**MAIN RESEARCH ETHICS BOARD INITIAL APPLICATION FORM**

Date form complete:

**Please note: All studies should be submitted to the Research Operations Department at** **researchoperations@thp.ca** **or your dedicated Research Operations Analyst to complete study feasibility prior to submitting to the REB**

**Instructions for Completion and Submission:**

There are **2 required components** to the Trillium Health Partners Research Ethics Board Application Form

1. **Main Research Ethics Board Initial Application Form** (To be completed for all research studies)
2. **Study Appropriate Appendices** (please check and fill out all appendices that apply):

|  |  |
| --- | --- |
|[ ]  Appendix A: Interventional Studies |
|[ ]  Appendix B: Retrospective Chart Review and Retrospective Biological Sample Analysis and Secondary Analysis Studies |
|[ ]  Appendix C: Prospective Research Studies (Non-Interventional Studies) |
|[ ]  Appendix D: Genetic / Biobank Research Studies |
|[ ]  Appendix E: Waiver of Consent Consideration |

**Application Submission Checklist - *ONE*** *copy of each of the following applicable documents needs to be submitted electronically*

|  |  |  |
| --- | --- | --- |
|[ ]  Main Application Form (signed and dated) |  |
|[ ]  Study appropriate Appendix(es) (listed above) |  |
|[ ]  Study Protocol |  |
|[ ]  All questionnaires/study instruments to be used in the study (i.e. data collection form(s)) |  |
|[ ]  Consent/Assent form(s) / Waiver of Consent Consideration (Appendix E) |  |
|[ ]  Health Canada Authorization (NOL/ITA/NOA, etc.)  | [ ]  N/A |
|[ ]  Sponsoring company investigator brochure/product monograph/Device Manual | [ ]  N/A |
|[ ]  Advertisements and/or other recruitment tools (i.e. flyers, posters, brochures, email scripts) | [ ]  N/A |
|[ ]  Any other documents that will be given to participants  | [ ]  N/A |
|[ ]  Principal/Local Investigator(s) CV(s) (if not already on file) |  |

Please email completed application form and supplemental documents to THPREB@thp.ca

**Notification of Privacy Breaches**

If during the course of the study, the Sponsor(s), the Principal Investigator (PI), Co-investigator(s) or the Study Co-ordinator(s) become aware that the privacy of study participants has been breached, please contact the REB Coordinator at THPREB@thp.ca They will address the incident in keeping with Trillium Health Partners’ Incident Reporting and Management protocol.

# GENERAL STUDY INFORMATION

1. **Study Title:**
2. **Short Title** (max 50 characters):
3. **Abstract:** Please provide a summary of the study suitable for a lay audience,maximum 750 characters:
4. **Duration of study conduct at THP**
5. Anticipated start date:
6. Anticipated study completion date:

 e) **Study Design** (Select all that apply):

| **Epidemiological:** | **Experimental:** | **Qualitative:** |
| --- | --- | --- |
| [ ]  Descriptive | [ ]  Regulated Clinical Trial | [ ]  Grounded theory |
| [ ]  Case Series | [ ]  Non-Regulated Clinical Trial | [ ]  Ethnographic |
| [ ]  Descriptive surveys | [ ]  Other Interventional Trial | [ ]  Narrative Research |
| [ ]  Observational |  | [ ]  Phenomenology |
| [ ]  Cross-sectional |  | [ ]  Case study |
| [ ]  Case-Control |  |  |
| [ ]  Cohort |  |  |

[ ]  Other (please specify):

# SCOPE OF ENGAGEMENT

**Indicate the location and scope of study engagement for each Trillium Health Partners site** (select all that apply):

| **Location of Study** | **Scope of Study** |
| --- | --- |
| [ ]  Mississauga Hospital Site | [ ]  Full Study Conduct |
| [ ]  Queensway Health Centre Site | [ ]  Recruitment Only |
| [ ]  Credit Valley Hospital Site | [ ]  Continuation of Study Conduct Initiated External to THP |
| [ ]  Reactivation Care Centre  | [ ]  Other (Please Specify):       |

# STUDY TEAM INFORMATION

1. **Contact details of the person filling out the application**

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| Phone Number:       | Email:       |
| Role:       |  |

