

Research Ethics Board Initial Application Form

**INSTRUCTIONS**

**All sections** of this application **MUST** be completed before it will be considered for review by the Michael Garron Hospital (MGH) Research Ethics Board (REB). Please submit the following with your application:

* A separate detailed protocol
* Completion of the [Research Intake and Approval Form](https://forms.office.com/pages/responsepage.aspx?id=zrAEUX-1UEmtdyib3BsCQ5XAES0UhG1Il3V5zW8lZZRUNlNWMlU5MUI0RUdNTDhCUFdRVlNXS0hZUS4u&route=shorturl)
* Appendix A: Conflict of Interest (If applicable)
* Appendix B: Study Personnel Log (Required)

**SECTION 1: GENERAL INFORMATION**

**1. LOCAL MGH PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

|  |
| --- |
| **Title:**      **First Name:**      **Last Name:**       |
| **Credentials (MD, PhD, etc.):** |
| Dept/Div:      Program:      Email:       |  |  |

**2. STUDY INFORMATION**

|  |
| --- |
| Study title:       |
| Version date of your application:       |
| Sponsor Protocol Number (if applicable):       |
| Study period: Expected start date:       Total study duration:       |
| Is this protocol directly related to a previously approved study at MGH (e.g., extension, rollover, subsequent to a pilot study)? [ ]  Yes [ ]  No |
| If yes, indicate name of MGH Local Principal Investigator:      MGH REB number:       |

**3. SCOPE OF STUDY AT MGH**

**Please specify the scope of the study conducted at MGH.**

[ ]  Referral or advertisement only (i.e., Referring potential participant to external study site, consent not performed at MGH)

|  |
| --- |
| [ ]  Recruitment only (i.e., Participant identification and consent only)  |
| [ ]  Recruitment and study activities performed at MGH  |
| [ ]  Data analysis only:       |
| [ ]  Other (Please specify):       |

**4. SOURCE OF FUNDING**

**Is the study funded?**

[ ]  Yes

[ ]  No; Please explain

**Please identify the study funding source(s):**

|  |  |
| --- | --- |
| [ ]  Industry or Private Sector:        |  |
| [ ]  Granting Agency:       |  |
| [ ]  Internal Funding:       |  |
| [ ]  Other:       |  |

**5. INVESTIGATORS**

### 5A. EXTERNAL LEAD PRINCIPAL INVESTIGATOR CONTACT INFORMATION

### Complete this section if the Local MGH Principal Investigator is not the lead investigator for the entire study.

Not Applicable [ ]

|  |  |  |
| --- | --- | --- |
| Title:       | Last Name:       | First Name:       |
| Dept/Div:       | Program:       | Institution:       |
| Telephone:       | Street Address:       |
| City:       | Province:       | Postal Code:       | Email:       |

5B. CO-INVESTGATOR(S) CONTACT INFORMATION

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1 | Title:       | Last Name:       | First Name:       | Institution:       |
| Dept/Div:       | Program:       |
| 2 | Title:       | Last Name:       | First Name:       | Institution:       |
| Dept/Div:       | Program:       |
| 3 | Title:       | Last Name:       | First Name:       | Institution:       |
| Dept/Div:       | Program:       |
| 4 | Title:       | Last Name:       | First Name:       | Institution:       |
| Dept/Div:       | Program:       |
| 5 | Title:       | Last Name:       | First Name:       | Institution:       |
| Dept/Div:       | Program:       |

**6. CONFLICT OF INTEREST**

**If there are multiple conflicts of interest (COI) that need to be disclosed to the REB, please use Appendix A to fill out one form per disclosure.**

COIs do not imply wrong-doing. A COI may exist even if no unethical or improper act results from the conflict. Researchers and research staff should identify and manage COIs to maintain the public confidence and trust and to maintain the independence and integrity of the research process. If a COI cannot be avoided, procedures should be in place to manage and/or mitigate the conflict (N2 SOP 105B; Conflicts of Interest – Researcher).

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

[ ]  Not applicable. There are no COIs to disclose.

**NOTE:** This disclosure does not replace institutional guidelines and requirements for declaration and management of COIs.

