JREB FILE NUMBER:	(office use)

ONTARIO SHORES CENTRE *for* MENTAL HEALTH SCIENCES (OS) and ABILITIES CENTRE
HUMAN SUBJECTS RESEARCH ETHICS APPLICATION
(Form Adopted from Toronto Academic Health Sciences Network for OS and AC Use)

INSTRUCTIONS

- **All sections** of this application **MUST** be completed before it will be considered for JREB review.
- A complete application must be submitted to **each site** where this research will take place.
- A separate detailed protocol must be included with each application.
- All research must be compliant with:
  - The Tri-Council Policy Statement, available at **http://www.pre.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf**
  - The Ontario Personal Health Information Protection Act (2004), available at **http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm**
  - Any other relevant regulations or guidelines.
- In the case of studies receiving harmonized ethics review at a single site as per MoU between Waypoint and Ontario Shores JREB, either board may request or share information related to the review, approval and continuing ethics review of research conducted at each other sites.

SECTION I: GENERAL INFORMATION

1. PRINCIPAL INVESTIGATOR (PI) NAME

Title:	Last Name:	First Name:
Credentials (MD, PhD, etc.):		

2. FULL STUDY TITLE

Sponsor Protocol Number (if applicable):

2A. Study Period

Expected start date at this institution:
Total study duration at this institution:

2B. Is this protocol directly related to a previously approved study at this institution (e.g., extension, rollover, subsequent to a pilot study)? ☐ Yes ☐ No

If **YES**, specify:

Name of Principal Investigator:
JREB file number:

3. INVESTIGATORS

3A. Principal Investigator Contact Information and Signature

PRINCIPAL INVESTIGATOR AGREEMENT – I assume full responsibility for the scientific and ethical conduct of the study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects, Personal Health Information Protection Act (2004) and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the Protocol, the conditions of the JREB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I certify that all researchers and other personnel involved in this project at this institution are appropriately qualified or will undergo appropriate training to fulfill their role in this project.

Dept./Div.:	Program:		Institution:	
Telephone:	Pager:		Fax:	
Street Address:				Room/Suite #:
City:	Province:	Postal Code:	Email:	
Signature of Principal Investigator		Date		

3B. Co-Investigator(s) Contact Information and Signature

CO-INVESTIGATOR AGREEMENT – I agree to participate in this study as described in this application and submitted protocol and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant laws, regulations or guidelines. I also agree that if I receive any personally identifiable information (including but not limited to personal health information and biological samples), I will only use or disclose the information as set out in the Protocol, the conditions of the JREB, the research participant's consent (unless consent is waived), and the conditions and restrictions imposed by the relevant information guardian who supplies the information. I will notify the Principal Investigator immediately if there is any deviation from the Protocol or other adverse event.

If one or more co-investigators are students participating as part of an academic training program, 3C must be completed.

1	Title:	Last Name:	First Name:	Institution:

	Dept./Div.:	Program:	Signature	
2	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
3	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
4	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	
5	Title:	Last Name:	First Name:	Institution:
	Dept/Div:	Program:	Signature	

3C. Is this research part of an academic (University) **training program** (student/fellow/resident research studies) Yes ☐ No ☐ Not Applicable ☐
If yes, please indicate, type of research

☐ Post-Doctoral ☐ PhD ☐Masters ☐Undergraduate ☐Resident/Clinical Fellow

Name(s) of Student(s):			
Name of Supervisor:			
Dept./Div.:	Program:	Institution:	
Telephone:	Pager:	Fax:	
Street Address:			Room/Suite #:
City:	Province:	Postal Code:	Email:

4. STUDY COORDINATOR/CONTACT PERSON FOR THIS APPLICATION IF NOT THE PRINCIPAL INVESTIGATOR (e.g. study coordinator, research administrative contact, research student, institutional liaison).

☐ Not Applicable

Title:	Last Name:		First Name:
Dept./Div.:	Program:		Institution:
Telephone:	Pager:		Fax:
Street Address:			Room/Suite #:
City:	Province:	Postal Code:	Email:

Indicate to whom correspondence should be sent: ☐ Principal Investigator ☐ Study Coordinator/Contact Person

5. DEPARTMENT/DIVISION/PROGRAM HEAD APPROVAL (refer to your institutional guidelines).

Approval must come from the Department / Division / Program Head of the same department as the PI. If PI is external to the institution, approval must come from the local PI's departmental head.