1. **Lead Principal Investigator** *(i.e.* *the designated principal investigator who is responsible for the ethical conduct of the study for all sites*)

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| Organization and Position/Title:       |  |
| Street Address:       | City:       |
| Province:       | Postal Code:       |
| Phone Number:       | Email:       |
| Description of role in the study:       |  |
| CV attached [ ]  Yes [ ]  No [ ]  On file  |  |
| TCPS2 Certificate attached [ ]  Yes [ ]  No [ ]  On file [ ]  Incomplete  |  |

\****Please note:*** *All studies require a local investigator who is responsible for overseeing the local activities at THP (exception: REB review and oversight authority delegated to THP REB for* studies occurring external to THP*).*

1. **Local Investigator** *(i.e.* *the designated principal investigator who is responsible for the ethical conduct only at THP; this person must have a Faculty Appointment at IBH)*

 [ ]  Same as Lead Principal Investigator

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| THP Position/Title:       |  |
| Street Address:       | City:       |
| Province:       | Postal Code:       |
| Phone Number:       | Email:       |
| Description of role in the study:       |  |
| CV attached [ ]  Yes [ ]  No  [ ]  On file  |  |
| TCPS2 Certificate attached [ ]  Yes [ ]  No [ ]  Incomplete [ ]  On file Other:        |  |

Please confirm that you have obtained all of the required credentials for conducting this research project, including any mandatory trainings

1. **Additional Study Team Members**

|  |
| --- |
| First Name:       Last Name:       |
| Role |
| [ ]  Recruitment[ ]  Data Analysis[ ]  Consent[ ]  Data Collection[ ]  Screening [ ]  Data Entry [ ]  Participant Interaction[ ]  Accessing Personal Health Information |
| Qualifications:      Institutional Affiliation:        |
| *For Co-Investigators please fill in* [*Appendix 1*](#Text84) *at the end of the application. For any additional study team members, please fill out the study team information sheet.* *If external study personnel will be engaging in study activity at THP, contact Research Operations (**ResearchOperations@thp.ca**) to obtain administrative clearance.* |

1. **Contact for Correspondence with the THP REB**

All correspondence will be sent to the Principal/Local Investigator by default. If you wish to have all correspondence about the study directed to another study team member, please provide their contact information below

|  |  |
| --- | --- |
| First Name:       | Last Name:       |
| Phone Number:       | Email Address:       |

# CONFLICT OF INTEREST DECLARATION

Researchers hold trust relationships with research participants, research sponsors, THP, their professional bodies and society. Researchers, THP and the REB are required to identify and address actual, potential and perceived conflicts of interest ("Conflict of Interest") to maintain public confidence and trust, ensure the integrity of research, discharge professional obligations and ensure accountability.

A Conflict of Interest does not necessarily imply wrongdoing, as a Conflict of Interest depends upon the circumstances, not on the character of the staff members.

A Conflict of Interest does not mean that the research cannot proceed. Many (but not all) Conflicts of Interest can be managed, but always require identification, disclosure to research participants, and if required, other steps to manage Conflicts of Interest. It is up to the REB to determine if the Conflict of Interest can be managed and if the proposed mitigation measures are adequate.

All Conflicts of Interest must be clearly identified by the Principal Investigator. Through completion and sign off of this section of the application, the Principal Investigator is making this Declaration on behalf of themselves and the members of the research team (collectively referred to in the Declaration as "Research Team").

1. Please disclose any/all **[Conflict(s) of Interest](#conflict" \o "When a person or organization has multiple roles / duties / interests / responsibilities that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest, individual or organization)** (COI) **(**[**potentia****l**](#Potiential)**,** **[perceived](#perceived" \o "Where a third party could form the view that other individuals, institutions or seconday interests could improperly influence the primary interest)** and **[actual](#Acutal" \o "Real conflict between a person's primary interest and other institutions, individuals or seconday interest )**) related to this study and how it/they will be managed.