**Describe any Conflicts of Interest (Check all that apply)**

|  |
| --- |
| **Name of Individual:**  |
| [ ]  This individual engaged as an advisor, employee, officer, director, or consultant for the study sponsor.[ ]  This individual has direct or indirect financial interest in the drug, device or technology employed in this research study (including patents or stocks).[ ]  This individual is an inventor and/or owner of any intellectual property that is being used in this research. [ ]  This individual received any other non-peer reviewed research or non-research funding, including in-kind support, from the sponsors/funders/other third parties involved in this research study. [ ]  Holdings – This individual has holdings (shares, options, partnership interest, or any other beneficial interest) in any of the sponsors/funders/other third parties involved in this research study.[ ]  Roles – This individual has other relationships not already disclosed that may be perceived to impact on their ability to perform their duties and responsibilities on this research study (including community relationships, academic interests, or other financial interests).[ ]  The sponsor/funder/other third party involved in the research study is providing funding beyond reimbursement for the direct expenses of conducting this research study.Other, please specify:  |
| **Describe the potential/perceived/actual benefit to the individual:** [ ]  Financial [ ] Status [ ] Undue influence [ ]  Competing interestPlease specify the total compensation received:  |

**Describe the management plan for the COI:**

|  |
| --- |
|       |

**Declaration by MGH Lead Principal Investigator**

[ ]  I confirm that all COIs have been declared to the Institution and MGH’s Research and Innovation Department.

[ ]  I confirm that any new conflicts that arise for any study team member during the conduct of the study will be declared to the MGH REB.

**7. OTHER ETHICS/SCIENTIFIC/SCHOLARLY REVIEW**

|  |  |
| --- | --- |
| **Identify the REBs that have reviewed and/or approved the study outlined in this application, below:** | **\*Application for Ethics Review and Approval Status**(Indicate date where applicable): |
| **To Be Submitted** | **Applied, Review Pending**(date) | **Reviewed**(date) | **Approved**(date) |
|        | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]  | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |
|       | [ ]  | [ ]        | [ ]        | [ ]        |
|       | [ ]   | [ ]        | [ ]        | [ ]        |

**Include all relevant correspondence related to ethics and scientific review (e.g., REB review letter, replies, approval letter).**

**8. CLINICAL TRIAL APPLICATION**

This section must be completed for clinical trials only. See TAHSN guidelines for Health Canada’s definition of a clinical trial.

Not applicable [ ]  If not applicable proceed to Question 10.

**8A. If this study involves any of the following, check all that apply:**

|  |
| --- |
| [ ] Investigational drug(s) - drug name(s):,  |
| [ ] Approved drug for new indication, dosage, or formulation (e.g., new patient population) - drug name(s): |
| [ ]  Investigational biologics – name(s) of biologics:,  |
| [ ]  Investigational natural health products (NHP) – NHP name(s): ,  |
| [ ]  Investigational medical devices – device name(s): ,  |

**8B. Is the study regulated under Health Canada’s Food and Drug Act:**

[ ]  Yes

[ ]  No

**If yes, is the Health Canada “No objection letter” or regulatory authorization attached?**

[ ]  Yes

[ ]  No

**If no, when is it expected?**

**8C. Is the study regulated under the US Food and Drug Administration (FDA)?**

[ ]  Yes

[ ]  No

**If yes, please provide the IND number (drug studies) or PMA number (device studies):**

**FDA IND #:**  [ ]  Pending

**PMA #:**  [ ]  Pending

Not Applicable [ ]

**Note:** final approval will not be granted until the appropriate regulatory approval has been received.

**9. CLINICAL TRIAL REGISTRATION**

The International Committee of Medical Journal Editors (ICJME) has indicated that clinical trials will not be published without the registration of that trial prior to participant enrolment. A clinical trial is defined by ICJME as, "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. This definition includes drugs, surgical procedures, devices, behavioural treatments, process-of-case 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."

**Given the above definition, indicate whether this trial will be registered (e.g., www.clinicaltrials.gov, www.controlled-trials.com/isrctn/).**

 [ ]  Yes

 [ ]  No

 [ ]  Not Applicable

**If Yes, provide registration site:**

**SECTION 2: STUDY SUMMARY**

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

**10. ABSTRACT**

**Please provide a summary of the study written in plain language.**

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| (Max ¼ page)      |

**11. RATIONALE AND HYPOTHESIS/RESEARCH QUESTION**

**11A. Indicate the rationale for this study.**

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| --- |
| (Max ¼ page)      |