Department/Division/Program Head Approval - I am aware of this proposal and support its submission for ethics review. I consider it to be feasible and appropriate. I attest that the Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study". **This section cannot be signed by the Principal Investigator or a Co-Investigator.** An alternative approval signature is required.

Title:	Last Name:	First Name:
Signature of Dept./Div./Program Head	Date	

6. FUNDING

6A. Source of Funding

Company Name:	
Granting Agency Name:	
Internal Funding:	
Other:	

6B. Funding Type/Categories:

List the funder(s):
What category do(es) the funder(s) belong to? (check all that apply)
☐ Industry (e.g. Pharmaceutical Company/ Test or Medical Device Companies / Biotech Company)

☐ Government Funding Agency (e.g. National Institutes of Health, Canadian Institutes for Health Research,
☐ Government (e.g. National Health Service, Ministry of Health, Department of Defense)
☐ Charitable Foundation (e.g. American Heart Association, The Bill and Melinda Gates Foundation, Wellcome Trust)
☐ Contract Research Organization
☐ Others (describe):

6C. Status of Funding

☐ Funding obtained	
☐ Funding applied for	Expected date of decision:
☐ No funding required	Explain:

6D. If funding is not awarded, do you plan to proceed with the study? ☐ Yes ☐ No
NOTE: If **YES**, Please complete Question 26B. If **NO**, the JREB Review **may be held** until confirmation of funding is obtained. Please advise the JREB if you would like a letter confirming JREB submission for the funder.

7. WHAT DOES THIS STUDY INVOLVE?

Please specify the nature of the study (and sub-studies), check **all** that apply.

☐ Chart Review (specify*):* ☐ Retrospective ☐ Prospective

☐ Clinical Trial (please also complete Question 11)

☐ Investigational Product or Device study

(Specify): ☐ Phase I ☐ Phase 2 ☐ Phase 3 ☐ Phase 4 ☐ unknown ☐ n/a

- ☐ Investigational drug(s)
- ☐ Investigational biologic(s)
- ☐ Investigational natural health product(s)
- ☐ Investigational medical device(s)
- ☐ Approved product for new indication (e.g. new patient population), dosage, or formulation

Name(s) of Investigational Product(s) or Device(s):

☐ Health-related Intervention(s) (e.g. surgical procedures, behavioural treatments, process-of-case changes, dietary interventions, etc.)
(Specify):

☐ Qualitative (please check all that apply)

- ☐ Focus Groups
- ☐ Interviews
- ☐ Observational (e.g. naturalistic, field etc.)
- ☐ Questionnaires/Surveys
- ☐ Other (specify):

☐ Human Tissue and Biological Specimens (e.g. cadavers, biological fluids, etc.)

- ☐ Banking
- ☐ Biomarker
- ☐ Genetic

☐ Other (e.g. pharmacokinetic/pharmacodynamic etc.) (specify): Indicate if the material is ☐ **INTEGRAL** to the main study or ☐ **OPTIONAL** to the main study.
☐ Sub-study; indicate the JREB# of main/related study:
☐ Case Study
☐ Educational
☐ Epidemiological / Database
☐ Quality Assurance / Quality Improvement
☐ Other (specify):

8. MANAGING CONFLICTS OF INTEREST

Conflicts of Interest do not imply wrong-doing.

It is the responsibility of the PI to determine if **any of the conflicts** listed below apply to **any persons** (listed in Question 3) involved in the research study or any member of their immediate family. Disclose all contracts and any conflicts of interest (actual, apparent, perceived, or potential) relating to this project. Conflict of interest may also arise with regard to the disclosure of personal health information.

NOTE: This disclosure does not replace institutional guidelines and requirements for declaration and management of Conflicts of Interest

☐ Not applicable. There are no Conflicts of Interest to disclose.

