives for future care or eligibility for future research?**

☐Yes ☐No

***If 'Yes':** ***Explain:** Click here to enter text.

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

☐Yes ☐No

***If 'Yes':** ***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':** ***Describe:** Click here to enter text.

***If 'No':** ***Justify:** Click here to enter text.

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

☐Yes ☐No

***If 'Yes':** ***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':** ***Please upload DSMB/C charter**

Upload Document

***If 'the DSMB/C charter contains some of this information':** ***Please provide the additional information that is not covered in the DSMB/C Charter:** Click here to enter text.

***Please upload DSMB/C charter:**

Upload Document

If 'the DSMB/C charter does not contain any of this information': ***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.

If 'Yes': ***Is it independent?**

☐Yes ☐No

If 'No': ***Justify:** Click here to enter text.

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

☐Sponsor

☐Outside agency (e.g. CRO)

☐Other:

If 'Outside Agency (e.g. CRO)': ***Specify outside agency:** Click here to enter text.

If 'Other': ***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*

SECTION 7.0 - PRIVACY AND CONFIDENTIALITY

7.1 *What (if any) Personal Information or Personal Health Information is the sponsor requesting on the study data collection tools (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/gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Ontario health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-Mail address
- ☐Full face photograph
- ☐Voice/audio recording
- ☐Other

Q7.1: All identifiers disclosed/provided to the sponsor through data collection, must be selected. Identifiers must be included in the Confidentiality Section of the consent form, (e.g., initials, DOB, pathology#, age, sex**) except for** identifiers such as date of admission, discharge or death, which are not specific identifiers.

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

***If 'Other':* *Specify other information:** Click here to enter text.
***If 'Other':* *Justify other information:** Click here to enter text.
***If 'Full name':* *Justify full name:** Click here to enter text.
***If 'Full initials':* *Justify full initials:** Click here to enter text.
***If 'Partial initials':* *Justify partial initials:** Click here to enter text.
***If 'Full date of birth':* *Justify full date of birth:** Click here to enter text.
***If 'Partial date of birth':* *Justify partial date of birth:** Click here to enter text.
***If 'Full date of death':* *Justify full date of death:** Click here to enter text.
***If 'Partial date of death':* *Justify partial date of death:** Click here to enter text.
***If 'Age':* *Justify age:** Click here to enter text.
***If 'Sex/gender':* *Justify sex/gender:** Click here to enter text.
***If 'Full postal code':* *Justify full postal code:** Click here to enter text.
***If 'First 3 digits of postal code':* *Justify first 3 digits of postal code:** Click here to enter text.
***If 'Pathology specimen number':* *Justify pathology specimen number:** Click here to enter text.
***If 'Medical device identifier':* *Justify medical device identifier:** Click here to enter text.
***If 'Admission date':* *Justify admission date:** Click here to enter text.
***If 'Discharge date':* *Justify discharge date:** Click here to enter text.

If 'Medical record number': ***Justify medical record number:** Click here to enter text.
If 'Ontario health card number': ***Justify Ontario health card number:** Click here to enter text.
If 'Driver's license number': ***Justify driver's license number:** Click here to enter text.
If 'Address': ***Justify address:** Click here to enter text.
If 'Telephone number': ***Justify telephone number:** Click here to enter text.
If 'Fax number': ***Justify fax number:** Click here to enter text.
If 'E-Mail address': ***Justify E-mail address:** Click here to enter text.
If 'Full face photograph': ***Justify full face photograph:** Click here to enter text.
If 'Voice/audio recording': ***Justify voice/audio recording:** Click here to enter text.

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

7.3 *Will there be a code linking identifiers to the study participant?
☐Yes ☐No
If 'Yes': ***Who will have access to the code?** Click here to enter text.

7.4 *How will the sponsor collect/receive the study data? (select all that apply)
☐Fax
☐Electronic (online) data collection
☐Private courier
☐Canada Post registered mail (e.g., Priority, or other secure shipping method)
☐Other
If 'Other': ***Specify:** Click here to enter text.

7.5 *Does the sponsor plan to put a data transfer agreement (DTA) in place with each participating centre to ensure secure transfer and storage of the study data?
☐Yes ☐No
If 'No': ***Justify:** Click here to enter text.

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

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

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

7.9 *Is there a plan to link any of the study data with any other data sets, databases or registries (e.g., health registries, Statistics Canada)?
☐Yes ☐No
If 'Yes':
***Identify the data sets, databases or registries to which it will be linked:** Click here to enter text.
***Explain the purpose for the linking:** Click here to enter text.
***Describe how the linking will be done:** Click here to enter text.
***Describe the likelihood that identifiable data will be created through the linkage:** Click here to enter text.
***Describe the security measures that will be in place to protect the confidentiality of the data:** Click here to enter text.

