- MCGILL UNIVERSITY HEALTH CENTRE -

APPLICATION TO CONDUCT HUMAN SUBJECTS RESEARCH WITH HEALTH RECORDS INFORMATION

1. STUDY TITLE

MUHC Study Code: _____
(REO use only)

_____

_____

_____

PLEASE ANSWER ALL QUESTIONS AND CHECK ALL THAT APPLY

- ➢ ***This symbol requires you to take note of the information.***
- ✓ ***This symbol indicates a supplementary document may be required to complete the review.***

2. RESEARCH PERSONNEL

a) **Principal Investigator:** _____ **MUHC Dept:** _____

tel: _____ **email:** _____ **office:** _____

b) **Study Coordinator:** _____ **MUHC Dept:** _____

tel: _____ **email:** _____ **office:** _____

c) **Has PI been granted the "Privilege to Conduct Research" at the MUHC?** ◯ **Yes** ◯ **No**

- ➢ ***Please refer to the RI MUHC website for questions concerning the "Privilege to Conduct Research" at http://muhc.ca/research/page/clinical-research-review***
- ✓ ***You must identify each member of the study team who will require access to the records by answering the appropriate questions in the eReviews submission system. You will receive from eReviews the "Access to Health Records for Research Purposes" form to submit for review by the Director of Professional Services.***
- ➢ ***Each person who will access records must sign a Confidentiality Agreement and a copy of each form must be retained in the research study files.***

3. DESCRIPTION OF RESEARCH PROJECT

- ✓ ***You must attach a dated research protocol including study title, objectives, methodology, statistical analysis and literature review or references describing the proposal.***

a) **Has the research been reviewed for scientific or scholarly merit?** ◯ **Yes** ◯ **No**

If Yes, identify the reviewing agency or committee: _____

- ✓ ***If Yes, attach the report from the scientific or scholarly merit review.***

b) **What source(s) of funding will be used to conduct the research?**

☐ **Industry** ☐ **Internal** ☐ **Mixed Public-Private** ☐ **Private Agency** ☐ **Public Agency**

c) **Identify the sponsor *(PI is sponsor for internal funding)*:** _____

d) **Is there a study agreement involved with conducting the research?** ◯ **Yes** ◯ **No**

e) **Is the Principal Investigator receiving personal financial or material support from any source to undertake the conduct or administration of this study?** ◯ **Yes** ◯ **No**

If Yes, please explain: _____

_____

f) **Is there any potential for commercialization of the extracted information?** ◯ **Yes** ◯ **No**

If Yes, please comment: _____

_____

g) **Will you collect or receive data held by an institution other than the MUHC?** ◯ **Yes** ◯ **No**

✓ ***If Yes, identify the institution and attach its ethics approval document:*** _____

4. ACCESSING HEALTH RECORDS INFORMATION

a) **What is the projected number of subjects about whom you will collect information?** _____

b) **Will it be necessary to contact a patient regarding the study for any reason?** ◯ **Yes** ◯ **No**

If Yes, please explain: _____

_____

c) **To which MUHC records will you require access to conduct the study *(specify)*?**

☐ **Administration** ☐ **Clinic** ☐ **Medical** ☐ **Pharmacy** ☐ **Data/Bio bank** ☐ **Other:** _____

d) **At which MUHC site(s) will you require access to health information?** ***or*** ☐ **Non-MUHC**

☐ **LH** ☐ **MCH** ☐ **MCI** ☐ **MGH** ☐ **MNH** ☐ **QE Family Med** ☐ **RVH** ☐ **Vaccine Centre**

e) **Will you require access to MUHC records 'prior to obtaining' written informed consent from the person whose data you seek?** ◯ **Yes** ◯ **No** ◯ **N/A**

✓ ***If Yes, do not complete this form. Please proceed to eReviews on the RI MUHC website and submit your study for review using the electronic system.***

f) **Will you request informed consent from the person whose data you seek?** ◯ **Yes** ◯ **No**

If No, please justify not seeking individual informed consent: _____

_____

_____

5. DATA ACCESS AND SECURITY

- ***You are asked to review and implement the safeguards to protect the confidentiality and security of research data described in MUHC policies and standard operating procedures.***

a) **Will the extracted research data be used to populate a data or bio bank?** ◯ **Yes** ◯ **No**

If Yes, identify the data/bio bank and its location: _____

_____

b) **Will the extracted research data be transferred off-site from the MUHC?** ◯ **Yes** ◯ **No**

- ✓ ***If Yes, a "Material Transfer Agreement" to set terms for "data sharing" may be required. Please contact the RI MUHC Office of Clinical Contracts to discuss MUHC requirements.***

c) **Will the extracted research data be linked with other information?** ◯ **Yes** ◯ **No**

If Yes, please explain: _____

_____

_____

d) **Will the extracted data be recorded with any identifying information?** ◯ **Yes** ◯ **No**

If Yes, please explain: _____

_____

e) **How will you protect and maintain the security and confidentiality of the research data?**

_____

_____

f) **How and when will the research data eventually be disposed of?** _____

_____

_____

6. AUTHORIZING DECLARATIONS AND SIGNATURES

a) An application to conduct human subjects research using records held by the MUHC requires making the following declarations and providing appropriate signatures.

- **The private information recorded as study data shall be used only as described in the current research protocol approved by the REB.**
- **Principal Investigator will obtain written REB approval for any substantive modification to the research, including changes to the study procedures, financial arrangements and/or resource utilization before initiating the change in the study.**
- **Principal Investigator will report to the REB every breech of confidentiality, intrusion of privacy or other unanticipated problem that may arise in the course of the study.**
- **Principal Investigator will comply with all REB and DPS requests for study information.**
- **Principal Investigator will maintain the research records according to the applicable regulatory requirements and institutional policies and procedures.**
- **If the research is authorized the study will be subject to Quality Assurance evaluation.**
- **Each member of the research team will comply with the applicable requirements for training and certification in the responsible conduct of research at the MUHC.**
- **If the research continues beyond twelve months from the date of final REB approval, the study will be subject to ongoing oversight by the REB including Continuing Review.**
- **When the research concludes, the Principal Investigator will advise the institution by submitting a Study Completion Report to the REB.**

If these conditions are not met ethics approval to conduct the study may be withdrawn.

The following signatures certify that: ***(original ink signatures are required)***

b) As Principal Investigator, I will comply with all relevant research regulations, policies and guidelines that concern the conduct of human subjects research. I understand that this research cannot be conducted without appropriate written ethics approval.

Signature: _____ ***Date:*** _____
Day / Month / Year

c) As Department/Divisional Head, I assure the REB the Principal Investigator is professionally qualified to conduct the research, and has met departmental requirements to conduct the proposed study. (In cases where the Department/Divisional Head is involved in the research project, an academic superior must make this declaration.)

Print Name: _____ ***Dept/Div:*** _____

Signature: _____ ***Date:*** _____
Day / Month / Year