☐ Function as an advisor, employee, officer, director or consultant for the study sponsor
☐ Have direct or indirect interest in the drug, device or technology employed in this research study (including inventorship, patents or stocks)
☐ Receive an honorarium or other personal benefits from the sponsor (apart from fees for service)
☐ Using services of a family member or a company in which you or a family member has a direct interest.
☐ Receive direct or indirect financial benefit from the disclosure of personal health information
☐ Competing interest (situations in which the researcher may be influenced to draw conclusions against the interest of the sponsor or another interested party to the study because the researcher or a family member has an opposing interest related to the research, including a legal suit against a company or sponsor or a financial interest in a competing company or product)
☐ Other (describe)

Describe and detail any Conflicts of Interest.

(Max ¼ page)

How will any Conflicts of Interest be managed?

(Max ¼ page)

9. OTHER INSTITUTIONAL ETHICS REVIEW

9A. Please answer the following and attach ALL RELEVANT CORRESPONDENCE related to ethics and scientific review (e.g. REB review letter, replies, approval letter).

In order to facilitate the JREB review process through harmonization and coordination of REB activity, **identify if any of the REBs below have reviewed and/or approved the study** outlined in this application (check all that apply):		**Ethics Review and Approval Status** (check all that apply and indicate date where applicable):			
		Application To Be Submitted	**Applied, Review Pending**	**Reviewed**	**Approved**
☐	Baycrest	☐	☐	☐	☐
☐	Holland Bloorview	☐	☐	☐	☐
☐	Centre for Addiction and Mental Health	☐	☐	☐	☐
☐	Hospital for Sick Children	☐	☐	☐	☐
☐	Mount Sinai Hospital	☐	☐	☐	☐
☐	St. Michael's Hospital	☐	☐	☐	☐
☐	Sunnybrook Health Sciences Centre	☐	☐	☐	☐
☐	Toronto Rehabilitation Institute	☐	☐	☐	☐
☐	University Health Network	☐	☐	☐	☐
☐	Women's College Hospital	☐	☐	☐	☐
☐	University of Toronto	☐	☐	☐	☐
☐	Other:	☐	☐	☐	☐

9B. Has the research undergone other scientific/scholarly review prior to this JREB submission?

☐ Yes (to facilitate further review, please attach all relevant documents) ☐ No

10. RESEARCH IS SUBJECT TO HEALTH CANADA REGULATION

☐ Not applicable (proceed to Question 11).

10A. DOES THIS STUDY INVOLVE SUBMISSION TO HEALTH CANADA UNDER THE FOOD AND DRUG ACT:
☐ Yes ☐ No

If **YES**, is a Health Canada "No Objection Letter" or other regulatory authorization attached? ☐ Yes ☐ No

If **NO**, has an application been made? ☐ Yes ☐ No When?

NOTE: The JREB review **may be held** and **final approval will not be granted** until the appropriate regulatory approvals have been received.

10B. Who is the Regulatory Sponsor (i.e. who is listed on the clinical trial application)?

10C. Provide the FDA IND Number (Drug Studies) or PMA Number (Device Studies):

FDA IND **#:** ☐ Pending ☐ Not Applicable
PMA **#:** ☐ Pending ☐ Not Applicable

11. CLINICAL TRIAL REGISTRATION (NOTE: You must complete this section if you identified the study as a Clinical Trial in Question 7; this question may be relevant even if Question 10, above is not applicable).
The International Committee of Medical Journal Editors (ICMJE) has indicated that clinical trials will not be published without the registration of that trial prior to participant enrolment. In June 2007, the ICMJE adopted the World Health Organization's definition of clinical trial: "Any research study that prospectively assigns human participants of groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-care changes and the like. A trial must have at least one prospectively assigned concurrent control or comparison group in order to trigger the requirement for registration." Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

Given the above definition, indicate whether this trial will be registered (e.g., www.clinicaltrials.gov, www.controlled-trials.com/isrctn/). ☐ Yes ☐ No

If **YES**, provide registration site:

If **YES**, provide Clinical Trial Registration #:

If **NO** please justify:

(Max ¼ page)

SECTION II: STUDY SUMMARY

(The full protocol must still be attached)

Responses to this section are not a substitute for the full protocol.

