Guidelines for Completing a Request for Access to Personal Health Information Application Form

General Information

These guidelines are to be used in conjunction with the application form "PHRPC Request for Access to Personal Health Information" ("the application"). The application has been developed and approved by the Provincial Health Research Privacy Committee (PHRPC) and is intended to be used to request use of Personal Health Information (PHI) maintained by any Manitoba trustee for research.

The requirement for PHRPC Review is governed by the Manitoba Personal Health Information Act (PHIA) and associated regulations. Researchers are encouraged to review the document on the webpage "Does My Project Require PHRPC Review" which provides guidance on the PHIA requirements used to determine the need for a PHRPC Review. Researchers should review this document in its entirety.

On page 1 of the application form, please indicate the reasons for submitting an application to PHRPC (as per section 2 of the document "Does My Project Require PHRPC Review") (check all that apply).

Applicants are required to email one (1) copy of the application to PHRPC at PHRPC@researchmb.ca along with the supporting documents

Application files should be collated so that they can be easily sent to the individual PHRPC members for review. See our website "Submission Requirements" for a complete list of the required documents for the submission package. Submissions must be received no later than the posted monthly submission deadline, to be reviewed at the applicable scheduled PHRPC meeting. Meeting dates and submission requirements are posted online at: https://www.rithim.ca/deadlines.

Complete ALL questions on the application. Applications that are not completed in full will not be reviewed by PHRPC. Referencing the protocol and/or attachments is not acceptable as an alternative to completing each section of the application. If a question does not apply, indicate this with N/A.

It is the responsibility of the applicant to provide PHRPC with a submission package that is complete, clear and concise. Please use simple, non-technical terms and try to avoid medical jargon and acronyms. It is helpful if the project is explained in lay terms so that all members can review the submission with a clear understanding of its content.

Filling out the application in MSWord: The document is protected from inadvertent edits. Text can only be entered in the designated input fields, such as Enter text. or date fields such as Enter a date.

Checkboxes may be checked by clicking with a mouse or using the space bar. **All information must be type-written in the spaces provided. Do not use a font size smaller than 11 points**. Completed application form should be hand-signed by the PI and then scanned into pdf format, or electronic signature can be added in the designated field. For student projects, the form must also be signed by the advisor.

The RITHIM Program Officer can be consulted during the completion of this application. **In this case it is recommended that a copy of the application form is submitted to the RITHIM Program Officer for review and feedback at least one week prior to the posted submission deadline.**

Definitions

Aggregate Data: Aggregate data present the total number of occurrences within a defined population (stratified by age, gender, or geographic area) or over a given time period. Administrative health data can only be presented in aggregate form for the purposes of reporting or for publication, with cell sizes of at least five (5) or more (smaller rates of occurrence or cell sizes must be suppressed, meaning characteristic data for geographic areas with populations below a specified size is deleted to protect the privacy and confidentiality of individuals; data are not suppressed when the actual event count is zero).

Identifiable Information: Includes all unique direct identifiers (such as PHIN) as well as quasi-identifiers that could reasonably be used to re-identify individuals represented in the data set when combined with other quasi-identifiers.

Line-level Data: Identifiable information relating to a single individual and is considered Personal Health Information.

Personal Health Information: As defined in *The Personal Health Information Act* (C.C.S.M. c. P33.5),

Means recorded information about an identifiable individual that relates to:

(a) the individual's health, or health care history, including genetic information about the individual,

(b) the provision of health care to the individual, or

(c) payment for health care provided to the individual, and includes

(d) the PHIN and any other identifying number, symbol or particular assigned to an individual, and any identifying information about the individual that is collected in the course of, and is incidental to, the provision of health care or payment for health care

Quasi-Identifiers: Specific elements of data that do not directly identify an individual but can be used to re-identify an individual indirectly if linked to additional data containing other quasi-identifiers. Examples include but are not limited to, age, diagnosis, admission and discharge dates and postal codes.

Research Project: A time-limited research endeavor with specific objectives and/or research questions.

I. Researcher Information

Enter the name and address for all correspondence for the principal investigator (PI).

If the PI is a student involved in a project wherein their work on the project is towards a degree and/or will constitute the bulk of their thesis, enter the name and address of the student's primary academic advisor. The student's academic advisor is also required to sign the application.

II. Study Personnel

Enter the name(s) and primary affiliation of the project's co-investigators and other study personnel in the provided table. Indicate their primary role on the project (e.g., data analyst, statistical consultant, etc.) and indicate whether or not this individual will have access to the Line-level Data. **All individuals who will be accessing Line-level Data must be identified.** If more space is needed, attach a separate list of study personnel and their roles and access levels, in similar format.

NOTE: If the research team will consist of individuals based outside of the province of Manitoba, they may not be allowed access to Line-level Data unless they travel to this province, depending on the trustee policy.

