Provincial Health Research Privacy Committee (PHRPC)

Request for Access to Personal Health Information Application Form

As of January 1, 2022, amendments to the Personal Health Information Act (PHIA) were proclaimed. The PHIA amendments bring a NEW REQUIREMENT for researchers. Importantly, the Health Information Privacy Committee (HIPC) was replaced by the new Provincial Health Research Privacy Committee (PHRPC).

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 to confirm the need for PHRPC Review.

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):

This research project requires use of personal health information (PHI) that:

☐ (2.1.1) is maintained by government or a government agency where authorization for use was previously determined by the HIPC; or

☐ (2.1.2) is maintained by any Manitoba Trustee where there will be no contact with the individuals that may be participating in the study and no plan to obtain consent from those individuals regarding the use of PHI; or

☐ (2.1.3) is maintained by a Trustee to identify eligibility and/or contact patients to discuss participation in a study and all potential patients have not already provided consent to be contacted for the purposes of the research; or

☐ (2.1.4) is required to link data from multiple Trustees (e.g., more than one health care institutional Trustee); or

☐ (2.1.5) involves the collection of personal health identification numbers (PHINs) by the researcher.

Complete ALL questions on the application form. Application forms that are not completed in full will not be reviewed by the Provincial Health Research Privacy Committee (PHRPC).

One (1) copy of the application and supporting documents must be submitted by email to Research Manitoba, PHRPC@researchmb.ca.

For more detailed information, please see the following pages on the RITHIM website:

- Guidelines for Completing a PHRPC Submission Form
- Submission Requirements

This application form will be used temporarily by the PHRPC until the online application portal (i.e., the RITHIM Provincial Research Administration System – RITHIM-PRAS) is ready. For more information on the status of the online application portal, visit http://rithim.ca/pras.

Application Information

Date of Request (YYYY/MM/DD): **Enter a date.**

Title of Research Project: **Enter text.**

I. Researcher Information

Principal Investigator's name (PI): Enter text.

Affiliation: **Enter text.**

Phone: **Enter text.**

Email: **Enter text.**

Fax: **Enter text.**

Address: **Enter text.**

Line-level data access?

☐ Yes ☐ No

Academic Advisor (if PI is a student): Enter text.

Affiliation: **Enter text.**

Phone: **Enter text.**

Email: **Enter text.**

Fax: **Enter text.**

Address **Enter text.**

Line-level data access?

☐ Yes ☐ No

II. Study Personnel

List all co-investigators and other study personnel, their affiliation and *specific* role (e.g., data analyst, statistical or clinical consultant, data collection) in the proposed research project. If the PI is a student, please list all Advisory Committee Members. If more space is needed, attach a separate list of study personnel, in similar format.

Name	Affiliation	Primary role	Line-level data access? Yes/No
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**

Enter text.	**Enter text.**	**Enter text.**	**Enter text.**
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**

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?

YES ☐ NO ☐

If yes, please complete the Conflict of Interest Disclosure Form available on this page:

IV. Description of the Research Project

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

From: **Enter a date.** To: **Enter a date.**

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

Enter text.

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

Note: The description should include the context and/or background, design, methods and analysis plan, variables of interest, anticipated results and significance of the study. Limit the description to one page and do not refer to the protocol and/or attachments.

Enter text.

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

YES ☐ NO ☐

If yes, please describe how potential research project participants will be (or have been) identified and if consent will be (or was) obtained prior to identification.

Enter text.

With your submission, please provide one (1) copy of the introductory letter, Information and Consent Form, questionnaires, or any other materials that potential participants will receive.

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

YES ☐ NO ☐

If yes, please describe the process and identify who is responsible:

Enter text.

V. Specific Data Required

(a) Please attach a Data Extraction Form to indicate ALL databases to be accessed, years of data required, the variables of interest, and the rationale for such requests. Please be as specific as possible.

The Data Extraction Form template has been provided below. If additional space is required, please include as an attachment, using a similar format.

Note: The Personal Health Information Act (PHIA) requires that only the minimum information necessary to accomplish the purpose of the research project be released to researchers.

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 re-reviewed by PHRPC. Amendments would not be required for adding new years of data if 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.