12. ABSTRACT (suitable for a public access or lay audience).

(Max ¼ page)

13. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION

13A. What is the rationale for this study?

(Max ¼ page)

13B. What are the study hypotheses or research questions?

(Max ¼ page)

13C. What is the significance of the study (i.e. the overall anticipated public and/or scientific benefit)?

(Max ¼ page)

14. STUDY DESIGN

Many of these questions apply to clinical research studies. If any of the items are not applicable to your study, indicate N/A.

14A. Describe the design and methodology (e.g. pre/post design, pilot, study visits, procedures, study intervention).

(Max ½ page)

14B. Describe the primary outcome measures/goals of the study.

(Max ¼ page)

14C. List all criteria for withdrawal of a participant from the study.

Not Applicable ☐

(Max ¼ page)

14D. Is a placebo used in this study? ☐ Yes ☐ No

If **YES**, explain how this is this justified (e.g. no alternative standard treatment available). Include any provisions in place to minimize risks to participants assigned to placebo (e.g., increased monitoring, rescue medication).

(Max ¼ page)

14E. Does this study involve deception or intentional lack of disclosure? ☐ Yes ☐ No

If **YES**, justify and indicate how participants will be debriefed.

(Max ¼ page)

14F. Will the participant be withdrawn from or denied usual therapy for any condition in order to participate in the study? ☐ Yes ☐ No

(This would include medications that are prohibited or restricted in order to be eligible for the study or that may be prohibited or restricted during the course of the study.)

If **YES**, explain.

(Max ¼ page)

14G. Will the participant be subject to other restrictions (e.g., lifestyle) during the study? ☐ Yes ☐ No

If **YES**, explain.

(Max ¼ page)

15. PARTICIPANT/CONTROLS

15A. List the inclusion and exclusion criteria.

(Max ¼ page)

15B. Are there any age, ethnicity, language, gender or race-related inclusion or exclusion criteria?
☐ Yes ☐ No

If **YES**, justify.

(Max ¼ page)

15C. Indicate the rationale for control group(s).
Not applicable ☐

(Max ¼ page)

15D. Indicate how many participants will be enrolled.

Total study enrollment:	
Number of participants to be enrolled at this site?	Total Number of charts to be reviewed at this site?
Time period for enrollment:	
Approximate size of eligible population from institution/practice (number, or number/year):	

15E. Is sample size justified in the protocol? ☐ Yes ☐ No

If **YES**, indicate protocol page:

If **NO**, provide sample size justification.

(Max ¼ page)

16. STUDY INTERVENTIONS OR PROCEDURES

Not Applicable ☐ (e.g. observational studies). If not applicable, go directly to Question 17 (Data Analysis)

16A. Document the usual standard of care for this population.

Not Applicable ☐

(Max ¼ page)

16B. What procedures will be carried out in the study that are not considered part of the diagnostic, therapeutic "routine" or standard of care? Attach a copy of all non-standardized instruments (e.g., questionnaires, rating scales).

(Max ¼ page)

16C. Indicate the additional risks associated with the study as compared to usual standard of care. Do not refer to other sections of this form.

(Max ½ page)

16D. Indicate duration of study visits and extra time commitment (length, number, and frequency of test sessions) for study participation

(Max ½ page)

17. DATA ANALYSIS

Briefly explain what methods will be used to analyze study data.

References to protocol for this question are acceptable. Indicate applicable page(s) of protocol.

(Max ¼ page)

SECTION III: ETHICAL ISSUES

18. RECRUITMENT AND CONSENT

Any document to be viewed by a study participant (e.g., recruitment posters/letters, consent/assent forms, information sheets) **must be included with your submission**.

18A. Are you seeking a waiver or permission to do research without consent?
☐ Yes ☐ No

i) If YES, explain how your request for consent to be waived will comply with TCPS 2 Articles 3.7 to 3.11 and PHIPA 44, 3c and d.

(Max ¼ page)

18B. What tools will be used to identify potential participants for recruitment into the study?