**11B. Indicate the hypothesis for this study or research question.**

|  |
| --- |
| (Max ¼ page)      |

**11C. Indicate the significance of the study (i.e. the overall anticipated public and/or scientific benefit).**

|  |
| --- |
| (Max ¼ page)      |

**12. 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.

**12A. Describe the design and methodology (e.g., pre/post design, pilot, study visits, procedures, study intervention).**

|  |
| --- |
| (Max ½ page)      |

**12B. Describe the primary outcome measures/goals of the study.**

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| --- |
| (Max ¼ page)      |

**12C. List any criteria for premature withdrawal of a participant from the study for safety concerns.**

Not Applicable [ ]

|  |
| --- |
| (Max ¼ page)      |

**12D. 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 reduce risks to participants assigned to placebo (e.g., increased monitoring, rescue medication).**

|  |
| --- |
| (Max ¼ page)      |

**12E. Does this study involve deception or intentional lack of disclosure?**

[ ]  Yes

[ ]  No

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

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| --- |
| (Max ¼ page)      |

**12F. Will the participant be withdrawn from or denied usual therapy for any condition in order to participate in the study or be subject to other restrictions during 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)      |

**13. PARTICIPANT/CONTROLS**

**13A. Indicate the main inclusion and exclusion criteria.**

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| (Max ¼ page)      |

**Indicate the age range of eligible participants:**

**13B. If applicable, indicate the rationale for control group(s).**

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| --- |
| (Max ¼ page)      |

**13C. Does the study use Bayesian statistics?**

[ ]  Yes

[ ]  No

**If yes, please provide the minimum sample size according to safety and effectiveness endpoints:**

Please describe:

**13D. Enrollment**

|  |
| --- |
| **i) Total study enrollment across all sites:**        |
| **ii) Number of participants to be enrolled at MGH:**        |
| **iii) Number of participants per study arm/population**:        |
| **iv) Indicate the time frame for enrollment at MGH:**       |
| **v) Approximate size of eligible population at MGH:**       |

**13E. Is sample size justified in the protocol?**

[ ]  Yes

[ ]  No

**If Yes, indicate protocol page:**

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

|  |
| --- |
| (Max ¼ page)      |

**14.STUDY INTERVENTIONS OR PROCEDURES CONDUCTED AT MGH**

Not Applicable [ ]  (e.g., observational studies). If not applicable, go directly to 15. DATA ANALYSIS

**14A. Document the usual standard of care at MGH for this population.**

Not Applicable [ ]

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| --- |
| (Max ¼ page)      |

**14B. Indicate what procedures are to be carried out in the study at MGH, which are not considered part of the diagnostic, therapeutic “routine” or indicate how standard of care is altered. Attach a copy of all instruments used in this study (e.g., questionnaires, rating scales).**

|  |
| --- |
| (Max ¼ page)      |

**14C. 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)      |

**14D. Indicate duration of study visits and extra time commitment (length, number, and frequency of test sessions) for study participation.**

|  |
| --- |
| (Max ¼ page)      |

**15. 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.

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| --- |
| (Max ¼ page)      |

**SECTION 3: ETHICAL CONSIDERATIONS**

**16. IDENTIFICATION AND SCREENING OF POTENTIAL RESEARCH PARTICIPANTS**

Not Applicable [ ]

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

**A. ELIGIBILITY**

**16A. Please describe how potential participants will be identified for recruitment into the study.**

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| --- |
| (Max ¼ page)      |

**16B. Indicate 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 Local MGH Principal Investigator maintain the database? [ ]  Yes [ ]  No
	+ If No, identify the entity that maintains the database:

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. |
| [ ]  Advertisements, including web based recruitment tools (attach) |
| [ ]  Other (specify):       |

**16C. Indicate who will identify potential study participants**

[ ]  Investigator/study personnel

[ ]  Other healthcare professional (e.g., non-study personnel)

[ ]  Self-referral (e.g., response to advertisement)

**i) Select the identifying information that will be collected, used, or disclosed from the records for screening and identification of potential participants.**

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

**ii) Will this identifying information be retained for all individuals screened for this study, (i.e., stored in a screening log)?**

