**Health Information Privacy Committee**

**Protocol Amendment Form**

Changes to the original approved Health Information Privacy Committee (HIPC) application **must** be submitted to the HIPC for review and approval in advance of their implementation.

**The HIPC 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 in this form where a change is requested. Please see the ‘Guidelines for Completing a Protocol Amendment Form for the Health Information Privacy Committee’for more detailed information or consult the HIPC Coordinator for additional questions or inquiries.

**Please email one (1) signed copy of the completed protocol amendment form to the HIPC Coordinator at** **HIPC@gov.mb.ca** **and Cc the organization responsible for housing the dataset. The HIPC Coordinator will forward the protocol amendment to the HIPC Chairperson for approval.**

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

**[ ]  1. Change in Co-investigators**

Please list all of the currently-approved co-investigator(s) and the new co-investigator(s) to be added in the tables below. If a co-investigator is expected to be the lead author on resulting manuscripts or reports, this individual must be identified to the HIPC 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.

**Approved Co-investigators**

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

**New Co-Investigators**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Affiliation** | **Primary role** | **Line-level data access? Yes/No** |
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Do any of the new co-investigators 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 HIPC website.

**Rationale for change**

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

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**[ ]  2. Additional Years of Data**

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.

Manitoba Health, Seniors and Active Living (MHSAL) administrative data is generally organized according to fiscal years beginning April 1st through March 31st, though this data is also available by calendar year.

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 the HIPC Coordinator to determine if a new project submission is required.

The HIPC will not prospectively approve access to data beyond what is currently available. Updates must be submitted as a protocol amendment request to the HIPC when such data become available.

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| **List of Approved Databases**  | **Additional Years Requested/Rationale** |
| **Database** | **Years** |
| Example: |
| Hospital Separation Abstracts | 1984/1985– 1999/2000 | 2000/2001– 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 cases will be identified, increasing our statistical power to a sufficient level.  |
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**[ ]  3. Change in Datasets**

Please list all databases (including the years of data for each) originally approved for access and those to be added or removed. For additional databases, please also specify 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 the HIPC Coordinator to determine if a new project submission is required.

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| **List of Approved Databases** | **Change in Database(s)** |
| **Database** | **Years** | **Database/Data Elements/Rationale/Methods** | **Years** |
| **Example:** |
| Medical Claims  | 1984/1985– 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.  | 1984/1985– 1999/2000 |
|       |       | **Add:** |  |
|       |       |
| **Remove:** |  |
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**[ ]  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 HIPC 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.

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| **Summary/Original Objectives** | **Additional Objectives** |
|       | **Objectives/Methods/New Data** |
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**[ ]  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.

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| **Original Location**  | **New Location**  |
|       | **Address/Security measures/Rationale**       |

**[ ]  6. Change in Funding Source and/or Sponsor:**

The HIPC **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 HIPC Coordinator 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.

**If the study is funded by private industry, please review the guidelines on Private Industry-Sponsored Research by MHSAL. These Guidelines are available upon request from the HIPC Coordinator.**

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| **Original funding Source**As listed in the original HIPC approved submission | **New or Additional Funding Source**Please provide proof of new research funds. |
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**[ ]  7. Other Changes**

**Before you use this section to request a change, please contact the HIPC Coordinator 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 for these updates, please indicate so in your amendment form.

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| **Original** | **Change(s)**(please provide all necessary supporting documents) |
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**8. Signatures**

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| SignaturePlease Print Name:      |  | Date  |
|  |  |  |
|       |  |       |
| Signature of Academic Advisor (If a Student PI)Please Print Name:       |  | Date |