☐ Permanent health record/clinical chart (specify source):
☐ Existing database (specify): ○ Does the Principal Investigator maintain the database? ☐ Yes ☐ No ○ If **NO**, identify the entity that maintains the database: ○ Has access/use for research purposes been granted? ☐ Yes ☐ No ☐ Yes pending JREB approval **NOTE** The creation and maintenance of a database for research purposes is a research activity that may require a separate JREB application. Consult your institutional JREB.
☐ Advertisements, including web based recruitment tools (attach) ○ Where will these be posted? (specify)
☐ Other (specify):

18C. Who will identify potential study participants?
☐ Investigator/study personnel
☐ Other healthcare professional (e.g. non-study personnel)
☐ Self-referral (e.g. response to advertisement)

18D. Who will make initial contact with potential participants or an authorized third party? Is this individual(s) already known to the participant or authorized third party? How will contact be made (e.g., in person, phone, letter, e-mail, website)? Attach a copy of the script or any written materials if applicable. Not Applicable ☐

(Max ¼ page)

18E. Describe the consent process (e.g. will consent be written, oral, telephone (include script). If the study population requires special consent considerations (e.g., child, incompetent adult, unable to communicate), refer to 18F.
Not Applicable ☐

(Max ¼ page)

i) Who will obtain consent?

(Max ¼ page)

ii) Is there is a relationship between the participants and either of the following:
Person obtaining consent ☐ Yes ☐ No
Investigator ☐ Yes ☐ No

iii) If YES, explain the nature of the relationship (e.g., physician, employer) and what steps will be taken to avoid the perception of undue influence.

(Max ¼ page)

iv) How much time will be given to participants to review the information before being asked to give consent?

(Max ¼ page)

18F. Does your research involve any of the following:

i) Special Considerations (check all that apply):

☐ Women of child bearing potential
☐ Pregnant women
☐ Healthy volunteers
☐ Students
☐ Staff
☐ Genetic research
☐ Tissue samples
☐ Fetal tissue or placenta
☐ Prisoners
☐ Participants unable to communicate
☐ None of the above
☐ Other (specify):

ii) Capacity/Competency (check all that apply):

☐ Children
☐ Emergency patients
☐ Individuals temporarily unable to assent
☐ Individuals who lack the capacity to assent
☐ None of the above (skip to Question 18Fiii)

Describe **by whom** and **how** capacity will be assessed for any individuals in 18Fii.

(Max ¼ page)

If participants are incapable of providing consent, how will substitute decision-makers be identified?

(Max ¼ page)

When inability to provide an informed consent is expected to be temporary, describe what procedures will be used to regularly assess capacity and to obtain consent if the individual later becomes capable of providing consent.

(Max ¼ page)

iii) Communication Difficulties (check all that apply):

☐ Individuals who may require translation
☐ Individuals who are illiterate
☐ Participants who have trouble understanding and/or producing speech (and require special support Including the use of assistive devices)
☐ None of the above (skip to Question 18G)

Provide an explanation of what procedures will be used to address any communication difficulties (e.g., the use of translated forms, translator, and impartial witness)

(Max ¼ page)

18G. What steps will be taken to determine if the participants are already enrolled in other studies or are likely to be enrolled in other studies during the term of this study? If enrollment in multiple studies likely to be an issue in this population, indicate how this will be addressed.

(Max ¼ page)

SECTION IV: RISKS, BENEFITS AND SAFETY

19. RISK/BENEFIT ESTIMATES

19A. Potential Harms (injury, discomfort and inconvenience) to participant (including psychological factors).

No known risks ☐

i) List the known risks of study intervention(s) including approximate rates of occurrence, severity and rates of reversibility.

(Max ¾ page)

ii) List the risks of any tests, procedures or other protocol-mandated activities that are conducted for research purposes only, including approximate rates of occurrence, severity and reversibility.

(Max ¾ page)

iii) For studies involving placebo, washout, or withholding treatment, list any risks related to withdrawal or absence of treatment.

Not Applicable ☐

(Max ¾ page)

iv) Include a summary of the data regarding reproductive risks such as teratogenicity or embryo toxicity of the study drug, any risk with breastfeeding, or risk to men regarding conception
Risks unknown ☐ Not Applicable ☐

(Max ¼ page)

v) Does participation in this study affect alternatives for future care?
☐ Yes ☐ No

If **YES**, explain.