Q7.9: refers to databases that are separate from/external to the Sponsor's database (e.g., ICES).

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

☐Yes ☐No

If 'Yes':

***Please specify:** Click here to enter text.

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

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

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

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

Q7.10: refers to databases that are not directly related to the study – i.e., NOT the Sponsor's database (e.g., investigator's database for secondary use of data for future use)

7.11 ***Please indicate to what extent the study participant is able to withdraw their data after the data have been shipped offsite 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:

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

☐Yes ☐No

***If 'Yes': *Who will have access to the code or link?** Click here to enter text.

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

SECTION 8.0– FUNDING

8.1 *Study funder(s) (select all that apply):

☐Industry (e.g. pharmaceutical or biotech company)
☐Government funding agency
☐Government
☐Charitable foundation
☐Granting agency
☐Internal funding
☐US federal funds
☐Other
☐None

If 'Other':
***Specify other funder(s):** Click here to enter text.

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

If 'Industry (e.g. pharmaceutical or biotech company)':
Industry (e.g., pharmaceutical or biotech company)
***Name(s):** Click here to enter text.

If 'Government funding agency':
Government funding agency
***Name(s):** Click here to enter text.

If 'Government':
Government
***Name(s):** Click here to enter text.

If 'Charitable foundation':
Charitable foundation
***Name(s):** Click here to enter text.

If 'Granting agency':
Granting agency
***Name(s):** Click here to enter text.

If 'Internal funding':
Internal funding
***Name(s):** Click here to enter text.

If 'US federal funds':
US federal funds
***Name(s):** Click here to enter text.

8.2 *Does the study involve any industry support?

☐Yes ☐No

If 'Yes': *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': *Describe:** Click here to enter text.
***If 'Other': *Describe:** Click here to enter text.

8.3 ***Please upload the sponsor's proposed study budget:**
Upload Document

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

8.4 ***Will study participants receive any compensation to participate in the study (e.g., money for time or gifts, etc.)?**
☐Yes ☐No
***If 'Yes':* *Please provide the payment details (amount, payment schedule, justification):** Click here to enter text.

8.5 ***Does the budget allow for reimbursement of study participants for additional costs that may occur due to their participation in the study such as travel, parking and meals?**
☐Yes ☐No
***If 'Yes':* *Please describe:** Click here to enter text.
***If 'No':* *Justify:** Click here to enter text.

8.6 ***Will the sponsor cover the cost of the investigational agent(s) used in the study for the duration of the study?**
☐Yes ☐No
***If 'No':* *Justify:** Click here to enter text.

8.7 ***Will the sponsor cover the cost of comparator drugs used in the study for the duration of the study?**
☐Yes ☐No
***If 'No':* *Justify:** Click here to enter text.

8.8 ***Are there mechanisms in place to provide ongoing access to the investigational agent post study if the participant is benefiting from treatment?**
☐Yes ☐No
***If 'No':* *Explain and justify:** Click here to enter text.
***If 'Yes':* *Are there any restrictions to the access?**
☐Yes ☐No
***If 'Yes':* *Explain and justify the restrictions:** 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':* *Describe the management plan:** Click here to enter text.

SECTION 9.0 – TRANSLATIONS

9.1 ***Are there translated 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', 9.2 and 9.3 will appear:

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

Upload Document

9.3 **Please upload all translation certificates:**

Upload Document

NOTE. Translation certificates 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 the Research Ethics Board to make changes to your application' (question 1.0) is 'Yes', this section will appear in the application.

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

Q10.1: a response letter is required each time the applicant re-submits the PIA, unless the changes are only to the consent form. 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. Retain all PA/PI response letters previously uploaded in this section.

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

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

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

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.

11.1 *Provincial Applicant Signature - Attestation

- 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 for this trial;
- As the Provincial Applicant:
    - I attest that this application is and all subsequent trial-related provincial 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 with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
    - I attest that the Provincial Co-Applicant listed in this application (if applicable) is appropriately qualified to assume my responsibilities as Provincial 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 (provincial):
    - 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, to the provincial application, 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 submission 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 application forms including attachments, review letters, other correspondence between the REB and the Provincial Applicant, approval letters, etc.) will be shared with all Ontario sites participating in this trial;
- 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, and the names of the participating centres and PIs.