[ ]  **N/A**

|  | **Areas of Conflict of Interest** | **Type of Conflict of Interest** |
| --- | --- | --- |
| 1. | Choose an item. | Choose an item. |
| 2. | Choose an item. | Choose an item. |
| 3. | Choose an item. | Choose an item. |
| 4. | Choose an item. | Choose an item. |

|  |
| --- |
| Individual(s) involved:       |
| 1. Describe the nature of the Conflict of Interest(s) identified above:
 |
| 1. Mitigation strategies (how it/they will be managed, e.g., disclosure in consent form, declining role/position with sponsors, additional monitoring strategies such as monitoring the consent process):
 |

1. Please confirm all conflicts identified above been declared to the Trillium Health Partners Research Operations Department? [ ]  Yes [ ]  No [ ]  N/A
2. **Declaration by Principal Investigator**

Should a Conflict of Interest arise for any Investigator, Co-investigator or Study Team member during the course of the study, it will be declared in writing to the Trillium Health Partners Research Ethics Board.

I hereby declare that I have read this Declaration, have discussed this Declaration with the members of my Research Team, and that to the best of my knowledge and belief, my responses are true and complete.

|       |  |       |
| --- | --- | --- |
| Name of Principal Investigator | Signature | Date |

# STUDY SPONSORSHIP INFORMATION

There are various types of sponsorship responsibilities associated with research studies. Sponsorship categories include financial, regulatory, serving as a lead site and product supply. In order for the REB to understand the overarching responsibilities of the various individuals/institutions involved in the study you will need to identify each of the individuals/institutions responsible for various components of the study.

1. **Who developed the study protocol?** (Select all that apply):

|  |  |
| --- | --- |
| [ ]  Local Investigator | [ ]  Cooperative Research Group |
| [ ]  Principal Investigator at other institution | [ ]  Private Sector Company |
| ☐ Other (please specify):  | Name of sponsor(s): |

1. **Is the study funded?** [ ]  Yes [ ]  No
2. Funding status: [ ]  Obtained [ ]  Applied for Expected notification date:
3. Who is funding the study(select all that apply):

|  |  |
| --- | --- |
| [ ]  Trillium Foundation | [ ]  Trillium Health Partners |
| [ ]  Federal or Provincial Granting Agency | [ ]  Private Sector Company |

[ ]  Other: Name of funder(s):

# SCIENTIFIC PEER REVIEW

1. **Select one of the following options:**

|  |
| --- |
| [ ]  This study has undergone an internal Scientific Peer Review |
| [ ]  This study was reviewed by an external Scientific Peer Review Committee/agency (e.g. funding agencies, scientific review and approval process post-secondary/academic scientific review) |
| [ ]  This study **has not** undergone Scientific Peer Review |

Please submit a copy of the documents from the Scientific Peer Review that have occurred (i.e. reviewer’s comments, reviewer’s sign-off or itemized response to reviewer).

# SCIENTIFIC MERIT

|  |
| --- |
| 1. Provide a clear description of the rationale for the study:
 |
| 1. State the study hypothesis:
 |
| 1. State the secondary hypothesis:

 [ ]  **N/A** |
| 1. State the research question(s):
 |
| 1. Primary outcome measure:
 |
| 1. Other outcome measures:

[ ]  **N/A** |
| 1. Explain the significance in finding an answer to the research question and provide details on the potential benefits of the study to society:
 |

# STUDY METHODOLOGY

1. Please describe the study method(s):
2. Describe the different methods that will be used to identify potential participants (e.g. health records search, decision support, departmental database):

# STUDY POPULATION

| 1. Please describe the study population (e.g. age range):
 |
| --- |
| 1. List the inclusion criteria:
 |
| 1. List the exclusion criteria:
 |
| 1. Will participants be excluded from the study due to any of the following criteria?

[ ]  Yes [ ]  No |

1. If yes, select all that apply:

|  |  |  |
| --- | --- | --- |
| [ ]  Gender | [ ]  Literacy | [ ]  Pregnancy |
| [ ]  Geographic Location | [ ]  Ethnicity  | [ ]  Weight |
| [ ]  Language | [ ]  Physical Disability | [ ]  Capacity to Consent |
| [ ]  Mental Health Condition | [ ]  Height | [ ]  Other (please specify):       |

1. **If any of the above are selected**, please provide an adequate rationale for the exclusion criteria indicated above:
2. **Sample size:** Study wide:       Trillium Health Partners:
	* 1. Please provide the page number and section of the protocol that contains the sample size justification:
3. Anticipated number of research participants at THP that will be screened for eligibility:
4. Does the research team have previous experience working with the community/population it seeks to engage in research? [ ]  Yes [ ]  No
5. If yes, describe:       If no, please explain what steps will be taken to engage the relevant communities/populations in the research study?

