**APPENDIX A: INTERVENTIONAL STUDIES**

Please complete this form **ONLY** if you are conducting a regulated/non-regulated clinical trial or any other interventional study.

Date form Completed:

**Study Title:**

1. **INTERVENTIONS:**
2. Indicate the type of intervention (select all that apply):

| [ ]  Drug | [ ]  Natural Health Product | [ ]  Surgical (e.g. technique, alteration in care pathway) |
| --- | --- | --- |
| [ ]  Device | [ ]  Behavioural | [ ]  Clinical (e.g. clinical assessment, alterations in technique or care pathway) |
| [ ]  Diagnostic  | [ ]  Biologic | Other:       |

1. Provide the brand and generic name of the interventional product(s) (if applicable) or the name of the interventional procedure(s):
2. Describe the study intervention(s):
3. Describe who will be administering the intervention(s) and where this will occur?
4. Provide the frequency of administration of the intervention(s):
5. Provide the length of time participants will be receiving/using the intervention(s):
6. Provide the protocol page reference for the intervention(s):
7. If applicable, who is providing the product(s) under investigation?
8. **STUDY ARMS OR GROUPS**
9. Will THP study participants be assigned to arms or groups? [ ]  Yes [ ]  No
10. If yes, please complete the table below with information about each study arm:

| Arm/group name/number | Arm Type | # of THP participants to be enrolled | Arm assignment (e.g. randomized) | Length of participation |
| --- | --- | --- | --- | --- |
|       | Choose an item. |       |       |       |
|       | Choose an item. |       |       |       |
|       | Choose an item. |       |       |       |
|       | Choose an item. |       |       |       |

1. Provide a brief description of the time commitment required for study participants (e.g. participants will be seen weekly for two months and then seen yearly for 10 years afterwards):
2. **STUDY PROCEDURES**
3. Will any study specific procedures and activities occur with study participants?

[ ]  Yes [ ]  No

1. If yes, Indicate which types of procedures and activities are being done in this study for research purposes only (check all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  Participant Visits | [ ]  Imaging | [ ]  Biological Samples |
| [ ]  Instruments/ Questionnaires | [ ]  Interviews | [ ]  Education |
| [ ]  Observation | [ ]  Focus Groups  | [ ]  Administration of a drug or natural health product |
| [ ]  Use of medical device | [ ]  Surgical Procedure | [ ]  Other (please specify):       |

*Include only those* ***procedures which are added on to standard of care and not considered part of the diagnostic/therapeutic "routine" care*** *of participants, including all participant contact (e.g. telephone, surveys), number of additional blood samplings, increased volumes of blood, additional test on a routine sample, etc.*

* 1. **PARTICIPANT VISITS**
1. Type of visit (Check all that apply): [ ]  N/A

| [ ]  Extension of a regular visit | [ ]  Extra hospital/clinic visit |
| --- | --- |
| [ ]  Participant visit to an external site | [ ]  Study visit to participant’s home |
| [ ]  Other (please specify):       |  |

1. Frequency of each type of visit:
2. Number of each type of visit:
3. Describe what will happen at each participant visit (provide protocol page reference):
4. Duration of each study visit (please provide in minutes):
5. Protocol page reference for rationale for the visits:
	1. **IMAGING occurring above standard of care**

(If there are no imaging above standard of care, please skip sections a – i)

1. Type of imaging (check all that apply): [ ]  N/A

| [ ]  MRI | [ ]  X-ray | [ ]  MUGA | [ ]  Ultrasound |
| --- | --- | --- | --- |
| [ ]  PET/CT | [ ]  Mammogram | [ ]  Angiogram | [ ]  Resting SYMA Scan |
| [ ]  CT | [ ]  Fluoroscopy | [ ]  Bone Scan | [ ]  Submaximal Stress Test |

1. Will sedation or anesthesia be required for any of the imaging being done in this study? [ ]  Yes [ ]  No
2. If yes, what is the length of time of sedation or anaesthesia:
3. Total time for clinical purposes:

1. Additional time for research purposes:
2. Who will be administering the sedation or anaesthesia?
3. Is a contrast agent being used for any of the imaging being done in this study?

