Manitoba
Health, Healthy Living and Seniors
Health Information Management
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Health Information Privacy Committee

Request for Access to Personal Health Information Held by the Government of Manitoba

An Example Submission Prepared at MCHP Focusing on Fields Relevant for Projects Using the Population Health Research Data Repository

Annotations and Examples Highlighted in Yellow **Recommended Responses in Blue**

Complete ALL questions on the application form. Application forms that are not completed in full will not be reviewed by the HIPC. One (1) copy must be submitted by email to the HIPC Coordinator at HIPC@gov.mb.ca. Ten (10) hard copies must be delivered to the HIPC Coordinator at 4040-300 Carlton Street, Winnipeg, Manitoba, R3B 3M9. For more detailed information, please see the 'Guidelines for Completing a Request for Access to Personal Health Information Held by the Government of Manitoba' and 'Submission Requirements' on the HIPC website.

Date of Request (MM/DD/YYYY): <Date>

Title of Research Project:

<The title should be the same as the title for the HREB submission and approval>

I. Researcher Information

Principal Investigator (PI):

Affiliation: <Note that for U of M REB, the PI must be a U of M investigator> **Phone:**

Email: **Fax:**

Address: <Full mailing address>

Academic Advisor (if PI is a student):

Affiliation: **Phone:**

Email: **Fax:**

Address:

II. Co-investigators

List all co-investigators, 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. Attach a list of co-investigators if more space is needed.

<ALL co-investigators who will have access to the line level data need to be identified here.>

<Please try to identify all team members who are working on the project, including planned manuscript authors, if possible. If authors of the planned manuscript are yet to be determined please ensure to submit an amendment to HIPC and Repository Access Unit at MCHP, once the final authors have been determined and prior to publication.>

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

III. Conflict of Interest

(a) 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 accessible through the HIPC website.

IV. Description of the Research Project

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

From: To:

(b) Is this project part of a program of research? Yes ☐ No ☐

If yes, has the program of research already received HIPC approval-in-principle?

Yes ☐ No ☐

- **HIPC File Number:**
- **Briefly summarize the program of research:**

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

<Provide a summary paragraph including specific objectives, which should be consistent with the Research Ethics Board Submission.

Note: Any publications arising from the project need to relate back to the objectives.

Reminder: Referencing the proposal and/or attachments is no longer acceptable as an alternative to completing each question of the HIPC submission form.>

(d) 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. <u>Limit the description to one page and do not refer to the protocol and/or attachments</u>.

(e) Will the study involve direct access to potential study participants? Yes ☐ No ☐

If yes, provide one (1) emailed copy and ten (10) hard copies each of the introductory letter that will be sent to the potential participants, the Information and Consent Form, questionnaires and any other materials that potential participants will receive.

(f) Will the study involve correspondence with potential participants that is mailed out? Yes ☐ No ☐

If yes, will Manitoba Health, Seniors and Active Living be asked to facilitate a blind* mail-out?

Yes ☐ No ☐

****The researcher would not know the identity of those who are mailed letters.***

V. Specific Data Required

(a) Please attach a <u>Data Extraction Form</u> (unless only one database is requested) to indicate <u>ALL</u> 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.

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.

ALL data being used must be listed, not just that from Manitoba Health

Data Extraction Form Template			
Database Name of database requested **e.g.,** Hospital Discharge Abstract	**Years** Years 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

* Manitoba Health, Seniors and Active Living administrative data is organized according to fiscal years beginning April 1st through March 31st.
* If data prior to 1985 is required, please consult the HIPC Coordinator.
* The HIPC will not prospectively approve access to data beyond that which is currently available. Updates must be submitted as a protocol amendment request to the HIPC when such data does become available.
* Please mention specific years for the in the data extraction form (asking for the "latest available" is not acceptable).

(b) Inclusion/exclusion criteria (e.g. age, gender, region of residence, diagnoses)

(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:

(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: Select #5, Highly Sensitive, below in Section V. Level of Intrusion>

If yes, 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.

(e) Will data held by a department or agency of the Government of Manitoba be linked or merged with data from another department or external source(s)? Yes ☐ No ☐

<Usually yes. Specify below the categories of databases as well as the linkage key(s) >

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.

e.g.

a) non-MHHLS data: In order to link database records across data files (e.g. Income Assistance data with health data and education data), MHHLS has undertaken the translation process, where all personal identifiers have been removed and numeric identifiers encrypted. Although postal code is required to link census use data to database records, presentation of data at the individual postal code will not be done.

b) MHHLS data: Using the scrambled PHIN numbers provided to MHHLS, data extracted from the physician's electronic medical record (EMR) will be linked to patient records in the repository at MCHP. This will allow a validation process of the administrative data and facilitate the indicator development.