# RECRUITMENT AND CONSENT OF POTENTIAL RESEARCH PARTICIPANTS

* 1. RECRUITMENT PROCESS
1. How will potential participants be identified and/or referred?

|  |  |
| --- | --- |
| [ ]  Healthcare professional | [ ]  Permanent health record/clinical chart |
| [ ]  Database (please specify):       | [ ]  Advertisements, included web-based recruitment tools |
| [ ]  Other (please specify):       |  |

1. Describe the recruitment process: (*If the manner in which potential study* participants *are being recruited is different for each study arm/group, please include these details):*
2. Who will make initial contact with study participants and their relationship to the patient? *(Please note that first contact must be someone known to the potential* participants, i.e. within the participants’ circle of care*):*
	1. What is this individual’s relationship to study participants?
3. How will initial contact with study participants be made?
	1. CONSENT PROCESS

*Please ensure that all information provided to* participants *meets a 6th–8th grade level for readability.*

1. Are you requesting a waiver and/or deferral of consent for any research related activity occurring in this study? [ ]  Yes [ ]  No

If yes, please fill out appendix E: waiver of consent considerations, to justify a waiver of consent requirements to the satisfaction of the REB (*skip to section 11: Data management).*

1. Describe the consent process, including who will obtain consent and how consent will be documented (*if the person obtaining consent is different for each arm/group, please include these details):*
2. Will an alternative method to written consent be used? [ ]  Yes [ ]  No
3. If yes, please justify:
4. How much time will be given to study participants to review the information before being asked to give consent? *(Please be sure to include an explanation of the appropriateness of the time given):*
5. Please indicate whether there is a relationship between the study participant and study team members below:

|  | Yes | No |
| --- | --- | --- |
| Person obtaining consent |[ ] [ ]
| Investigator |[ ] [ ]
| Person conducting the consent discussion |[ ] [ ]

1. Explain the nature of the relationship(s) identified above and what steps will be taken to minimize and/or mitigate potential coercion:
2. Language Considerations:

|  |
| --- |
| Will non-English speaking/reading individuals be included in the study? [ ]  Yes [ ]  No1. If yes, what provisions have been made?
2. If no, provide justification for not making provision(s) to facilitate the inclusion of this population:
 |

f) Participants incapable to consent:

|  |
| --- |
| 1. Does the study involve study participants who are incapable of providing consent on their own behalf? [ ]  Yes [ ]  No
2. If yes, provide justification for the inclusion of these study participants :
 |
| 1. Will assent be sought from those who are unable to provide consent on their own behalf? [ ]  Yes [ ]  No
2. If no, provide justification for not seeking assent from these study participants:
 |

# DATA MANAGEMENT

* 1. **PERSONAL INFORMATION AND PERSONAL HEALTH INFORMATION AND RESEARCH DATA**
1. Indicate the personal information and/or personal health information you will be collecting for this study (select all that apply):

|  |  |  |
| --- | --- | --- |
| [ ]  Names | [ ]  Dates, except year | [ ]  Telephone numbers |
| [ ]  Geographic data | [ ]  FAX numbers | [ ]  Social insurance numbers |
| [ ]  Email addresses | [ ]  Medical record numbers | [ ]  Account numbers |
| [ ]  Health plan beneficiary numbers | [ ]  Certificate/license numbers | [ ]  Vehicle identifiers and serial numbers including license plates  |
| [ ]  WEB URLs | [ ]  Device identifiers and serial numbers | [ ]  internet protocol addresses  |
| [ ]  Full face photos and comparable images  | [ ]  Biometric identifiers (i.e. retinal scan, fingerprints) | [ ]  Any unique identifying number or code |
| [ ]  Any other characteristic that could uniquely identify the individual (please specify):       |  |  |

| * + 1. Please describe why the collection of the data selected above is necessary to achieve the objective(s) of this study and what measures will be taken to protect this information:
 | [ ]  **N/A** |
| --- | --- |

[ ]  ***No personal information and/or personal health information will be collected for this study***

1. Describe how data will be collected, used/or disclosed:
	1. **DATA ANALYSIS PLAN**
2. Please describe the data analysis plan:
	1. **DATA COLLECTION FORMS**

Identifiable personal health information and/or personal information should not be included on study data collection forms (i.e. the research participants' names, THP patient numbers, and other directly identifiable information).