[ ]  Yes [ ]  No

1. Frequency of each type of imaging:
2. Length of time of each type of imaging

(Indicate whether this is an extension of time to imaging that the participant is undergoing for clinical purposes):

1. Who will be responsible for medical oversight of the participant, during and following the imaging procedure?
2. Protocol page references for rationale for imaging:
	1. **BIOLOGICAL SAMPLES** [ ]  N/A
3. Type of samples being collected (check all that apply):

| [ ]  Blood  | [ ]  Urine |
| --- | --- |
| [ ]  Tissue  | [ ]  Saliva  |
| [ ]  Bone marrow  | [ ]  Other (please specify):       |

1. The sample will be taken:

| [ ]  by separate sample collection | [ ]  with routine sample collection | [ ]  both |
| --- | --- | --- |

1. If samples are taken by a separate sample collection, describe the process for collection of samples, including who is obtaining these samples:
2. Indicate the location where the samples will be collected:
3. Will there be genetic testing on any of the samples collected in this study

[ ]  Yes [ ]  No If yes, please also fill out Appendix D

1. Is there a pain management plan for sample collection? ☐ Yes ☐ No
2. If yes, describe the pain management plan (e.g. will a topical anesthetic be used?):
3. Will any of the samples be retained for future use? [ ]  Yes [ ]  No

If yes,

* 1. describe where the samples will be kept, the length of time they will be stored, and the process for disposal:

*Please note that a separate consent statement for retention of samples needs to be included in your consent form.*

1. Describe when and how the samples will be discarded or destroyed:

1. Describe the plan for handling any incidental findings that may arise from the use of the samples:
2. Will the samples be de-identified [ ]  Yes [ ]  No
	1. If yes, how will the samples be de-identified?

* 1. If no, what measures will be used to maintain patient confidentiality?
1. Will samples and/or the results of the analysis of the samples be linked to other information about a participant? [ ]  Yes [ ]  No

* 1. If yes, please describe what information will be linked and provide the rationale/justification for this linkage:
1. **Samples being collected** (please complete the table using the following information)**:**
2. **Quantity** - Provide quantity of sample taken for research purposes (please specify the quantity taken each time a sample is collected for research purposes)
3. **Frequency** - Describe the frequency of sample collection
4. **Protocol page** - Provide protocol page reference for rationale for collection and use of this biological sample(s)
5. **Type of sample** – Indicate the type of sample(s) being taken for research purposes (this section is only relevant for “tissue” and “other”).

| **Samples** | **Quantity** | **Frequency**  | **Protocol page** | **Type of sample** |  |
| --- | --- | --- | --- | --- | --- |
| Blood |       |       |       |  | [ ]  N/A |
| Urine |       |       |       |  | [ ]  N/A |
| Tissue |       |       |       |       | [ ]  N/A |
| Saliva  |       |       |       |  | [ ]  N/A |
| Bone Marrow |       |       |       |  | [ ]  N/A |
| Other (please specify):       |       |       |       |       | [ ]  N/A |

* 1. **INSTRUMENTS: /QUESTIONNAIRES/SURVEYS, INTERVIEW SCRIPTS, FOCUS GROUP GUIDES**

[ ]  N/A

1. Please indicate which of the following will be used in this study (select all that apply):

[ ]  Questionnaires/Surveys [ ]  Interview Script/Focus Group Guide

|  |
| --- |
| 1. Will an online data collection platform be used (e.g. Survey Monkey)?

 [ ]  Yes [ ]  No   |
| 1. If yes, provide the name of and location of the server for the online data collection platform:
 |
| 1. Will validated questionnaires and/or surveys be used in this study?

[ ]  Yes [ ]  No   |
| 1. If yes, please list the validated questionnaires/surveys:
2. Have/will any modifications been made to the validated questionnaires/surveys for use in this study?
3. Has/will the instruments/questionnaires been piloted?

 [ ]  Yes [ ]  No  *All instruments/ questionnaires and interview scripts that will be used in this study with copyright dates should been included with the REB submission package.* |
| 1. **Recordings** [ ]  N/A
2. What type of recording will be used to record the interview or focus group (e.g. Audio, video or both)?
3. Will the recording be de-identified? [ ]  Yes [ ]  No

 1. If yes, how will they be de-identified?
2. Describe where you will be storing the recordings:
3. How will recordings be securely destroyed at the end of the data retention period?
* *if recording is optional, a consent statement should be included on the consent form*
 |
| 1. Who will be administering/conducting the survey, questionnaire, interview or focus group?
2. Please indicate the method of instrument administration:

[ ]  In Person [ ]  By Telephone [ ]  Other, please specify:      1. Provide the frequency of the questionnaires, interview, or focus group(s) sessions:
2. Provide the length of time for questionnaire completion, interview sessions or focus group(s):
 |
| 1. Will the data collected from the questionnaires, interviews, or focus groups be:

[ ]  De-identified [ ]  Anonymized [ ]  Anonymous  |

1. **WITHDRAWAL**
2. Do study participants have the option to withdraw from continued participation in the study? [ ]  Yes [ ]  No
3. If no, provide justification:
4. If yes, what procedures will be followed for study participants who wish to withdraw at any point during or after the study (e.g., how does the participant withdraw, what will happen with data collected up to the time of withdrawal)?
5. List any criteria for premature withdrawal of a study participant from the study for safety concerns, as well as how it will be handled:       [ ]  N/A
6. Please provide protocol page reference for the description of the withdrawal process, and ensure the process for withdrawal has been documented in the consent form:
7. **RESEARCH PARTICIPANT REIMBURSEMENT AND RECOGNITION**

