**HUMBER RIVER HEALTH INITIAL PROSPECTIVE**

# HUMAN PARTICIPANTS RESEARCH ETHICS APPLICATION

**INSTRUCTIONS**

* All sections of this application MUST be completed before it will be considered for REB review.
* A separate detailed protocol must be included with each application.
* All research must be compliant with:
  + The Tri-Council Policy Statement, available at

https://ethics.gc.ca/eng/documents/tcps2-2022-en.pdf

* + The Ontario Personal Health Information Protection Act (2004), available at

<http://www.e-laws.gov.on.ca/html/statutes/english/elawsstatutes_04p03_e.htm>

* + Any other relevant regulations or guidelines.

**SECTION I: GENERAL INFORMATION**

**1. PRINCIPAL INVESTIGATOR (PI) NAME**

Please note that an HRH affiliated staff member must be listed as the PI for all HRH REB submissions

|  |  |  |
| --- | --- | --- |
| 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 REB approved study at HRH** (e.g., extension, rollover, subsequent to a pilot study)? Yes  No

If **YES**, specify:

|  |
| --- |
| Name of Principal Investigator: |
| REB 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 REB, 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: Humber River Health. Please note that an HRH affiliated staff member must be listed as the PI for all HRH REB submissions | | |
| 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 REB, 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 is a student participating as part of an academic training program, 3C must be completed.**

**PLEASE NOTE: Only Humber River Health affiliated Co-Investigators listed on the study application are required to sign. If you have any questions, please contact the REB office at reb@hrh.ca.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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. Faculty Supervisor (for student/fellow/resident research studies)**  Not Applicable.

**NOTE:** If this research is part of an academic (University) **training program**, please provide the following information.

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: | |

**4A. 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

**4B. OTHER RESEARCH STAFF (any remaining research staff who will be involved with study activities, e.g. Statistician, data analyst)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title: | Last Name: | | First Name: | |
| Dept/Div: | Program: | | Institution: | | |
| Telephone: | Pager: | | Fax: | |
| Street Address: | | | | Room/Suite #: |
| City: | Province: | Postal Code: | Email: | |
| Role in Study: | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title: | Last Name: | | First Name: | |
| Dept/Div: | Program: | | Institution: | | |
| Telephone: | Pager: | | Fax: | |
| Street Address: | | | | Room/Suite #: |
| City: | Province: | Postal Code: | Email: | |
| Role in Study: | | | | |

**5. DEPARTMENT/DIVISION/PROGRAM HEAD APPROVAL (refer to the HRH Impact Form).** 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 can not 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: |  |

Is this research supported by the United States Federal Government (including funding by a US governmental agency?  **Yes  No**

(Please note if your research study is supported by, conducted in collaboration with, or is funded by a United States government agency (such as NCI, DHHS, DOJ) that is subject to the Common Rule or that is subject to the Food and Drug Administration (FDA) review and approval you must indicate ‘Yes’.)

**6B. Funding Type/Categories:**

|  |
| --- |
| List the funder(s): |
| Is study PI led or industry initiated? |
| Country of origin of funding agenc(ies): |
| 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 Institute of Health, Canadian Institutes for Health Research, Medical Research Council) |
| 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**, Question 26B. **MUST** be completed. If **NO**, the REB Review **may be held** until confirmation of funding is obtained. Please advise the REB if you would like a letter confirming REB submission for the funder.

**7. WHAT DOES THIS STUDY INVOLVE?**

Please specify the nature of the study (and substudies), 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 REB# of main/related study: |
| Case Study/Report |
| Educational |
| Database |
| 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.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **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 |  |  |  |  |
|  | University Health Network |  |  |  |  |
|  | Women’s College Hospital |  |  |  |  |
|  | University of Toronto |  |  |  |  |
|  | Other: |  |  |  |  |
| **Is HRH the lead site?**  Yes  No | | | | | |

**9B. Has the research undergone other scientific/scholarly review prior to this REB 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 REB 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. The ICMJE definition of a clinical trial includes “any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioural treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are 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?**

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| --- |
| (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?** YesNo