Identifiable personal health information is information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context.

Each study participant should be assigned a unique study identifier code at the time of enrollment.

The master list linking the study identifier to a particular participant must be kept securely and separately from the data collection files. The PI is responsible for ensuring that the master list remains confidential and inaccessible to individuals who are not part of the research team, or do not have a need to access this information.

* + 1. Attach all data collection forms including forms which capture identifiable and de-identified participant information. [ ]  Data collection forms attached
		2. Will data be retained for individuals that have:

|  | Yes | No |
| --- | --- | --- |
| 1. Withdrawn from the study
 |[ ] [ ]
| 1. Been removed from the study
 |[ ] [ ]
| 1. Screened and found to be ineligible for the study
 |[ ] [ ]

* + 1. If “yes” is selected above (section 11.3b), include with this application the screening/enrollment log.
	1. **DATA SOURCE**

All individuals that will be accessing personal health information (e.g. health records, Electronic Patient Records (EPR), clinic or research databases) must be listed in Section 3 (Research Team) above.

**SHARED SYSTEMS**

When at THP you can only access THP records; You are never permitted to access participant information at other hospital or health center through THP electronic system; All access to participant information at other institutions must take place directly through that institution, subject to their REB approval. For instance, never use the Connect Ontario portal to access participant info at other hospital.

1. **Database/Registries** [ ]  **N/A**

Indicate all sources of data that you will be requesting permission to access for screening and/or for enrollment (provide details on the database/registry selected below, i.e. name, location, content etc.):

|  |
| --- |
| [ ]  Clinical Division/Department Database  |
| [ ]  Research Database/Registry  |
| [ ]  External Database/Registry:       |
| [ ]  Local Database/Registry:      REB Study # of Database/Registry:      * + 1. Was consent obtained from the participants included in this registry or database for the use of future research? [ ]  Yes [ ]  No
		2. If no, please provide justification:
 |

1. **Data Linkage**

1. Do you plan on linking locally collected data with any other data set (e.g. other hospitals OHIP, ICES data, etc.)? [ ]  Yes [ ]  No
2. If yes, please provide the following details: (1) Identify the data set, (2) explain why these linkages are required, (3) identify how the linkage will occur, (4) explain the provisions that will be put into place to keep the data secure:
3. What research data is being sent to third parties and what research data is being received from third parties?
4. **Additional Data Sources**
5. Will you be using any other sources not previously listed? [ ]  Yes [ ]  No
6. If yes, please list all other sources\* of data that you will be using:
* If you are using data that was previously collected by someone else for other purposes (secondary analysis), also complete Appendix B (Retrospective Chart Review, Biological Sample Analysis and Secondary Analysis Studies).
	1. **DATA STORAGE AND DESTRUCTION**

| 1. How is the data being stored?
 |
| --- |
| [ ]  Physical Storage[ ]  Electronic Storage[ ]  Both |

1. Indicate the physical safeguards that will be used to securely maintain the data as per THP's policy which requires that PHI be stored utilizing at least 2 security mechanisms.

|  |  |
| --- | --- |
| [ ]  Locked office | [ ]  Biometric authentication |
| [ ]  Locked storage unit | [ ]  Cipher/coded locks |
| [ ]  Locked cabinet in a locked room | [ ]  Access cards |
| [ ]  Designated individual responsible for controlling access to data | [ ]  Other (please specify):      |

1. Please indicate which electronic safeguards will be used to securely maintain the data

|  |  |
| --- | --- |
| [ ]  Password protected files/folders | [ ]  Encrypted laptop |
| [ ]  Password protected computers and electronic devices  | [ ]  Encrypted USB key |
| [ ]  Restricted network drive access | [ ]  Firewalls  |
| [ ]  Other (please specify):       |  |