*(Any reimbursements, recognitions or incentives to the participant need to be addressed in the consent process)*

1. Will there be any financial expenses incurred by study participants tied to their participation in this study? [ ]  Yes [ ]  No

1. If yes, please describe the expenses:
2. Have specific funds been provided in the budget for reimbursements or gifts to participants, e.g. travel, parking, time spent, etc.? [ ]  Yes [ ]  No

1. How will study participants be recognized or compensated for their participation in this study? [ ]  N/A

| [ ]  Thank you letter | [ ]  Certificate |
| --- | --- |
| [ ]  Community service hours | [ ]  Financial compensation for participation |
| [ ]  Gift/Gift Card | [ ]  Other (please specify):       |

1. Please state the value of the selected item(s) and provide justification:
2. How is this cost being covered?
3. **CLINICAL TRIALS**

1. **Select the Clinical Trial Type**: [ ]  N/A

| [ ]  Pharmaceutical Trial – Phase I | [ ]  Natural Health Product Trial | [ ]  Pilot Trial |
| --- | --- | --- |
| [ ]  Pharmaceutical Trial – Phase II | [ ]  Medical Device Trial | [ ]  Registry Based Trial  |
| [ ]  Pharmaceutical Trial – Phase III | [ ]  Surgical Trial | [ ]  Psychotherapy Trial  |
| [ ]  Pharmaceutical Trial – Phase IV |  |  |

*Pharmaceutical Trials:*

* *Phase I: initial use in humans, to determine the safety, route and schedule for a new investigational agent/intervention (drug, device, natural health product, surgical procedure, biologic or behavioural intervention), to identify side effects.*
* *Phase II: to provide preliminary information about how well an investigational agent/intervention works, to generate more information about safety and benefit of the investigational agent/intervention.*
* *Phase III: to compare a new investigational agent/intervention or combination of clinical interventions or a procedure with current standard therapy, to obtain additional safety and efficacy data.*
* *Phase IV: - following regulatory approval of the investigational agent/intervention, the investigational agent/intervention, study drug is used for the approved indication, to determine if efficacy can be improved.*

1. **STUDY SPONSORSHIP INFORMATION:**
2. Who is responsible for submitting the clinical trial application to Health Canada?

| [ ]  Cooperative Research Group | [ ]  Local Investigator | [ ]  N/A |
| --- | --- | --- |
| [ ]  Private Sector Company | [ ]  Other  | Name of regulatory sponsor:       |
| [ ]  Principal Investigator |  |  |

1. **REGULATORY REQUIREMENTS:** ☐ N/A

Please confirm which authorizations have been obtained for this study and provide a copy of the authorization notifications.

| [ ]  No Objection Letter (NOL) | [ ]  US FDA authorization |
| --- | --- |
| [ ]  Notice of Authorization (NOA) | [ ]  Investigational New Drug (IND) |
| [ ]  Investigational Device Exemption (IDE) | [ ]  Pre-Market Approval (PMA) |
| [ ]  Investigational Testing Authorization (ITA) | [ ]  Pending       |

1. Provide the name of the registry where the trial is registered (e.g. clinicaltrials.gov) and the registration number:       [ ]  N/A
2. List all investigational or protocol treatment interventions that will be used in the study:

|  |
| --- |
| 1. CONTROL GROUP [ ]  N/A
2. Please justify use of this control group:
 |
| 1. PLACEBO USE [ ]  N/A
2. Provide justification for use of placebo (e.g. no alternative standard treatment available). Include any provisions in place to reduce risks to participants assigned to placebo (e.g. increased monitoring):
 |
| 1. WASHOUT OR WITHHOLDING OF TREATMENT [ ]  N/A
2. Indicate any risks (actual or potential) related to absence of treatment:
 |
| 1. BLINDING [ ]  N/A
2. Describe how blinding will be used and the blinding mechanism:
3. Please provide justification for the blinding:
 |
| 1. STEERING COMMITTEE/DATA SAFETY MONITORING BOARD (DSMB) [ ]  N/A
2. Identify the members of the study steering committee and their role:

*Include a copy of your DSMB plan (version dated) with this application.*ii. If there is no DSMB, please provide justification:       |
| 1. INTERIM ANALYSIS PLAN [ ]  N/A
2. Who will conduct the interim analysis?
 |
| 1. ADVERSE EVENTS
2. Identify and describe all known adverse events/effects associated with the investigational or protocol treatment (probability, frequency, time span, etc.):
3. Describe the monitoring and reporting procedures for adverse events/effects occurring in this study:
 |