(Max ¼ page)

19B. Potential Benefits to Participants
No direct benefits anticipated ☐

List anticipated benefits to the participant, if any.

(Max ¼ page)

20. REMUNERATION

Not Applicable ☐

What payment(s) will be provided to participants or substitute decision makers (if applicable)?

☐ Reimbursement for expenses incurred as a result of research Amount: (specify e.g., travel, meals):
☐ Gifts for participation Value:
☐ Compensation for time Amount: Provide justification if compensation for time will be provided. (Max 1/4 page)
☐ Other forms of compensation:

21. SAFETY MONITORING

21A. Is there a safety monitoring plan for the study?
☐ Yes ☐ No ☐ Not Applicable

If **YES**, provide details. If **NO**, justify.

(Max ¼ page)

21B. Is an interim analysis planned? ☐ Yes ☐ No ☐ Not Applicable

If **YES**, describe briefly.

(Max ¼ page)

21C. Is there a steering committee? ☐ Yes ☐ No ☐ Not Applicable

NOTE: If **YES**, attach a copy of the terms of reference (mandate) of the steering committee.

21D. Is there a Data and Safety Monitoring Board (DSMB)?
☐ Yes ☐ No ☐ Not Applicable

If **YES**, forward a copy of the DSMB charter when available or provide a description of the DSMB, including its purpose, membership, relationship to the sponsor, and whether the committee will review un-blinded study data etc. **Refer to the protocol as needed.**

(Max ¼ page)

21E. Is the DSMB independent of the sponsor? ☐ Yes ☐ No

If **NO**, justify and explain what alternative arrangements are in place to monitor the safety data and **by whom and how** the overall risk/benefit information will be communicated to the JREB.

(Max ¼ page)

22. PUBLICATION/DISSEMINATION OF RESULTS

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

TO PARTICIPANTS:	**TO OTHER STAKEHOLDERS:**
☐ Individual debriefing at end of test session	☐ Presentation
☐ Group debriefing	☐ Publication
☐ Letter of appreciation at end of study	☐ Other (specify):
☐ Publication	☐ No plan, justify below.
☐ Other (specify):	
☐ No plan, justify below.	

If no plan is in place, provide justification.
Not Applicable ☐

(Max ¼ page)

SECTION V: PRIVACY AND CONFIDENTIALITY

23. COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

Investigators must comply with the duties set out for researchers in the Personal Health Information Protection Act (PHIPA), with the privacy and confidentiality and consent guidelines outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans and other requirements and guidelines as per the TAHSN Principles for Development of Policy and Guidelines on Security of Personal Health Information Used for Research Purposes (February 4, 2008).

It is a requirement of the institution and PHIPA that a **complete information access log** be kept for each study and for the duration of the study to identify **all personnel** who have access to personal health information for research purposes. The JREB or the Institution may require access to this log as part of the monitoring process or for investigational purposes. This log must be kept as part of the recruitment and study conduct processes.

23A. Identify all persons including non-institutional service providers, that will have access to the personal health information now or in the future, their roles in the study (e.g., chart review), their reason for access (e.g. eligible study recruits), and related qualifications. Attach additional pages if required.

1	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
	Reason for Access (e.g. recruitment, study conduct, other – specify):		
2	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
	Reason for Access (e.g. recruitment, study conduct, other – specify):		
3	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
	Reason for Access (e.g. recruitment, study conduct, other – specify):		
4	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
	Reason for Access (e.g. recruitment, study conduct, other – specify):		
5	Title:	Last Name:	First Name:
	Institution:	Qualifications:	Role in Study:
	Reason for Access (e.g. recruitment, study conduct, other – specify):		

23B. Has your research team been given training in privacy and confidentiality issues for this study?
☐ Yes ☐ No

If **NO**, when will training be provided?

(Max ¼ page)

23C. Who on the research team other than the PI is responsible for the protection of privacy and confidentiality?

☐Not applicable; no other member of the research team is responsible.