Data Extraction Form Template			
Database Name of database requested e.g., Hospital Discharge Abstract	**Years / months** Years & months of data requested e.g., April 2000 - March 2012	**Data Fields / Variables** Specific information or data fields required from a database e.g., Admission date, Separation date, Diagnoses, Procedures	**Rationale** Describe in general terms how the information to be collected relates to the study purpose, hypotheses, and study questions. If the information does not relate directly to these, provide explanation as to why the information is being collected. e.g., To develop indicators of health status, health services use and health risk
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**
Enter text.	**Enter text.**	**Enter text.**	**Enter text.**

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

** Please mention specific years in the data extraction form (asking for the "latest available" is not acceptable).*

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

Enter text.

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

YES ☐ NO ☐

If yes, please describe the matching ratio and criteria for the control group and provide a rationale for the specific parameters requested:

Enter text.

(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, Metis or Inuit populations?

YES ☐ NO ☐

If yes, please provide a copy of the letter of support from the Manitoba First Nations Health Information Research Governance Committee and/or other First Nations, Métis, or Inuit partners as appropriate and complete Section X, f) of this form.

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

YES ☐ NO ☐

If yes, please describe the nature of the linkage (e.g., the data/databases that will be linked), including the process for linking data from varied sources.

Enter text.

If a database is a clinical patient registry, please provide a copy of the Information and Consent Form requesting the patient's permission to link data in the clinical registry to other data sources. If informed consent was not obtained, please explain.

Enter text.

VI. Level of Intrusion

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

1) ☐ **Minimal or no Intrusion:** Aggregate statistical information or person specific information with no individual identifiers or record linkages, which could potentially identify individuals.

2) ☐ **Potential Intrusion:** Person specific information in de-identified form with data linkages that create the risk of identification of individuals. The degree of risk increases with the type of data linkage as follows:

   a) ☐ Minimal linkage or specificity of use of data, which create no potential for the identification of individuals (e.g., linking the Hospital Abstracts and the Medical Claims databases with aggregate level data for a certain geographic location within a Regional Health Authority);

b) ☐ Multiple linkage or specificity of use of data which may create the potential for identification of individuals (e.g., linking the Hospital Abstracts, Medical Claims, and DPIN databases);

c) ☐ Linkage of data files to other publicly available and aggregate level data sources where all individual identifiers have been removed or modified (e.g., linking the Hospital Abstracts, Medical Claims, and DPIN databases with outside neighborhood level data from the census);

d) ☐ Linkage of data files to other person--specific data files where individual identifiers have been removed or modified, or in the case of surveys, no direct contact with the individual will be made (e.g., linking the Hospital Abstracts, Medical Claims, and DPIN databases with data from Statistic Canada's Canadian Community Health Survey). *This does not include cases where the population group or information concerned falls within category 5.*

3) ☐ **Moderate Intrusion:** Person-specific information such as patient charts, surveys or personal interviews will be used but the individuals affected will be asked for their consent prior to the disclosure of any personal health information to the researcher. *This does not include cases where the population group or information concerned falls within category 5.*

4) ☐ **High Intrusion**: Person -specific information involving linkage of data files to other person-specific- files for which the researcher has access to individual identifiers without consent, for example, patient information collected in clinical settings, specialized programs, and disease registry files with identifying information. *This does not include cases where the population group or information concerned falls within category 5.*

5) ☐ **Highly Sensitive**: Requests for information which would otherwise fall into categories 2b or higher where the population involved is vulnerable or dependent (e.g., minors), where the nature of the information is highly personal and sensitive (e.g., persons with mental disabilities, sexually transmitted infections), or where there will be a focus of interest and/or an intent to stratify outcomes by First Nations, Métis, or Inuit populations.

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

Note: PHIA, 24(3) requires that PHRPC must determine that the research is of sufficient importance to outweigh the necessary intrusion into privacy from the disclosure of personal health information.

Enter text.

VII. Data Security

(a) Please indicate specifically where the data will reside (i.e., the research organization where the data analysis will occur):

Enter text.

Complete address (including room/office number): **Enter text.**

If applicable, please identify an electronic data capture system and/or file hosting service where the data will reside (e.g., REDCap, Medidata Rave; MS OneDrive, Google Drive, Dropbox, etc.):

Enter text.

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.

Enter text.

(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 of privacy. Please include a description of the physical, administrative, and technical safeguards that will be implemented for your project. The safeguards should be commensurate with the level of identifiable or potentially identifiable data that is being requested. Physical safeguards may include, but are not limited to, the use of locks on filing cabinets and offices, and the location of computers containing research data away from public areas. Administrative safeguards may include, but are not limited to, measures such as the development and enforcement of organizational policies about who has access to Personal Health Information about participants. Technical safeguards may include, but are not limited to, the use of computer passwords, firewalls, anti-virus software, encryption and other measures that protect data from unauthorized access, loss, or modification.

