#  APPLICATION TO ACCESS RETROSPECTIVE DATA FOR RESEARCH PUPOSES

Markham Stouffville Hospital (MSH)

Adapted from the Toronto Academic Health Sciences Network (TAHSN) Application

### 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.
* Any email address must be a 'safe' or organization assigned accounts or ONE Mail account.

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**SECTION I: GENERAL INFORMATION**

# PRINCIPAL INVESTIGATOR NAME \*

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|       |  |       |  |       |
| Title (e.g. Dr.) |  | Last Name |  | First Name |

\* MSH requires the PI to be a staff member. The on-staff investigator accepts the role and responsibilities of PI at this institution

# FULL STUDY TITLE

|  |
| --- |
|       |
| Study Name |

|  |
| --- |
|       |
| Sponsor Protocol Number (if applicable) |

2A. Study Period

|  |  |
| --- | --- |
| Expected start date at MSH: |       |
| Total study duration at MSH: |       |

2B. Is this protocol directly related to a previously approved study at this institution

 (e.g. Extension, Rollover, subsequent to a pilot study)?

|  |  |  |
| --- | --- | --- |
| [ ]  NO |  |  |
| [ ]  YES, |       |  |       |
|  | Principal Investigator | REB Number |

# SOURCE OF FUNDING

|  |  |
| --- | --- |
| Sponsor Name: |       |
| Granting Agency Name: |       |
| Internal Funding: |       |
| Other: |       |
| Funding obtained: |       |
| Funding applied for: |       | Expected date of decision: |       |
| No funding required: |       | Explain: |       |

# INVESTIGATORS

4A. 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 TriCouncil Policy Statement: Ethical Conduct for Research Involving Human Subjects and any other relevant regulations or guidelines. 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.

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| Dept/Div: |  | Program |  | Institution |

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|       |  |  |       |  |       |
| Telephone: |  |  | Office Number: |  | Fax Number: |

|  |
| --- |
|       |
| Street: |

|  |  |  |  |  |  |  |
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|       |  |       |  |       |  |       |
| City |  | Province |  | Postal Code |  | Email Address  |

|  |  |  |
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|  |  |       |
| Signature of Principal Investigator |  | Date |

4B. CO-INVESTGATOR(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 2: Ethical Conduct for Research Involving Humans and any other relevant regulations or guidelines.

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| 1 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Dept/Div. |  | Program |  | Institution |
|  |       |  |       |
|  | Signature of Principal Investigator |  | Date |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 2 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Dept/Div. |  | Program |  | Institution |
|  |       |  |       |
|  | Signature of Principal Investigator |  | Date |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 3 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Dept/Div. |  | Program |  | Institution |
|  |       |  |       |
|  | Signature of Principal Investigator |  | Date |

4C. CONTACT PERSON FOR THIS APPLICATION IF NOT THE PRINCIPAL INVESTIGATOR

[ ]  Not Applicable (e.g. Study coordinator, research administrative contact, research student, institutional liaison)

**Contact’s Role in Study:** Indicate to whom correspondence should be mailed: [ ]  PI [ ]  Other

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| Title (e.g. Dr.) |  | Last Name |  | First Name |
|       |  |       |  |       |
| Dept/Div. |  | Program |  | Institution |
|       |  |  |       |  |       |
| Telephone: |  |  | Office Number: |  | Fax Number: |
|       |
| Street: |
|       |  |       |  |       |  |       |
| City |  | Province |  | Postal Code |  | Email Address \*\* |

# DEPARTMENT/DIVISION/PROGRAM APPROVAL\*

\* For institutions that require the PI to be a staff member, approval must come from the Department / Division / Program Head of the same institution as the PI. When the Division/Department Head/Program Director is the investigator, the signature of an individual one level above the investigator is required.