[ ]  Yes

[ ]  No

**iii) If yes, describe where this information will be retained and for how long, after identification and screening of all potential participants?**

|  |
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| (Max ¼ page)      |

**iv) Describe the security measures that will be taken to protect the confidentiality of this information.**

|  |
| --- |
| (Max ¼ page)      |

**B. RECRUITMENT OF POTENTIAL RESEARCH PARTICIPANTS**

**16D. Please describe the recruitment process used for this study:**

|  |
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| (Max ¼ page)      |

**16E. Indicate who will make initial contact with potential participants or authorized third party, and their relationship to the potential participant (i.e., are they already known to the individual)?**

|  |
| --- |
| (Max ¼ page)      |

**16F. Please indicate how contact will be made (e.g., in person, phone, letter, e-mail, website).** Attach a copy of the script or any written materials if applicable.

|  |
| --- |
| (Max ¼ page)      |

**C. CONSENT PROCESS**

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

**16G. Are you requesting a waiver and/or deferral of consent for any research related activity occurring in this study?**

[ ]  Yes

[ ]  No

**If yes, please justify how your request meets the conditions for TCPS2 Article 3.7A and PHIPA 44.3c:**

|  |
| --- |
| (Max ¼ page)      |

**16H. If no, describe the consent process and who will obtain consent (e.g., will consent be written, oral, telephone (include script). Please describe where consent will be documented.** If the study population requires special consent considerations (e.g., child, incompetent adult, unable to communicate).

|  |
| --- |
| (Max ¼ page)      |

**i) Indicate if there is a relationship between the participants and either of the following:**

 Person obtaining consent:

 [ ]  Yes

 [ ]  No

Investigator:

[ ]  Yes

[ ]  No

**ii) 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)      |

**iii) Indicate how much time will be given to participants to review the information before being asked to give consent.**

|  |
| --- |
| (Max ¼ page)      |

**16I. i) Does the research include any of the following groups (check all that apply):**

[ ] Patients [ ]  People institutionalized\*

[ ]  Healthy Volunteers [ ]  Prisoners/persons in detention\*

[ ]  Students\* [ ]  People in poverty/economically disadvantaged\*

[ ]  Staff\* [ ]  Educationally disadvantaged people\*

[ ]  People with mental health issues\* [ ]  People who are unable to read or write\*

[ ] Children\* [ ]  Pregnant people

[ ]  People in medical emergencies \* [ ]  Elderly people

[ ]  People who lack capacity to consent\* [ ]  People in palliative care

[ ]  Cognitively impaired individuals\* [ ]  People in long-term care

[ ]  Individuals with physical disabilities\* [ ]  Indigenous people and/or ethno-cultural minorities\*

[ ]  Adults who are temporarily unable to [ ]  Individuals who may require translation provide consent (e.g. unconscious)\* [ ]  Other; please specify:

[ ]  People who have trouble understanding

 and/or producing speech\*

If any of the \* options are selected, please describe how coercion and undue influence will be minimized:

**ii) If participants are incapable of providing consent, provide information on how substitute decision makers will be identified.** Please refer to the Capacity Guidelines for more information.

Not Applicable [ ]

|  |
| --- |
| (Max ¼ page)      |

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

Not Applicable [ ]

|  |
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| (Max ¼ page)      |

**16J. If potential participants might be approached for recruitment in other studies, indicate the steps that will be taken to minimize the number of times that this will occur.**

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| (Max ¼ page)      |

**17. RISK/BENEFIT ESTIMATES**

**17A. Potential Benefits to Participants**

No direct benefits anticipated [ ]

**List anticipated benefits to the participant, if any.**

|  |
| --- |
| (Max ¼ page)      |

**17B. Potential Harms (injury, discomfort and inconvenience) to subject (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 absence of treatment.**

Not Applicable [ ]

|  |
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| (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[ ]

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| (Max ¼ page)      |

**v) Indicate whether participation in this study affects alternatives for future care.**

[ ]  Yes

[ ]  No

**If Yes, explain.**

|  |
| --- |
| (Max ¼ page)      |

**18. PARTICIPANT COMPENSATION**

Not Applicable [ ]

**18A. Indicate what compensation will be provided to participants or substitute decision makers if applicable.**

|  |
| --- |
| [ ]  Reimbursement for expenses incurred as a result of researchAmount:       Specify (e.g., travel, meals):       |
| [ ]  Token of appreciation for participation Value:       |
| [ ]  Compensation for timeAmount:      Provide justification if compensation for time will be provided. (Max 1/4 page)       |
| [ ]  Other forms of compensation:       |