Enter text.

Please indicate how long the data will be retained, as well as when and how the data will be destroyed:

Enter text.

(c) Will the data be accessed remotely?

YES ☐ NO ☐

If yes, by whom?

Enter text.

Where is the remote terminal located?

Enter text.

What level of data (i.e., aggregate vs. line-level) will be accessed?

Enter text.

Describe the specific security measures in place to ensure that data security is not compromised by remote access.

Enter text.

VIII. Publication of Study Results

(a) Who will be receiving the study results?

Enter text.

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

YES ☐ NO ☐

If yes, a copy may need to be sent to the Trustee(s) for review prior to publication. 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

Please describe any other information relevant to this application.

Enter text.

X. Attachments

Note: Projects will not receive full PHRPC approval until ALL appropriate/required documentation is received by the RITHIM Program Officer.

The following required documentation is attached:

a) Research Ethics Board (REB) final Approval?

YES ☐ NO ☐

If No, has a REB application been submitted?

YES ☐ NO ☐

If Yes,

What date was the REB Application submitted?

Enter a date. (YYYY/MM/DD)

Please submit final REB approval to PHRPC once received.

If No,

Anticipated date of submission to REB:

Enter a date. (YYYY/MM/DD)

Please submit final REB approval to PHRPC once received.

**** It is strongly recommended that REB applications be 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 (as submitted on any other applications for this research)

c) ☐ Data extraction table (as submitted on any other applications for this research)

d) If this study will involve direct access to potential project participants, please include the following documents:

i. ☐ Introductory letter or other recruitment material to be sent to potential participants

ii. ☐ Information and consent form and any accompanying information

iii. ☐ Questionnaires and/or any other materials the participants will receive

e) ☐ Proof of research funding

**** Required for every PHRPC submission.*

Please specify funding source:

Enter text.

**** All funding sources must be specified. Please submit a copy of a letter of support from the granting agency. If grant funding has not been awarded at the time of submission, a letter of support for alternative funding must be attached. For example, if internal departmental funds will be used in lieu of grant funding, a letter of support from the department head is required.*

Is the research being funded by Private Industry?

YES ☐ NO ☐

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

f) If this research requires Letters of Support from the Manitoba First Nations Health Information Research Governance Committee and/or other First Nations, Métis, or Inuit partners, have these been requested?

YES ☐ NO ☐

If Yes,

Please indicate organizations where Letter(s) of Support have been requested:

Enter text.

☐ Letter of Support(s) received and attached.

☐ Letter of Support(s) pending.

Please indicate which Letter(s) of Support are pending:

Enter text.

What date(s) were the Letter(s) of Support requested?

Enter a date. (YYYY/MM/DD)

Please submit to PHRPC once received.

If No,

Please indicate organizations where Letter(s) of Support will be requested:

Enter text.

Anticipated date(s) request(s) will be sent?

Enter a date. (YYYY/MM/DD)

XI. Declaration

I declare that:

a) This research project complies with *The Personal Health Information Act* of Manitoba.

b) I understand that it is the responsibility of the project PI to ensure that all study personnel accessing the PHI have the appropriate up-to-date PHIA training.

c) The information being requested will only be used for the purpose of the research project outlined in this application.

d) The information being requested is the minimum amount necessary to accomplish the objectives of the research project outlined in this application.

e) The security safeguards outlined in this application reasonably ensure the security and confidentiality of the personal health information and its destruction when the research project is finished.

Click centre to add signature image

Enter a date. Signature of Principal Investigator

Date (YYYY/MM/DD) *Please print name*: **Enter text.**

Click centre to add signature image

Enter a date. Signature of Academic Advisor (if PI is a student)

Date (YYYY/MM/DD) *Please print name*: **Enter text.**

XII. Declaration for Use of Identifiable Personal Health Information

To be signed only when identifiable personal health information is being requested.

I declare that this research cannot be done without using identifiable personal health information, and that it is impossible or impractical to obtain consent from the people the personal health information is about.

Click centre to add signature image

Enter a date. Signature of Principal Investigator

Date (YYYY/MM/DD) *Please print name*: **Enter text.**