Health Information Privacy Committee/ Provincial Health Research Privacy Committee Protocol Amendment Form

~ PLEASE ALWAYS USE THE **MOST RECENT VERSION** OF THIS FORM FROM THE WEBSITE ~
see 'Forms & Guides' at https://www.rithim.ca/phrpc-submission-information

Changes to the originally approved Health Information Privacy Committee (HIPC) / Provincial Health Research Privacy Committee (PHRPC) application must be submitted to PHRPC for review and approval in advance of their implementation.

PHRPC will not accept a protocol amendment for an approved research project until a research agreement has been signed by all parties involved. It is the researcher's responsibility to consult with the organization responsible for housing the dataset (i.e. the signatory on the research agreement) before submitting a protocol amendment.

Please complete the applicable section(s) in this form where a change is requested. Please see the 'Guidelines for Completing a Protocol Amendment Form' for more detailed information or consult the RITHIM Program Officer, PHRPC Lead for additional questions or inquiries.

Please email one (1) signed copy of the completed protocol amendment form and any attachments to RITHIM Program Officer at PHRPC@researchmb.ca and cc the organization(s) responsible for housing the dataset(s). A RITHIM Program Officer will forward the protocol amendment to the PHRPC Chairperson for approval.

Date:	
HIPC/PHRPC Project Number:	
Title:	
Principal Investigator:	
Advisor (If a Student PI):	
Email:	
Current Address:	

☐ 1. Change in Study Personnel

Please list all currently approved study personnel and the new personnel to be added in the tables below. If a person is expected to be the lead author on resulting manuscripts or reports, this individual must be identified to PHRPC even if they will not have access to the line-level data due to the requirement that lead authors assume responsibility for the analysis and interpretation of data. If more space is needed, attach a separate list, in a similar format.

Approved Study Personnel

Name	Affiliation	Primary role	Line-level data access? Yes/No

New Study Personnel

Name	Affiliation	Primary role	Line-level data access? Yes/No

Do any of the new study personnel have multiple roles/access to information within the context of this research or relationships with other organizations which may present a possible **conflict of interest**?

Yes ☐ **No** ☐

If yes, please complete the **Conflict of Interest Disclosure Form** accessible through the PHRPC website.

Rationale for Change

If any approved co-investigators are no longer a part of the research team, please indicate them here.

☐ 2. Additional Years of Data

New: PHRPC can approve the use of data for the length of the project, up to a maximum of 5 years, at which time the project must be reviewed by PHRPC. Amendments would not be required for adding new years of data if the data requested and the scope of the data to be used does not change. Substantial changes to the scope of the project after PHRPC approval will require an amendment to approve the use of any additional years of data if different from the range initially approved.

Please list the databases and the years of data originally approved, the additional years of data requested, and the rationale. **It is important to describe why the originally approved data was insufficient**. PHIA requires that only the **minimum** information necessary to answer the research objectives should be disclosed to researchers.

Please have data sets organized according to months and fiscal years beginning April 1st through March 31st, or by calendar year where appropriate.

If additional data is being requested to repeat a previously approved analysis to demonstrate time-trends or the effect of an intervention, this may be considered a new project. Please contact RITHIM Program Officer to determine if a new project submission is required.

If more space is needed, attach a separate list, in a similar format.

List of Approved Databases		**Additional Months/Years of Data Requested & Rationale**
Database	**Months/Years**	
Example:		
e.g., Hospital Separation Abstracts	e.g., April 1984/1985-March 1999/2000	April 2000/2001-March 2004/2005 **Rationale:** The number of 'cases' identified in the original years requested were insufficient to demonstrate a specific clinical outcome with enough statistical power. It is expected that with the additional 4 years of data, an additional 53 identified cases will be increasing our statistical power to a sufficient level.

☐ 3. Change in Datasets

Please list all databases (including the months and years of data for each) originally approved for access and those to be added or removed. For additional databases, please also specify the months and years of data required and information/variables to be collected from each data source. A brief description of the rationale/methods with the additional database is required. **It is important to describe why the originally approved data was insufficient.**

If a new research question or hypothesis is being tested, this may be considered a new project. Please contact RITHIM Program Officer to determine if a new project submission is required.

If more space is needed, attach a separate list, in a similar format.

List of Approved Databases		**Change in Database(s)**	
Database	**Months/Years**	**Database/Data Elements/Rationale/Methods**	**Months/Years**
Example:			
Medical Claims	e.g., April 1984/1985- March 1999/2000	**Physician Resource Registry** **Data Elements:** physician gender, specialty, years of practice **Rationale:** Through the course of analysis, it was determined that there was a significantly high proportion of procedures conducted by a select few physicians. By linking to the Physician Resource Registry, we will be able to adjust for the physician specialty in our multivariate analysis.	e.g., April 1984/1985- March 1999/2000
		Add:	
		Remove:	

☐ 4. Additional Research Objectives/Questions

Please provide a brief summary of the overall project, objectives, and methods to provide context. For additional research questions, please provide a description of the methods that will be used to analyze these objectives. If new data or databases are required, this must be indicated in section 2 and/or 3 above. **The PHRPC Chairperson will determine whether the proposed new analyses fit within the overall scope of the project.** If an additional research question, hypothesis, or analysis falls within the scope of the approved project, it may be considered an amendment to the original approval.

If more space is needed, attach a separate list, in a similar format.

Summary/Original Objectives	**Additional Objectives (Objectives/Methods/New Data)**

☐ 5. Change in Location of Data Storage and/or Analysis

Please indicate the originally approved location of data storage/access and the new location (address should be specific and include an office/room number where applicable). **A complete description of the data physical, administrative, and technical security procedures at the new location must be included** as well as how and when the data will be destroyed, and other relevant data protection issues. Please provide a rationale for the requested change in location.

It is important to be specific. If the data will be accessed remotely, list all those who will be granted access and the location of the remote terminal(s). Indicate whether or not line-level or aggregate data will be accessed and the specific security measures in place to ensure that data security is not compromised by remote access.

If more space is needed, attach a separate list, in a similar format.

Original Location	**New Location (Address/Security Measures/Rationale)**

☐ 6. Change in Funding Source and/or Sponsor:

PHRPC **must** be notified of any new or additional funding sources or sponsorships. A copy of the letter of support from the funder is required.

Please contact the RITHIM Program Officer to determine if a new source of funding would impact whether this change to the research project should be considered a protocol amendment or if a new submission is required. This is particularly relevant for private industry-funded research projects.

For research projects at MCHP and funded by Private Industry, MCHP will assist in facilitating all required approvals.

If more space is needed, attach a separate list, in a similar format.

Original funding Source As listed in the original HIPC/PHRPC approved submission	**New or Additional Funding Source** Please provide proof of new research funds.

☐ 7. Other Changes

Before you use this section to request a change, please contact RITHIM Program Officer to determine if the new change can be considered as a protocol amendment or if a new submission is required.

If you are submitting an amendment for an additional mail-out, please provide all relevant documents including the Study Information Letter, Consent Form, Questionnaire, etc., and highlight all the updates since they were previously approved. If you have applied to Ethics Board for these updates, please indicate so in your amendment form.

If more space is needed, attach a separate list, in a similar format.

Original	**Change(s)** (Please provide all necessary supporting documents)

8. Signatures

Signature _____ Date _____

Please Print Name: _____

Signature of Academic Advisor (If a Student PI) _____ Date _____

Please Print Name: _____