1. How long will the data be stored?*(Please refer to THP policies regarding research-related data retention)*

|  | **5 years** | **7 years** | **15 years** | **Other** |
| --- | --- | --- | --- | --- |
| Consent |[ ] [ ] [ ] [ ]
| Protocol |[ ] [ ] [ ] [ ]
| Personal Health Information |[ ] [ ] [ ] [ ]
| Other Collected Data |[ ] [ ] [ ] [ ]

If other, please specify:

1. Indicate the methods that will be used to destroy the data:

|  |
| --- |
| [ ]  Paper records will be disposed in THP confidential disposal bins |
| [ ]  Electronic records will be destroyed by contacting THP IS help desk |
| [ ]  Old CDs, DVDs, videos, USB keys, external hard drives and other technology will be destroyed according to hospital policies. |
| [ ]  Other (please specify)       |

1. **Future Access to Study Data**
2. Will anyone other than the current study team have access to the study data after the study is complete? [ ]  Yes [ ]  No
	1. If yes, please provide justification for permitting the above indicated individuals/organizations access to study data:
	2. **SECONDARY USE OF DATA** [ ]  **N/A**

Secondary use of data is defined as: The use in research of information originally collected for a purpose other than the current research purpose.

***\*\*Please note that REB approval is required for secondary use of data.***

1. Will you be using the identifiable data for reasons other than conducting this study (secondary use)? [ ]  Yes [ ]  No
2. If yes, please describe the secondary uses (include any reasonably foreseeable harms and benefits that could arise from the use of the information, and how these harms will be addressed):
3. Is secondary use a mandatory or optional component of study participation?

[ ]  Mandatory [ ]  Optional [ ]  N/A

1. If optional, please explain how withdrawal of the study participant’s consent to secondary issues will be addressed:

*If there is a plan to use identifiable data for reasons other than conducting this study (secondary use), please ensure that this information is included in the consent form.*

* 1. **TRANSFER OF DATA AND MATERIAL** [ ]  **N/A**

*Please note that a transfer agreement may be required, please contact the Research Operations Office.*

1. List the data/material(s) that will be transferred:

1. List the site(s) where data/material(s) will be transferred to and from:

1. How is data/material(s) being transferred?

1. Indicate what safeguards will be used to securely transfer the data/material(s) (e.g. biohazardous transport kits etc.):

# **ETHICAL CONSIDERATIONS**

12.1. STANDARD PRACTICE / STANDARD OF CARE

* + 1. What is the usual standard of care/standard practice at THP for this population, as it relates to the study interventions and procedures?       [ ]  N/A
		2. Has the local standard of care/standard practice been altered for the study specific interventions and procedures? [ ]  Yes [ ]  No
1. If yes, describe how they have been altered:

**12.2. RISK/BENEFIT ESTIMATES**

1. What are the potential risks and harms involved in this research study (e.g. sensitive questions/topics in interviews/questionnaires, blood work, etc.), not including risks of non-research related procedures:
	* 1. What safeguards will be used to prevent and/or reduce risks and harms?
2. Is enrollment in multiple studies likely for this participant population?

[ ]  Yes [ ]  No

1. If yes, what strategies will be used to mitigate potential issues (i.e. logistical issues, safety, burden to participants, validity)?
2. Does participation in this study affect alternatives for future care? [ ]  Yes [ ]  No
3. If yes, explain:
4. Are there specific harms/risks to equity-deserving groups or communities?

[ ]  Yes [ ]  No

1. If yes, describe:
2. What strategies/safeguards will be put in place to minimize and mitigate these harms/risks?
3. Might potentially hazardous duties be required of research personnel beyond the risks encountered in their normal work routine? [ ]  Yes [ ]  No
4. If yes, describe:
5. What strategies/safeguards will be used to prevent or reduce risks/harms to research personnel?
6. Are there any direct benefits anticipated for study participants? [ ]  Yes [ ]  No
	* 1. If yes, list all the anticipated direct benefits for participants:
7. What are the potential benefits of this study to society?
	1. **RESEARCH INVOLVING POTENTIALLY VULNERABLE PARTICIPANTS/ SITUATIONS** (According to the TCPS 2, vulnerability is defined as “a diminished ability to fully safeguard one’s own interests in the context of a specific research project. This may be caused by limited capacity or limited access to social goods, such as rights, opportunities and power. Individuals or groups may experience vulnerability to different degrees and at different times, depending on their circumstances”).