If the PI is a student, please list all advisory committee members as co-investigators.

If during the course of the research project other individuals become involved, a protocol amendment must be completed and approved by PHRPC before they can access Line-Level Data.

III. Conflict of Interest

Do you or the 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?

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.

If the PI or any other 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 application submission.

IV. Description of the Research Project

(a) What is the anticipated duration of this study (month/year)?

Provide the projected start and end dates of the project. The date does not have to be specific to the day. This will provide PHRPC members with a general idea of the length of the project. Please note that PHRPC will approve use of data for the duration of the project, up to a maximum of 5 years from the study start date identified in this section of the application.

(b) Please describe the purpose of the research project and list the specific research questions, objectives, and/or hypotheses that will be tested.

Describe the purpose of the research project and list the specific research questions, objectives, and/or hypotheses that will be tested. Any publications arising from the project need to relate back to the objectives in the application.

(c) Please provide a description of the research project, focusing on the proposed methodology.

Provide a description of the research project (limit to one page), focusing on the proposed methodology. The description should include context and/or background of the research and the significance of the study. The design, methods and analysis plan should be explained as well as where the research project data set will be stored and used. Identify the variables of interest and the anticipated results. Do not refer to the protocol and/or attachments because the PHRPC members may not review these documents.

(d) Will the study involve direct access to potential study participants?

Please indicate if the study requires direct access to potential study participants. This includes contact through a mail-out survey/questionnaire, or interviews (in person or via telephone). One (1) copy of the informed consent form as well as any questionnaires (or other supporting materials) that potential participants will receive must be included with this application. If the study requires direct access to study participants, please also describe:

(i) how potential study participants will be (or have been) identified

(ii) who will be approaching potential participants and whether that person is in their circle of care, and

(iii) if consent will be (or was) obtained prior to identification.

(e) Will the study involve correspondence with potential participants?

Please indicate whether the study will involve correspondence with potential participants, including mail-outs, email, etc. If so, please describe the process and identify who is responsible for facilitating the process. Please include one copy of the correspondence template with this application.

V. Specific Data Required

(a) Please attach a Data Extraction Form

The Data Extraction Form is mandatory to be included in the application, even if use of only one database is requested. The table may be completed within the application or attached as a separate file, formatted as described here.

Using the data extraction form template in the application, indicate **all** databases and/or registries to be accessed, the months and years of data required, and the **specific variables** that will be extracted and collected from each data source. The data extraction form should also include any databases that will be linked to Government of Manitoba databases.

Note: 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 have data set requests organized according to months and fiscal years beginning April 1st through March 31st, or by calendar year where appropriate. Please mention the specific months and fiscal years being requested in the data extraction form (asking for the "latest available" is not acceptable).

The Personal Health Information Act requires that only the minimum information necessary to accomplish the purpose of the research project be released to researchers. In the data extraction form, the rationale must explain why the requested information is necessary to complete the study objectives.

(b) Please describe the inclusion/exclusion criteria (e.g., age, gender, region of residence, diagnoses)

Indicate if there are specific inclusion or exclusion criteria required for the study cohort. Provide as much detail as possible.

(c) Is a control group required to be extracted for this study?

Indicate if a control group is required to be extracted and describe the matching ratio and criteria to be applied. Provide a rationale for the specific parameters requested.

(d) Will First Nations, Métis, or Inuit populations be a focus of interest and/or is there intent to stratify analyses or outcomes by First Nations, Métis or Inuit populations?

Indicate if First Nations, Métis and/or Inuit populations will be a focus of interest and/or whether there is intent to stratify analyses or outcomes by First Nations, Métis or Inuit populations. If yes, letter(s) of support from the Manitoba First Nations Health Information Research Governance Committee and/or other First Nations, Métis or Inuit partners is required, as appropriate. Please make sure you also complete Section X(f) of the application form.

(e) Will data held by one trustee be linked or merged with data from another trustee(s)?

Describe any and all planned linkages of one trustee data with other data sources including linkages to data maintained by other trustee(s). Describe the process for linking data from varied sources.

If the external database is a clinical patient registry, informed consent from the patients must be obtained. If informed consent is not going to be obtained, you must explain the reason to PHRPC.

VI. Level of Intrusion

Please indicate only the highest level of intrusion associated with the proposed research project.

The Personal Health Information Act subsection 24(3) requires that, in order to approve a request for access to Personal Health Information for research purposes, PHRPC must determine that the research is of sufficient importance to outweigh the necessary intrusion into privacy from the use of Personal Health Information.