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,

|  |  |  |  |  |
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|       |  |       |  |       |
| Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |  |       |
| Signature |  | Date |

# OTHER ETHICS/SCIENTIFIC/SCHOLARLY REVIEW

|  |  |
| --- | --- |
| In order to facilitate the REB review process through harmonization and coordination of REB activity, identify if any of the REBs below have reviewed and/or approved the study outlined in this application (check all that apply): | \*Ethics Review and Approval Status(Check all that apply and indicate date ( **dd/mm/yy**) where applicable): |
| Application to be Submitted | Review Pending (date) | Reviewed (date) | Approved (date) |
| [ ]  Baycrest Centre | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Bloorview Kids Rehab | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Centre for Addiction and Mental Health | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Hospital for Sick Children | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Mount Sinai Hospital | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  St. Michael’s Hospital | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Sunnybrook Health Science Centre | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Toronto Rehabilitation Institute | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  University Health Network | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  University of Toronto | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]  Lakeridge Health | [ ]        | [ ]        | [ ]        | [ ]        |
| [ ]       (Other e.g. Hamilton Health Sciences REB, University of Western Ontario Health Sciences REB, other GTA hospitals) | [ ]        | [ ]        | [ ]        | [ ]        |

Include all relevant correspondence related to ethics and scientific review

(e.g., REB review letter, replies, approval letter)

**SECTION II: STUDY SUMMARY**

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

# ABSTRACT Summary of study suitable for lay audience. (Max ¼ page)

# RATIONALE AND HYPOTHESIS/RESEARCH QUESTION

8A. Indicate the rationale and primary objective for this study. (Max ¼ page)

8B. Indicate the hypothesis for this study or research question. (Max ¼ page)

**8C. Indicate the significance of the study.** (i.e. the overall anticipated public and/or scientific benefit)(Max ¼ page)

# STUDY DESIGN

9A. Specify the data to be collected and attach the data collection form(s).

9B. Proposed number of retrospective research charts:

9C. Time period of charts to be reviewed:

      to       (in order to be considered retrospective research, inclusive dates cannot go beyond the present)

# 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.

**SECTION III: ETHICAL ISSUES**

# CONSENT

11A.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 TCPS2 Chapter 3, Article 5.5 and PHIPA 44, 3c and 3d.

11B. Indicate what tools will be used to access the retrospective data.

[ ]  Permanent health record/clinical chart (specify source):

[ ]  Existing database (specify):

[ ]  YES, the Principal Investigator maintains the database

[ ]  NO, the entity that maintains the database is:

Note: Creation and maintenance of a database for research purposes is a research activity that may require a separate REB application.

[ ]  Other (specify):

**SECTION IV: PRIVACY AND CONFIDENTIALITY**

**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.

# COLLECTION USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

12A. Indicate how study participants will be identified on data collection forms (e.g., study number, initials).

12B. Indicate how data will be stored.

[ ]  Computerized files (Fixed storage on Servers and/or Desktops and/or Laptops)

[ ]  Audio and/or Video recordings (regardless of media type: tape, disk, cloud, etc)

[ ]  Hard copy and/or printed materials

[ ]  Removal media such as USB thumb drive and /or Memory disk

[ ]  Other (e.g. PDA):

 Note: All data stored on laptops, CD, DVD, USB drives MUST be encrypted. Password protection is not enough.

1. **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.**

1. **Indicate who will have access to these data in the future.**

12C. Indicate if any information that could potentially identify study subjects will be disclosed outside of the institution (e.g., names, initials, DOB, OHIP #).

[ ]  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):

[ ]  NO

12D. If personal health information is to be linked to other databases (e.g., health registries, statistics Canada information) provide the following details: [ ]  Not Applicable

1. **Describe the data to which the personal health information will be linked.**

1. **Explain how the linkages will be made.**

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

12E. Indicate how long the personal health information will remain identifiable and explain why.

**[ ]** Not Applicable

12F. Identify all persons that will have access to the personal health information, their roles in the study, their reason for access, and related qualifications.

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| 1 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Institution |  | Qualifications |  | Role in Study |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 2 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Institution |  | Qualifications |  | Role in Study |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 3 |       |  |       |  |       |
|  | Title (e.g. Dr.) |  | Last Name |  | First Name |
|  |       |  |       |  |       |
|  | Institution |  | Qualifications |  | Role in Study |

12G. Has the research team completed training in privacy and confidentiality issues for this study?

[ ]  YES

[ ]  NO, when will training be provided:

**12H.** **List identifying information that will be collected, used, or disclosed from records during course of the proposed recruitment activities.**

[ ]  Name [ ]  Images (e.g. photographic, x-ray, MRI scan)

[ ]  Address [ ]  Social Insurance Number

[ ]  Telephone Numbers [ ]  Medical Record Number

[ ]  Email Addess [ ]  Date of Birth

[ ]  Health Card Number [ ]  Health Information (e.g. relating to inclusion exclusion criteria, medications)

[ ]  Other information (specify):

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

21J. 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.