According to Article 4.7 of the TCPS2, “individuals should not automatically be considered vulnerable simply because of assumptions made about the vulnerability of the group to which they belong. Their particular circumstances shall be considered in the context of the proposed research project”.

Vulnerability exists along a continuum and is influenced by many factors including (but not limited to) the following eight factors ([modified from the University of Virginia’s Institutional Review Board for the Social and Behavioral Sciences)](https://research.virginia.edu/irb-sbs/vulnerable-participants)

1. **Cognitive vulnerability:** may arise when individuals are unable to process, understand, appreciate, and reason through the consent documentation and/or explanations either by mental limitations (e.g. some cognitively impaired individuals, or some children).
2. **Communicative vulnerability:** may arise when participants do not lack capacity, but have limited or difficult ability to communicate with the researchers (e.g. individuals with reading disabilities, or individuals with language limitations).
3. **Institutional vulnerability:** may arise when individuals are participant to a formal authority and whose consent may be coerced directly or indirectly (e.g. incarcerated individuals, or persons in detention).
4. **Deferential vulnerability**: may arise when individuals are either formally or informally subordinate to authority figures (e.g. patients participating in their doctor’s research studies, or students participating in their Professors’ projects).
5. **Medical vulnerability:** may arise when persons who have health conditions for which no satisfactory standard treatment options are available or pregnant persons where risks to embryo, fetus and neonate requires extra considerations or disease states at risk of stigmatization which may impact their ability to make a decision regarding study participation.
6. **Socio-economic vulnerability:** may arise when individuals are at risk for discrimination (e.g. discrimination based on race, poverty, gender, ethnicity, age).
7. **Legal vulnerability:** mayarise when individuals do not have the legal right to consent or may be concerned that their consent may put them at risk for legal repercussions (e.g. research involving illegal substances, or research involving illegal behaviours).
8. **Study vulnerability:** may arise when individuals are made vulnerable by the study’s design (e.g. studies involving deception to participants, or studies involving withholding important information from participants).
9. Is there a potential that the study population is at higher risk of finding themselves in circumstances that may make them vulnerable in the context of the research (see above categories for examples)?

[ ]  Yes [ ]  No

1. Why is the study population considered vulnerable? (*Include details regarding who they are and in what circumstances they may be considered vulnerable):*
2. Provide justification for the use of this/these potentially vulnerable population(s) and outline the additional safeguards put in place to protect their rights:
	1. **MANAGEMENT OF INCIDENTAL AND/OR CLINICALLY SIGNIFICANT FINDINGS**
3. Describe the plan for managing any incidental findings. *(Incidental findings are defined as observations of potential significance unexpectedly discovered in research participants and unrelated to the purpose of the study)*:
4. Describe the plan for managing any clinically significant findings. *(Clinically significant findings are defined as findings that have potential health or reproductive significance for the individual study participants)*:

# PLAN FOR DISSEMINATION OF RESULTS

1. Will study results be disseminated to study participants? [ ]  Yes [ ]  No
2. Who will disseminate the study results to study participants?
3. Dissemination of study results:
4. Please indicate the methods of dissemination of study results that will be utilized for study participants (select all that apply):

|  |
| --- |
| [ ]  A lay summary or discussion of individual-level findings will be provided to each study participants at the end of their participation in the study |
| [ ]  Group debriefing at the end of study |
| [ ]  A study newsletter or summary letter of aggregate research findings will be mailed to all study participants at the end of the study |
| [ ]  Study, clinical or program website |

[ ]  Other (please specify):

1. How will study results be disseminated to the broader community, including the scientific/academic community and the general population? (select all that apply):

|  |  |
| --- | --- |
| [ ]  Scientific journal(s) | [ ]  Conference(s) |
| [ ]  Local rounds | [ ]  Public dissemination |

[ ]  Other (please specify):

1. Is there a risk that the study results will produce inequities or stigmatize equity-deserving groups or communities? [ ]  Yes [ ]  No
2. If yes, describe:
3. What strategies and safeguards will be put in place to ensure that the research findings do not produce inequities or stigmatize equity-deserving populations?