**19. MONITORING**

**19A. Indicate if there is a plan for monitoring of the study (e.g., sponsor-initiated site visits).**

[ ]  Yes

[ ]  No

[ ]  Not Applicable

**If yes, please describe.**

|  |
| --- |
| (Max ¼ page)      |

**19B. Indicate if an interim analysis is planned.**

[ ]  Yes

[ ]  No

[ ]  Not Applicable

**If yes, please describe.**

|  |
| --- |
| (Max ¼ page)      |

**19C. Indicate if there is a steering committee.**

[ ]  Yes

[ ]  No

[ ]  Not Applicable

**If yes, provide a copy of the terms of reference (mandate) of the steering committee.**

**19D. Indicate if there is 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)      |

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

|  |
| --- |
| (Max ¼ page) |

**20. PUBLICATION/DISSEMINATION OF RESULTS**

**Please note that all materials used to communicate study results with participants must be approved by the REB. If these documents are to be finalized at the end of the study, an amendment must be submitted for these materials.**

**20A. Indicate how the results will be communicated to participants. Check all that apply.**

|  |
| --- |
| [ ] Individual debriefing at end of study |
| [ ]  Plain language summary of individual-level findings/results provided at the end of study/visit |
| [ ] Group debriefing at the end of study/visit |
| [ ] Letter of appreciation at end of study |
| [ ] Publication |  |
| [ ]  No Plan |  |
| [ ] Other (specify):      |  |
|  |  |

**If no plan is in place, provide justification.**

Not Applicable [ ]

|  |
| --- |
| (Max ¼ page)      |

**20B. Indicate how the results will be communicated to partners or collaborators (e.g., advocacy groups, scientific community). Check all that apply.**

|  |  |
| --- | --- |
| [ ]  Publication in scientific journal(s) | [ ]  Poster presentation |
| [ ]  Local rounds | [ ]  Public dissemination/presentation |
| [ ]  Social media/podcast[ ]  Conference(s) | [ ]  No Plan[ ]  Other (specify):  |
|  |  |

**SECTION 4: PRIVACY AND CONFIDENTIALITY**

 **2: STUDY SUMMARY**

**21. COLLECTION USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION**

Investigators should comply with the duties set out for researchers in the Personal Health Information Protection ACT (PHIPA – effective in Ontario Nov. 1, 2004) and with the privacy and confidentiality and consent guidelines outlined in the Tri-Council Policy Statement 2 on Ethical Conduct for Research Involving Humans.

**21A. Select all personal health information and personal identifiers (e.g., name, DOB, postal code, etc.) required to be collected. For all non-clinical trials, attach data collection forms.**

|  |  |
| --- | --- |
| [ ]  Full name | [ ]  Medical record number |
| [ ]  Full initials | [ ]  Admission date |
| [ ]  Partial initials | [ ]  Discharge date |
| [ ]  Full date of birth | [ ]  Health Card Number |
| [ ]  Partial date of birth | [ ]  Driver’s license number |
| [ ]  Full date of death | [ ]  Address |
| [ ]  Partial date of death | [ ]  Telephone number |
| [ ]  Age | [ ]  Fax number |
| [ ]  Sex/gender | [ ]  E-mail address |
| [ ]  Full postal code | [ ]  Full face photograph |
| [ ]  First 3 digits of postal code | [ ]  Voice/audio recording |
| [ ]  Pathology specimen number | [ ]  Biometrics identifiers (i.e., retinal scan, fingerprints) |
| [ ]  Device identifiers and serial numbers | [ ]  Vehicle identifiers (i.e., license plates) |
| [ ]  Other identifiable information (specify):       |

**21B. Identify all sources of this personal health information collected in this study.**

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| (Max ¼ page)      |

**21C. Indicate how study participants will be identified on data collection forms (e.g., study number, initials).**

|  |
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| (Max ¼ page)      |

**21D. Indicate how data will be stored. (Note: All data stored on a laptop, USB memory stick MUST be encrypted, password protection is not enough.)**

|  |
| --- |
| [ ]  Computerized files (specify):       [ ]  Server and/or [ ]  Desktop [ ]  Laptop [ ]  USB Memory Stick[ ]  SharePoint / OneDrive |
| [ ]  Audio recordings |
| [ ]  Hard copy |
| [ ]  Video Recording |
| [ ]  Other (e.g., PDA):       |

i) Describe the safeguards to protect the confidentiality and security of the data, including any physical and technical safeguards (e.g., data will be stored in a locked and secure area – *give specific details*, the data will be stored on a secure server that is password protected, encryption.) Be specific.

|  |
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| (Max ¼ page)      |

ii) Indicate who will have access to these data in the future.