21K. 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.

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

21M. Will the data be reported publicly (e.g. publication)?

[ ]  NO

 [ ]  YES, provide details:

22N. Will the data be used (no or in the future) for commercial purposes?

[ ]  NO

 [ ]  YES, provide details:

**SECTION V: FUNDING AND CONTRACTS**

# BUDGET

[ ]  No budget required

 Attach an itemized study budget (applies to all full board and delegated review studies). The budget should reflect all costs at this institution.

[ ]  YES, funding is sufficient to cover all study costs.

[ ]  NO, explain how the shortfall will be made up

Indicate if any investigator will receive direct personal payments from the budget.

[ ]  YES, describe what these payments are for and the amount:

[ ]  NO, direct personal payments

# AGREEMENTS

14A. Contract/Research Agreement

 Indicate whether there is a contract/research agreement involved

[ ]  YES, provide name of sponsor/agency:

 Provide name of contract research organization (if applicable):

[ ]  NO, agreement

14B. Indicate whether the contract/research agreement has been submitted for review and signing.

[ ]  YES (See institution specific instruction page)

[ ]  NO

14C. i) Indicate if there is external (non-institutional) liability insurance.

[ ] YES

[ ]  NO

1. **Indicate 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.**

[ ] Sponsor

[ ] Institution

[ ] Other (specify):

14D. Publication Agreements

1. Indicate if there is an agreement between Investigator and Sponsor regarding the use, publication or disposal of the data.

[ ]  YES

[ ]  NO

1. If Yes, Indicate whether funding agency or sponsoring company places restrictions on publication of findings or interim results

[ ] YES

[ ] NO

1. If Yes, explain any restrictions.

# MATERIAL TRANSFER AGREEMENT

Indicate if there is a material transfer agreement (MTA) involving human material for this study.

This refers to an agreement for transfer of biological materials (e.g. tissues, cell lines) from the institution to another entity.

**[ ]** YES, attach a copy of the agreement.

**[ ]** NO

 **MSH REB Submission Instructions**

(Appendix 1)

1. **Required Documentation:**

For a list of documents to include with this application and the correct number of originals and copies, please review the document titled: *MSH REB Submission Checklist*

Submit applications to: MSH, Office of Research

 381 Church Street. Room A1701, Medical Administration,

 Markham, ON L3P 7P3

 Contact number: 905-472-7373 ext. 2279

1. Study Departmental Impact

Does the study impact / use / involve other hospital departments or services?

If YES, submit a copy of the protocol to the appropriate department lead. If a budget is required for the study and there is impact on the departments below, please include that budget for review by the department lead. Note that the Principal Investigator (PI) is responsible for all successful negotiations with departments

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Department/Committees** | **Yes** | **No** | **Department Lead** | **Signature\*** |
| Access & Flow | **[ ]**  | **[ ]**  |       |  |
| Alongside Midwifery Unit | **[ ]**  | **[ ]**  |       |  |
| Ambulatory Services | **[ ]**  | **[ ]**  |       |  |
| Care Transitions | **[ ]**  | **[ ]**  |       |  |
| Child Development Services | **[ ]**  | **[ ]**  |       |  |
| Childbirth & Children’s Services | **[ ]**  | **[ ]**  |       |  |
| Emergency | **[ ]**  | **[ ]**  |       |  |
| Health Records | **[ ]**  | **[ ]**  |       |  |
| Infection Prevention & Control | **[ ]**  | **[ ]**  |       |  |
| Mental Health | **[ ]**  | **[ ]**  |       |  |
| Oncology | **[ ]**  | **[ ]**  |       |  |
| Patient Experience | **[ ]**  | **[ ]**  |       |  |
| Pharmacy | **[ ]**  | **[ ]**  |       |  |
| Professional Practice | **[ ]**  | **[ ]**  |       |  |
| Surgical Services | **[ ]**  | **[ ]**  |       |  |
| Other  | **[ ]**  | **[ ]**  |       |  |
|       | **[ ]**  | **[ ]**  |       |  |

\*By signing as the Department Lead, you agree that the proposed research study protocol can be executed in your department and the budget is reasonable, if applicable. The study still requires REB review/approval and logistics/timing of research conduct will be negotiated with the PI or designee.