# INVESTIGATOR ATTESTATION

I certify that:

* I have received and read the protocol and its appendices and other materials provided by the Sponsor, as applicable. I agree to the terms of the study and to follow the provisions of the protocol and all appendices.
* This application contains the current and complete protocol and accompanying documents.
* The information in the application is accurate and complete to the best of my knowledge.
* I am responsible for reporting to the Trillium Health Partners REB any proposed modifications or amendments to any previously approved study documents (including investigator Brochures or Product Monographs and I will not make and/or implement any changes to the protocol without prior written approval from Trillium Health Partners REB.
* Either I or someone under my supervision will verbally explain the current Informed Consent form as approved by Trillium Health Partners REB in a language understood by the prospective research participants, where applicable. A signed copy will be given to each research participant for their records, as applicable.
* No study records that contain personal health information will be disclosed to any organization/countries that do not subscribe to ICH GCP.
* The methods used to conduct this study are in compliance with the most recent version of the Tri-Council Policy Statement; ICH Good Clinical Practices: Consolidated Guidelines; Division 5, Canadian Food and Drug Regulations (if applicable); the Personal Health Information Protection Act; and all other applicable laws, and regulations, as applicable.
* All tests, procedures and the dispensing of drugs required by the protocol will be performed by individuals who are qualified by education, license and/or local governance to perform these tasks.
* The study team is adequately equipped to manage adverse events that may occur during the course of this study and all external (non-local) and local serious adverse events (SAE) will be reported promptly to the Trillium Health Partners REB whether they are expected or not. All unexpected events will be reported to the Sponsor and the Trillium Health Partners REB, within 2 business days of becoming aware of the SAE and all fatal or life threatening events will be reported immediately.
* I acknowledge that I am responsible for reporting to Trillium Health Partners REB any and all unanticipated problems involving risks to study participants or others.
* I am responsible for reporting to Trillium Health Partners REB any significant protocol deviations within 10 business days of the site becoming aware of the event, and for obtaining REB approval of all Sponsor-granted exceptions prior to initiation except where necessary to eliminate apparent immediate hazard to human participant(s).
* I understand that Trillium Health Partners REB has the right to visit the research site at any time, with appropriate notice.
* I will renew this application annually (or at more frequent intervals if requested by Trillium Health Partners REB).
* I and the research staff will monitor participants for potential harm and take steps to minimize or mitigate those harms and risks when possible.
* I understand that falsification of information provided to Trillium Health Partners REB may result in sanctions by the REB, notification to the Sponsor and notification to the appropriate professional college.
* No study conduct will occur until Trillium Health Partners REB approval is received and, if required, a research agreement is executed.

**PRINCIPAL INVESTIGATOR:**

I hereby certify that the information on this Initial Application Form is accurate to the best of my knowledge. I attest that, as a Principal Investigator, I have read the Investigator Attestation and understand that I am responsible for the conduct of this research study. I acknowledge that Trillium Health Partners Research Ethics Board has the authority to oversee this study and suspend the study if necessary to protect the rights and welfare of the study participants.

|       |  |  |  |       |
| --- | --- | --- | --- | --- |
| Name of Principal Investigator |  | Signature |  | Date |

**APPENDIX 1: CO-INVESTIGATOR CERTIFICATION(S)** [ ]  **N/A**

No study records that contain personal information and/or personal health information will be disclosed to any organizations/countries that do not subscribe to ICH GCP.

The methods I/we will use to conduct this study are in compliance with the Tri-Council Policy Statement, ICH Good Clinical Practices: Consolidated Guidelines, Division 5, Canadian Food and Drug Regulations (if applicable), the Personal Health Information Protection Act, and all other applicable laws and regulations.

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| Name of Co-Investigator |  | Signature |  | Date |
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| Name of Co-Investigator |  | Signature |  | Date |