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).**

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| --- |
| (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 REB approval   **NOTE** The creation and maintenance of a database for research purposes is a research activity that may require a separate REB application. Consult your institutional REB. |
| Database to be created (specify location):  **NOTE:** The creation and maintenance of a database for research purposes is a research activity that may require a separate REB application. Consult the REB office at REB@HRH.CA. |
| 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) |

**v) Describe how research participants will be informed in a timely manner about new information relevant to their ongoing consent, throughout the course of the study, which may affect their willingness to continue participation. Describe the process for obtaining their ongoing consent (if applicable)**

|  |
| --- |
| (Max ¼ page) |

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

**i) Special Considerations (check all that apply):**

Women of child bearing potential  Tissue samples

Pregnant women  Fetal tissue or placenta

Healthy volunteers  Prisoners

Students  Participants unable to communicate

Staff  None of the above

Genetic research  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, impartial witness).

|  |
| --- |
| (Max ¼ page) |

**iv) Will you be actively trying to recruit participants from groups typically underrepresented in research?**

Yes  No

If **YES**, **please describe your recruitment plan.**

|  |
| --- |
| (Max ¼ page) |

If **No**, explain.

|  |
| --- |
| (Max ¼ page) |

**v) Which of the following criteria apply to this research (select all that apply)?**

|  |
| --- |
| Research conducted on First Nations, Inuit or Métis lands |
| Recruitment criteria that include Indigenous identity as a factor for the entire study or for a subgroup in the study |
| Research that seeks input from participants regarding an Indigenous community’s cultural heritage, artifacts, traditional knowledge or unique characteristics |
| Research in which Indigenous identity or membership in an Indigenous community is used as a variable for the purpose of analysis of the research data |
| Interpretation of research results that will refer to Indigenous communities, peoples, language, history or culture |
| None of the above |

If any criteria other than ‘none of the above’ is selected above, complete the below:

Is there a plan to engage the relevant community or communities?  Yes  No

If yes, please describe how the relevant communities have been or will be engaged, and provide a copy of any formal agreements, written decisions, or summary of advice received:

|  |
| --- |
| (Max ¼ page) |

**If no, provide the rationale:**

|  |
| --- |
| (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).**

**i) List the known risks of study procedure(s) that may result from study participation which have been disclosed in the study protocol and consent form** (include 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 embryotoxicity 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) |

**vi) Describe how any incidental findings will be managed and under what circumstances they would be disclosed to study participants:**

Not Applicable

|  |
| --- |
| (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): |
| Compensation 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 unblinded 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 REB.

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| (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:** |
| Individual debriefing at end of test session |
| Group debriefing |
| Letter of appreciation at end of study |
| Publication |
| Lay summary of study results |
| Other (specify): |
| No plan, please justify. |

**Any document** that will be viewed by a study participant **must be submitted to the REB for review and approval**. If any of the above material has not yet been developed and is intended for use at a later date, **it must be submitted as an Amendment prior to implementation**.

|  |
| --- |
| **TO OTHER STAKEHOLDERS:** |
| Presentation |
| Publication |
| Other (specify): |
| No plan, justify. |

**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 REB 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 proposed recruitment activities**. The box below lists the most common personal identifying information that might be collected, used and disclosed. 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**.

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| (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 **name of the person responsible** and **at what point** the destruction will occur

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| (Max ¼ page) |

**24. DO YOU KEEP A LOG OF PERSONNEL who have access to personal health information for recruitment purposes?**  Yes  No

**25. PERSONAL HEALTH INFORMATION AND PERSONAL IDENTIFIERS**

**NOTE: These questions deal with the ongoing study; 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.**

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| (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 HRH 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 be coded  Recordings will not capture date and time |
| Other: |

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

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| (Max ¼ page) |

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

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| (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).

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| (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.

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| --- |
| (Max ¼ page) |

**ii) Explain how the linkages will be made.**

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| --- |
| (Max ¼ page) |

**iii) Explain why these linkages are required.**

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| --- |
| (Max ¼ page) |

**iv) Describe the likelihood that identifiable data will be created through the linkage.**

|  |
| --- |
| (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.

|  |
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| (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.

|  |
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| (Max ¼ page) |

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

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

|  |
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| (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 HRH Study Impact Form)?  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.

|  |
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| (Max ¼ page) |