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| (Max ¼ page)      |

**21E. Indicate if any information that could potentially identify study subjects will be disclosed outside of MGH (e.g., names, initials, DOB, OHIP #*).***

[ ]  Yes

[ ]  No

If yes, justify and describe how this information will be transferred and any security measures to be used (e.g., anonymized data, secure network upload or download). (Note: All data disclosed outside of MGH that is stored on a laptop, USB memory stick MUST be encrypted, password protection is not enough.)

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| (Max ¼ page)      |

21F. 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)      |

1. **Explain why these linkages are required.**

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| (Max ¼ page)      |

###### 21G. Indicate how long the personal health information will remain identifiable and explain why.

Not Applicable [ ]

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| (Max ¼ page)      |

21H. Explain why the research cannot reasonably be accomplished without using personal health information.

Not Applicable [ ]

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| (Max ¼ page)      |

**21I. 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.**

Not Applicable [ ]

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| (Max ¼ page)      |

**21J. Describe any harms or benefits 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. \* Do not answer N/A.**

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| (Max ¼ page)      |

**21K. Describe specifically how and when the personal health information will be disposed of or returned to the health information custodian.**

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| (Max ¼ page)      |

**SECTION 5: INVESTIGATOR ATTESTATION**

 **2: STUDY SUMMARY**

**Local MGH Principal Investigator Attestation**

**I attest that:**

* This application contains the current and complete protocol and accompanying documents.
* To the best of my knowledge, the information in the application is complete, current and accurate.
* I assume full responsibility for the scientific and ethical conduct of the study at Michael Garron Hospital (MGH), the Toronto East Health Network (TEHN) as described in this application and submitted protocol.
* I agree to conduct this study in compliance with the current version of the Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans and the Ontario Personal Health Information Protection Act; ICH Good Clinical Practices: and if applicable, Division 5, Canadian Food and Drug Regulations; and all other applicable laws, and regulations, as applicable.
* I am responsible for reporting to the MGH REB:
* Any modifications or amendments to any previously approved study documents and I attest that any changes will not be implemented to the protocol without written approval from the MGH REB.
* All local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the trial.
* Continuing review form (annually or at more frequent intervals if requested by the MGH REB).
* Study completion or termination.
* I acknowledge that Michael Garron Hospital 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.
* I certify that all Co-investigators, 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; including training in privacy and confidentiality.
* I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval.
* I have declared all known conflicts of interest/relationships to the REB for myself, the Co-Investigator(s), and anyone connected to them (including their partners, family members, or their former or current professional associates).
* I certify that REB approval, and all external and local institutional approvals will be obtained before the study will commence.
* I attest that I have completed/will complete the Institutional Approval Form in accordance with MGH’s institutional requirements.
* Either I or a qualified research team member will verbally explain the current approved Informed Consent form 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.
* I understand that MGH REB has the right to visit the research site at any time, with appropriate notice.
* No study conduct will occur until MGH REB approval is received and, if required, a research agreement is executed.

**Privacy and Security Acknowledgement:**

* On behalf of all members of my research team, I am aware of my obligations of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information.
* I will ensure that the personal information is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of the study participants’ personal health information.
* I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the personal health information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations, and the Tri-Council Policy Statement.

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Name of Local Principal Investigator             Signature                 Date

**External Lead Principal Investigator (if applicable):**

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Name of External Principal Investigator             Signature                 Date

**Co-Investigators**

* 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 2: Ethical Conduct for Research Involving Humans and any other relevant 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.

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Name of Co-Investigator                           Signature                 Date

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Name of Co-Investigator                           Signature                 Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Name of Co-Investigator                           Signature                 Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_

Name of Co-Investigator                           Signature                 Date

**Department Approver/Department Head**

* I am aware of this proposal and support its submission for ethics review; I consider it to be feasible and appropriate.
* I attest that any internal department requirements will be met.
* I attest that the MGH Local Principal Investigator responsible for the conduct of this study is qualified by education, training, and experience to perform his/her role in this study.
* I attest that the PI has sufficient space and resources to conduct this research.
* There will be available care in the case of an emergency (for biomedical clinical trials).

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Name of Department Head                           Signature                 Date