

Research Ethics Board Initial Application Form to Access

Retrospective Data for Research Purposes

*(This Application may also be used for research involving non-identifiable human biological materials OR research involving secondary use of identifiable human biological materials where the researcher satisfies all the requirements in Article 12.3 of the TCPS.)*

**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 attachments 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 this institution (e.g., extension, rollover, subsequent to a pilot study)? [ ]  Yes [ ]  No |
| If Yes, indicate name of MGH Local Principal Investigator:       REB Reference number:       |

**3. INVESTIGATORS**

**3A. EXTERNAL LEAD PRINCIPAL INVESTIGATOR CONTACT INFORMATION**

**Complete this section if the Local MGH Principal Investigator is not the lead for the entire study**

Not Applicable [ ]

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

3B. CO-INVESTIGATOR(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:       |

**SECTION 2: STUDY SUMMARY AND ETHICAL CONSIDERATIONS**

(The full protocol must still be attached)

**4. ABSTRACT AND RATIONALE**

**Provide a study summary and rationale (written in plain language).**

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| (Max ¼ page)      |

**5. HYPOTHESIS/RESEARCH QUESTION**

**What is the primary objective and hypothesis?**

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| (Max ¼ page)      |

**6. PARTICIPANT/CONTROLS**

**List the inclusion and exclusion criteria.**

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| (Max ¼ page)      |

**7. DATA ANALYSIS**

**7A. 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)      |

**7B. Which of the following will this study involve?**

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| [ ]  **Retrospective data**  |
| [ ]  **Human biological materials (specify):** *(Defined in TCPS as: Tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. The term also includes materials related to human reproduction, including embryos, fetuses, fetal tissues and human reproductive materials.)*  [ ]  **Secondary use of identifiable human biological materials** (human biological materials originally collected for a purpose other than the current research purpose) [ ]  **Non-identifiable human biological materials**  |

**7C. To apply for access to retrospective data or human biological materials, an alteration or permission to do research without consent must be granted by the REB. Explain how your request for an alteration of consent will comply with** [**TCPS 2 Chapter 3**](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html#b:~:text=the%20participant%20belongs.-,B.%20Departures%20from%20General%20Principles%20of%20Consent,-Articles%203.1%20to)**,** [**TCPS 2 Articles 5.5**](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter5-chapitre5.html#d:~:text=retention%20of%20information.-,D.%20Consent%20and%20Secondary%20Use%20of%20Information%20for%20Research%20Purposes,-Secondary%20use%20refers) **and/or** [**12.3**](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html#c:~:text=1-,C.%20Consent%20and%20Secondary%20Use%20of%20Human%20Biological%20Materials%20for%20Research%20Purposes,-Chapter%205%20provides) **(human biological materials) and PHIPA 44, 3c, 3d.**

**(**[**https://ethics.gc.ca/eng/policy-politique\_tcps2-eptc2\_2022.html**](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html)**)**

**(**[**http://www.e-laws.gov.on.ca/html/statutes/english/elaws\_statutes\_04p03\_e.htm**](http://www.e-laws.gov.on.ca/html/statutes/english/elaws_statutes_04p03_e.htm)**)**

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**7D. What tools will be used to access the retrospective data or human biological materials?**

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| --- |
| [ ]  Health record/clinical chart (specify source(s)): * Number of charts in total (across all participating sites):
* Number of charts at MGH:
 |
| [ ]  Existing database (specify source(s)):  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  [ ]  Yes, pending REB approval [ ]  No **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. |
| [ ]  Human biological materials (specify source(s)):  |
| [ ]  Other (specify source(s)):  |

**7E. If multiple sources/databases will be used to access the retrospective data or human biological materials, will the data/materials be linked (i.e. to amass more data about particular individuals)?**

 [ ]  Yes

 [ ]  No

If **YES**, explain what data/materials will be linked, how it will be linked and why the linkage is required.

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| (Max ¼ page)      |

**7F. Date range of requested data or human biological materials e.g., 01/01/2000 to 31/07/2005 (in order to be considered a retrospective review, inclusive dates cannot go beyond the present).**

|  |
| --- |
| Start Date:        |
| End Date:       |

**7G. Indicate the expected duration (e.g., 2-3 months, 1 year) of this project:**

**SECTION 3: PRIVACY AND CONFIDENTIALITY**

**DEFINITIONS**

**DEFINITIONS**

*(Source: Tri-Council Policy Statement, unless otherwise specified.)*

**Personal Health Information (PHI):** In this Application, PHIhas the meaning ascribed to it in the *Personal Health Information Protection Act, 2004* (PHIPA). With limited exceptions, PHI is defined as identifying information about an individual in oral or recorded form, if the information,

a) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,

b) relates to the providing of health care to the individual,

c) is a plan of service within the meaning of the *Long-Term Care Act, 1994* for the individual,

d) relates to payments or eligibility for health care in respect of the individual,

e) relates to the donation by the individual of any body part or bodily substance of the individual or is derived from the testing or examination of any such body part or bodily substance,

f) is the individual's health number, or

g) identifies a provider of health care to the individual or a substitute decision-maker of the individual.