Last Name:	First Name:
Position:	Contact Information:

23D. List the identifying and identifiable information that will be collected, used, or disclosed from the records during the course of the <u>proposed recruitment activities</u>. The box below lists the most common personal identifying information that might be collected, used and disclosed (see the TAHSN Guidelines for completing this application for a more complete list). Please check the applicable boxes below or add additional identifying information.

☐ Name	☐ Images (e.g., photographic, x-ray, MRI scans)
☐ Address	☐ Social Insurance Number
☐ Telephone/Fax Numbers	☐ Medical Record Number
☐ Email Address/IP Address/URLs	☐ Date of Birth
☐ Health Card Number	☐ Health Information: (e.g., relating to inclusion /exclusion criteria, medications)
☐ Other information (specify):	

23E. Describe the security measures that will be taken to protect the confidentiality of this information.

(Max ¼ page)

23F. What will happen to this information at the completion of the recruitment process? NOTE: If information will be destroyed, provide the **<u>name of the person responsible</u>** and **<u>at what point</u>** the destruction will occur.

(Max ¼ page)

<u>24. DO YOU KEEP A LOG OF PERSONNEL,</u> who have access to personal health information for recruitment purposes? ☐ Yes ☐ No

<u>25. PERSONAL HEALTH INFORMATION AND PERSONAL IDENTIFIERS</u>

NOTE: These questions deal with the <u>ongoing study</u>; for information specific to recruitment see 23D.

25A. List all personal health information and personal identifiers (e.g. name, DOB) required to be collected. For all non-clinical trials, attach data collection forms.

(Max ¼ page)

25B. Identify all potential sources of this information.

☐ Permanent health record/clinical chart (specify source):
☐ Existing database (specify): ○ Does the Principal Investigator maintain the database? ☐ Yes ☐ No ○ If **NO**, identify the entity that maintains the database:
☐ Directly from the participant
☐ From other institutions (specify):
☐ Other (specify):

25C. Indicate how study participants will be identified on data collection forms (e.g. study number, initials).

☐ Participant Identification #
☐ Other (specify): If using other, please justify:

25D. Indicate how data will be stored.

☐ Computerized files (Specify): ☐ Server ☐ Desktop ☐Laptop Server (specify): ☐ Internal ☐Contracted Service Provider ☐Other ☐Third Party
☐ Hard copy
☐ Audio recordings
☐ Video recordings
☐ USB key or similar portable storage device
☐ PDA, E-reader or similar hand-held computer
☐ Other:

25E. Indicate where the data will be stored.

☐ On-site ☐ Off-site; specify location(s) including institution name, city and country: If off-site, will a back-up copy be stored on site? ☐ Yes ☐ No If **NO** justify:

25F. Indicate which of the measures will be undertaken to protect the confidentiality and security of the data, including any physical and technical safeguards

☐ Data stored on mobile devices will be encrypted
☐ Data will be password protected
☐ Data will be stored on a hospital or other institutional network drive that has firewalls and security measures in place
☐ Hard copy records will be stored in a locked cabinet in a secure location
☐ Access to records and data limited to authorized persons
☐ Study data will be **de-identified or coded.** A master linking log with identifiers will be kept and stored separately from the data
☐ Study data will be **anonymized.** All identifiers will be removed once the data has been: ☐collected ☐verified ☐analyzed
☐ Study data will be **anonymous.** Identifiers/identifying information will not be collected
If audio/video recordings will be used: ☐ Recordings will be destroyed upon ☐ transcription ☐ review ☐ verification ☐ analysis ☐ Recordings will coded ☐ Recordings will not capture date and time
☐ Other:

25G. Indicate if any, further measures will be taken <u>at the end of the study</u> (e.g., whether data will be anonymized at that point, etc.)

(Max ¼ page)

25H. Indicate who will have access to data in the future

(Max ¼ page)

25I. Indicate if any information that could potentially identify study participants will be disclosed outside of the custody of the Health Information Custodian (Hospital or responsible institution) (e.g., names, initials, DOB, OHIP #).

☐ Yes ☐ No

If **YES**, to whom?

