Guidelines for Completing a Protocol Amendment Form for the Health Information Privacy Committee/ Provincial Health Research Privacy Committee

General Information

Any proposed changes to an approved research project must be reported to the Chairperson of the Provincial Health Research Privacy Committee (PHRPC) for review and approval in advance of their implementation.

The completed and signed protocol amendment form should be submitted by email to the **RITHIM Program Officer at PHRPC@researchmb.ca** and the organization responsible for housing the data should be Cc'd. The RITHIM Program Officer will forward the protocol amendment to the PHRPC Chairperson for approval.

The 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 be advised that the time frame for receiving PHRPC approval is dependent on the complexity and completeness of the protocol amendment form. For more complex protocol amendments (e.g., a large amount of new data is being requested, several amendments are proposed at once, or a fair amount of time has passed since the project was originally approved by the HIPC/PHRPC), the PHRPC Chairperson may decide to have the full committee review the request at their next meeting.

The Protocol Amendment Form can be used to request amendments to:

1. Change co-investigator(s)
2. Add year(s) of data
3. Add dataset(s)
4. Add research question(s) or hypothesis(es) to be tested
5. Change the location of data storage and/or analysis
6. Change the funding source and/or sponsor
7. Other changes that do not fit in the above categories

If an additional amendment is requested that is not listed above between items 1 and 6, please contact the RITHIM Program Officer to determine if the new change can be considered as a protocol amendment or if a new research project submission is required.

Filling out the protocol amendment form: Using the tab or arrow keys, the cursor will advance to the next input field, with the document text being protected from inadvertent changes. Checkboxes may be checked by clicking with a mouse, using the space bar, or entering an 'x'. **All information must be type-written in the spaces provided. Do not use a font size smaller than 10 points**.

Complete each section that is applicable to your specific amendment request (e.g., if no additional Investigators are requested, this section does not need to be filled out). Examples are given but are intended as a guide only. You must provide a rationale for all your requested changes in order for the PHRPC Chairperson to determine if the request is of sufficient importance to outweigh the additional intrusion into privacy that would result from the changes.

1. Change in Study Personnel

PHRPC must be notified about study personnel who are being added to or removed from the research team. 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 of lead authors to assume responsibility for the analysis and interpretation of data.

Please list the name, affiliation, and primary role of each individual currently on the research team and whether or not they have access to line level data in the "Approved Study Personnel" table. If new personnel are being added to the research team, complete the "New Study Personnel" table. To prevent any undue delays for new personnel accessing the data, please ensure that requests are submitted at least two weeks before the new person is expected to begin work on the research project.

If the PI or any member of the research team is aware of a conflict of interest, they will need to complete the **Conflict of Interest Disclosure Form** available on the PHRPC website and include it with the submission.

A conflict of interest is a situation in which a personal interest could affect a public duty, or a primary professional obligation may be unduly affected by other interests. In health research, conflict of interest situations are more likely to occur where researchers have multifaceted professional roles and obligations. An example of a conflict in health research would be where researchers seek data to which they already have access in another capacity.

You must also provide a rationale as to why the new personnel are being added to the research team.

If study personnel are being removed from the research team, please list their names under "rationale".

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 database and the months and years of data for which access is already approved. In the adjacent column, list the additional months and years of data requested. A brief description of the reason for the additional data is also required. Note that it is important to describe *why* the originally approved data was insufficient, given that PHIA requires that only the **minimum** information necessary to answer the research objectives should be disclosed to researchers.

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 RITHIM Program Officer to determine if a new submission is required.

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

3. Change in Datasets

Please list all databases (including the months and years of data for each) for which access is already approved. In the adjacent column, list the additional databases and months and years of data required, as well as the fields of interest. A brief description of the linkage and/or analyses with the additional database is required. Note that it is important to describe why the originally approved data was

insufficient, given that PHIA requires that only the **minimum** information necessary to answer the research objectives should be disclosed to researchers.

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

4. Additional Research Questions or Hypotheses

Often through the course of research, a supplementary research question or hypothesis must be explored that was not considered at the time of preparing the original HIPC/PHRPC submission. If this additional research question, hypothesis, or analysis falls within the scope of the approved project, it may be considered an amendment to the original approval. Please provide a description of the methods that will be used to analyze the new objective(s) including a list of any new data that is required for these additional analyses.

Including a brief (one-page) summary description of the overall project and the purpose, objectives, etc. may be useful in providing some additional context. The PHRPC Chairperson will determine whether the proposed new analyses fit within the overall scope of the project.

Please contact the RITHIM Program Officer to determine if the new research objective, hypothesis, or analysis may be considered a protocol amendment or if a new submission is required.

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

In addition to assessing the importance of the research according to its potential to generate scientifically valid results and the likelihood that these may lead to some public benefit, the Committee also considers the protective measures to minimize the probability and implications of disclosure.

The PHRPC Chairperson must be notified if data will be stored or analyzed at a location other than that which was originally approved. Please include a description of the physical, administrative, and technical safeguards that will be implemented for your project. The safeguards are commensurate with the level of identifiable or potentially identifiable data that is being requested. Also indicate how long the data will be retained, and when the data will be destroyed.

Physical safeguards include the use of locks on filing cabinets and offices, and the location of computers containing research data away from public areas.

Administrative Safeguards include the development and enforcement of organizational policies about who has access to Personal Health Information about participants.

Technical Safeguards include the use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss or modification.

In the space provided, indicate the originally approved location of data storage/access. In the adjacent column, state the new location where analyses will take place and/or where the data will reside (address should be specific and include an office/room number where applicable), and describe how the confidentiality of the data will be protected. Describe the security measures, how and when the data will be destroyed, and other relevant data protection issues. 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 terminals. 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.

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 must be submitted along with the protocol amendment form.

For research projects at MCHP and funded by Private Industry, please review Private Industry-Sponsored Research Manitoba Center Policy Guidelines.

7. Other Changes

Before you use this section to request a change, please contact the 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 the 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 an Ethics Board for these updates, please indicate so in your amendment form.

8. Signatures

The Principal Investigator (PI) must sign and date the protocol amendment request form.

If the research project is in fulfillment of a graduate degree, then the student and the academic advisor are both required to sign the protocol amendment request form.