**Identifiable Information:** Information that may reasonably be expected to identify an individual, alone, or in combination with other available information. Also referred to as “personal information.”

**Directly Identifying Information:** The information identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number).

**Indirectly Identifying Information:** The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence or unique personal characteristic).

**Coded Information:** Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants (e.g., the principal investigator retains a list that links the participants’ code names with their actual name so data can be re-linked if necessary).

**Anonymized Information:** The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

**Anonymous Information:** The information never had identifiers associated with it (e.g., anonymous surveys) and risk of identification of individuals is low or very low.

**Data Set:** A collection of information to be used for research purposes, including human biological materials.

**Key Code:** A document that links the coded information with the identifying information of the individual. This must be stored separately from the data set.

**8. COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION AND DATA**

**DEFINITIONS**

**Please use Appendix B: Study Personnel Log to indicate all team members conducting research activities for this study.**

**8A. List the identifying information and personal health information that will be collected, used, or disclosed.** (**NOTE**: If any of the boxes below have been checked, each individual (i.e., patient) should be assigned a unique participant ID # to be included with the data set and a key code created to link the ID# with the information below.)

|  |  |
| --- | --- |
| [ ]  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):       |

**8B. List ALL data elements required for collection and/or attach a copy of the data collection form.**

(**NOTE**: The data collection form or list of data elements should NOT include any of the identifying information checked off in 6A above.)

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| (Max ¼ page)      |

**8C. Indicate how study participants will be identified on data collection forms.**

|  |
| --- |
| [ ]  Participant Identification #  |
| [ ]  Other (specify): If using other, please justify:  |

**8D. Indicate how data will be stored.**

|  |
| --- |
| [ ]  Computerized files (specify below): [ ]  Server (specify):  [ ]  Third Party:  [ ]  Internal [ ]  Contracted Service Provider: [ ]  Portal [ ]  SharePoint / OneDrive [ ]  Laptop with encrypted hard drive [ ]  Other:   |
| [ ]  Hard copy  |
| [ ]  Audio recordings |
| [ ]  Video recordings |
| [ ]  Encrypted USB key or similar portable storage device (must be encrypted) |
| [ ]  PDA, E-reader or similar hand-held computer |
| [ ]  Other:  |

**8E. 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:   |

**8F. Indicate which of the measures will be undertaken to protect the confidentiality and security of the data, including any physical and technical safeguards.**

|  |
| --- |
| [ ]  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 |
| [ ]  Other:  |

**8G. Indicate if any information that could potentially identify 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? (NOTE: A contract/agreement may be required, see Funding, Conflicts and Agreements section and contact your institutional department responsible for facilitating contracts/agreements.)

|  |
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| (Max ¼ page)      |

###### 8H. Indicate how long the personal health information will remain identifiable and explain why.

|  |
| --- |
| (Max ¼ page)      |

8I. Explain why the research cannot reasonably be accomplished without using personal health information.

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| (Max ¼ page)      |

**8J. 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, loss of reputation for the responsible organization) and how any consequences would be addressed.**

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| (Max ¼ page)      |

**8K. Indicate how long data will be retained after completion of the study and prior to confidentially destroying the data.**

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| (Max ¼ page)      |

**8L. Indicate who will have access to the data in the future.**

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| (Max ¼ page)      |

**8M. Will the data be reported publicly (e.g., publication)?**

**[ ]** Yes

**[ ]** No

If YES, provide further details.

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| (Max ¼ page)      |

**8N. Will the data be used (now or in the future) for commercial purposes?**

**[ ]**  Yes

**[ ]** No

If **YES**, provide further details.

|  |
| --- |
| (Max ¼ page)      |

**SECTION 4: FUNDING, CONFLICTS OF INTEREST**

**9. SOURCE OF FUNDING**

**DEFINITIONS**

##### Is this a multi-centre study?

##### [ ]  Yes

##### [ ]  No

If **YES**, identify the coordinating/lead site.

|  |
| --- |
| (Max ¼ page)      |

**Is the study funded?**

 [ ]  Yes

 [ ]  No

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

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

**10. CONFLICT OF INTEREST**

**DEFINITIONS**

**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 COI 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 to 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 interest 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:**

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|       |

**Declaration by the MGH Lead Principal Investigator**

[ ]  I confirm that all COIs have been declared to the Institution and MGH 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 Research Ethics Board.

**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.

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

Name of Local Principal Investigator             Signature                 Date

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

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

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

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

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