(Max ¼ page)

25J. Is there a contract or agreement in place that requires the transfer of data from the custody of the Health Information Custodian?

☐ Yes ☐ No

Justify and describe how this information will be transferred and any security measures to be used (e.g., de-identified data, secure network upload or download).

(Max ¼ page)

25K. If personal health information is to be linked to other databases (e.g., health registries, Statistics Canada information) provide the following details:

Not Applicable ☐

i) Describe the data to which the personal health information will be linked.

(Max ¼ page)

ii) Explain how the linkages will be made.

(Max ¼ page)

iii) Explain why these linkages are required.

(Max ¼ page)

25L. Indicate how long the personal health information will remain identifiable and explain why
Not Applicable ☐

(Max ¼ page)

25M. Explain why the research cannot reasonably be accomplished without using personal health information

(Max ¼ page)

25N. If personal health information will be collected, used or disclosed without consent from the individuals to whom the information relates, explain why obtaining explicit consent would be impractical.

(Max ¼ page)

25O. Describe any harms that could arise if personal health information was inappropriately released (e.g., embarrassment, refusal of employment or insurance coverage, stigmatization of individuals / groups) and how any consequences would be addressed.

(Max ¼ page)

25P. Describe how and when the personal health information will be disposed of or returned to the health information custodian.

(Max ¼ page)

SECTION VI: FUNDING, CONTRACTS AND AGREEMENTS

26. BUDGET

26A. Attach an itemized study budget (applies to all full board and delegated review studies). The budget should reflect all costs to complete the study (e.g. database extraction, student payments, participant reimbursement etc.)
OR ☐ No budget required, as described above, Question 6.

26B. Is funding sufficient to cover all study costs? ☐ Yes ☐ No

If **NO**, explain how the shortfall will be made up.

(Max ¼ page)

26C. Will any investigator receive direct personal payments? ☐ Yes ☐ No

If **YES**, describe what these payments are for and the amount.

(Max ¼ page)

27. CONTRACTS AND AGREEMENTS

"Institutions and REBs should require the satisfactory amendment or removal of any confidentiality clauses or publication restrictions that unduly limit either the content of the scientific information that may be disseminated or the timing of dissemination. Contract should also ensure that principal investigators have the necessary access to original trial data, and the opportunity to analyze them, to ensure that they can report trial findings fairly and accurately, particularly with respect to both efficacy and safety." (TCPS 2, 11E)

REBs also legitimately seek assurances that other contractual rights and obligations are consistent with the statements in the protocol. This is why the REB requests information regarding agreements related to transfers of personal information and biological material (for privacy issues), liability (to ensure that participant reimbursement is appropriately available) and publication. Review by the institution ensures that certain institutional policies are met.

27A. Contract/Research Agreement

Is there **any party** external to the institution involved with the research that will be entering into an agreement or contract with the institution? ☐ Yes ☐ No

If **YES**, provide names and roles of those involved (i.e. Regulatory Sponsor, contract research organization, funder, collaboration institution, vendor or researcher).

(Max ¼ page)

27B. Has the contract/research agreement has been submitted for review and signing (see institution specific instruction)? ☐ Yes ☐ No

27C. Transfer Agreement

Will biological materials (e.g. blood, other bodily fluids, tissues) or identifiable information (e.g. data, video and audio and other data) be transferred? If so, has an agreement related to the transfer (e.g., Material Transfer Agreement, Information Sharing Agreement, Service Provider Agreement, Vendor Agreement) been approved?

☐ Yes ☐ No ☐ Not applicable

If **NO**, explain.

(Max ¼ page)

28. LIABILITY

Who will cover reasonable out of pocket expenses to ensure that immediate medical care is provided if a participant suffers an injury as a result of participation in the study?

- ☐ Regulatory Sponsor (as listed above, Question 10B)
- ☐ Funder
- ☐ Institution
- ☐ Other (specify):

29. PUBLICATION

Has the funding agency or sponsoring company placed any restrictions on publication of findings (e.g., timing of manuscripts; approval process of manuscripts) or on reporting interim results? ☐ Yes ☐ No ☐ Pending

If **YES**, explain any restrictions.

(Max ¼ page)