Review the information pertaining to the different levels of intrusion in the application and indicate **only the highest** level of intrusion associated with the proposed research project. Please note that if results are stratified in a way that identifies First Nations, Métis or Inuit populations, or vulnerable or dependent populations, PHRPC will consider this an intrusion level of 5. Vulnerable and dependent populations include but are not limited to:

- Children
- Vulnerable persons as defined under *The Vulnerable Persons Living with a Mental Disability Act*
- Individuals with particularly rare medical conditions that increase the likelihood of identifying the individual
- Individuals with particularly sensitive medical diagnoses such as those pertaining to mental health or sexually transmitted infections

Please provide a rationale for your choice and discuss the importance of this research in relation to the level of intrusion.

Provide an explanation for why the research warrants the level of intrusion selected. Your explanation should indicate specifically who will benefit from this research and how it can benefit society as a whole.

VII. Data Security

(a) Please indicate specifically where the data will reside:

Indicate the research organization where the data analysis will occur, and the complete address (including the room/office number) that the dataset will be stored in.

If applicable, please identify an electronic data capture system and/or file hosting service where the data will reside (e.g., REDCap).

If applicable, please describe the process of sharing the study data between the members of the project team. If data transfer is planned, please include the process' details and data security measures.

(b) How will the confidentiality of the data be protected by the researcher(s)?

You must demonstrate that there are sufficient risk-mitigating safeguards in place to help ensure that the data is appropriately protected from breaches to privacy. 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.

(c) Will the data be accessed remotely?

If the data will be accessed remotely, list everyone on the research team who will be granted access and the location of the remote terminals. Indicate whether or not Line-level Data or Aggregate Data will be accessed and the specific security measures in place to ensure that data security is not compromised by remote access.

VIII. Publication of Study Results

(a) Who will be receiving the study results?

Identify the individuals or organizations that will be receiving study results, including intermediate or preliminary analytical results. For example, if preliminary results will be shared with a funding agency, please indicate the level of information to be provided (e.g. aggregate data, statistical tables, etc.).

(b) Will there be any publication of the study results?

Indicate whether or not the results of the analysis(es) will be published and/or disseminated. This includes public reports, articles in scientific journals, and presentations at conferences and/or meetings. All publication material resulting from the analyses must be submitted to the data trustee for review of confidentiality, privacy, and consistency with PHRPC approved protocol. Please use the following as guidance:

- *Publications, presentations, or reports that use Manitoba Health data should be submitted to PIMA@gov.mb.ca for review:*
    - *at least thirty (30) calendar days prior to any intended publication in learned journals or thesis presentation.*
    - *at least ten (10) calendar days prior to any oral presentation where presentation material will be physically released or distributed or posted on a website.*
- *Manitoba Health will review the publications, presentations and/or reports to ensure that the confidentiality of the information that was accessed is maintained, and that Manitoba Health has been properly represented.*
- *Other trustees may also require a copy prior to publication and should be consulted to determine requirements and timeframe.*

IX. Other Information

Use this space to provide any other information relevant to your application that was not included in the previous sections.

X. Attachments

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

a) Research Ethics Board (REB) approval or indication that the project has been submitted to a REB is required. The PHRPC will not fully approve a project until REB approval has been provided. It is strongly recommended that REB applications are submitted before or at the same time as PHRPC applications. By submitting your REB approval, you are consenting to sharing it with PHRPC and CHIPER. For studies requiring PHRPC review, the Committee for Harmonized Health Impact, Privacy and Ethics Review (CHIPER) must confirm that REB approval has been granted. You do NOT need to complete a separate application to CHIPER; RITHIM staff will forward your REB approval to CHIPER on your behalf

b) Research protocol or proposal

c) Data Extraction Form, formatted as described above

d) Introductory letter or other recruitment material, Informed consent forms, questionnaires if applicable

e) Proof of research funding must be included with the application and all funding sources must be specified. If grant funding has not been awarded at the time of submission to the PHRPC, a letter of support for alternative funding must be attached. If there is no funding, indicate this in the text box.

f) Letter of support from the Manitoba First Nations - Health Information Research Governance Committee and/or other First Nations, Métis or Inuit partners is required if First Nations, Métis or Inuit will be the focus of interest or if there is intent to stratify analyses or outcomes by First Nations, Métis or Inuit populations. Please provide requested details about the letter(s) in the designated spaces.

XI. Declaration

The PI must read and sign this declaration. Please include the date and the PI's name in the spaces provided. If the PI is a student, the student's advisor must also sign the declaration. Please see section VIII for timelines for the submission of reports, publications, and presentations to trustee(s).

XII. Declaration for Use of Identifiable Personal Health Information

The PI's signature is required if the PI is requesting record level data that contains any direct unique identifiers as well as any quasi-identifiers that could reasonably be used to re-identify individuals represented in the data set.

Identifiable Information includes all unique direct identifiers (such as PHIN) as well as Quasi-Identifiers that could reasonably be used to re-identify individuals represented in the data set when combined with other Quasi-Identifiers.