Note: If the external database(s) contains individual-level data, permission from the trustee is required and a copy of this permission must be submitted to the HIPC.

If the external 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.

VI. Level of Intrusion

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

<Note: for studies using MHHLS data, the most common level is # 2b; if non-MHHLS data are also being used, 2d would be more appropriate. Examples of Level 5 would include analyses involving First Nations, children at risk, elderly, individuals with mental disabilities, etc.>

☐ **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 anonymized 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:

☐ **2a.** Minimal linkage or specificity of use within Manitoba Health, Seniors and Active Living 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);

☐ **2b.** Multiple linkage or specificity of use within Manitoba Health, Seniors and Active Living data which may create the potential for identification of individuals (e.g. linking the Hospital Abstracts, Medical Claims, and DPIN databases);

☐ **2c.** Linkage of Manitoba Health, Seniors and Active Living 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);

☐ **2d.** Linkage of Manitoba Health, Seniors and Active Living 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 Manitoba Health, Seniors and Active Living 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 diseases), 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 the HIPC must determine that the research is of sufficient importance to outweigh the necessary intrusion into privacy from the disclosure of personal health information.

This project will involve secondary analysis of de-identified data files only, with linkages to other files where identifiers have been removed or scrambled. <e.g. Education data, Family Services Data, National Population Health Survey, Canadian Community Health Survey>. The research will provide valuable results to provincial and regional planners, to help guide policy and program initiatives to optimize population health and health service organization.

e.g. Level 2a. 2b: The project will involve de-identified data only, with linkages of various MHHLS data files. The datasets to be used will not contain identifiable personal information.

e.g.'s Level 2b, 2c:

-a) The project will involve de-identified health care utilization data housed at MCHP, with some linkage to public-use census files for measures such as neighborhood income. The datasets to be used will not contain identifiable personal information.

-b) The project will involve linkages of de-identified MHHLS data, as well as public use Census files.

e.g. Level 2d: The data we extract from the EMR will have all identifiers removed before the data is transferred to MCHP for linkage. The linkage will be made using PHINs which will be scrambled by MHHLS.

e.g. Level 5: As we will be seeking to identify at-risk children (e.g. those from low-income neighborhoods, children involved with Child & Family Services, and children identified as having FASD) in the data, we have selected the "highly sensitive" level of intrusion.

e.g. Level 5: As our research is focusing on older adults (age 65+) we have selected the "highly sensitive" level of intrusion.

VII. Data Security

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

All of the analyses will be conducted within the secure computer environment of the Manitoba Centre for Health Policy (MCHP).

Complete address (including room/office number):

MCHP

408-727 McDermot Avenue, Winnipeg, Manitoba R3E 3P5

(b) How will the confidentiality of the data be protected by the researcher(s)? Please include a discussion of the security measures, how and when the data will be destroyed, and other relevant data protection issues (e.g., physical, technical and administrative controls and safeguards).

MCHP operates according to rigorous standards regarding security, privacy, and confidentiality of data files contained in the Population Health Research Data Repository (Repository). Physical measures include restricted access to the facility through pass card authentication. Electronic measures include multiple levels of passwords with individual user identification, electronic firewalls, and separated analysis systems.

Repository data is in the form of de-identified records that are securely stored on a segregated data server with auditing capabilities. Privacy of information is protected through a number of measures, most notably no files at MCHP contain names or specific addresses and any individual identifiers have been encrypted by Manitoba Health Active Living and Seniors (MHSAL) prior to transfer to MCHP.

All projects that use the data at MCHP must have at minimum approval from the University of Manitoba Research Ethics Board and the Manitoba Provincial Health Information Privacy Committee. Approvals from non-MHSAL providers are also required as necessary. In addition to these approvals further approvals may be required following ethical and OCAP principles as outlined in the TCP2 guildelines. Any projects that identifies first nations individuals as part of any outcomes studied

must have approval from the First Nations Health and Social Secretariat of Manitoba Information Research Governance Committee.

All study associated data and programming code will be archived at the time of study completion and removed from MCHP's analysis system. Consistent with University of Manitoba protocols, archives will be maintained at MCHP for a period of at least seven (7) years and no more than ten (10) after project completion to allow time for questions and clarifications of publications and then all study-associated data will be destroyed. The programming code and algorithms used to generate analysis and intermediate data may be retained indefinitely. Restoration of data files from archives or backup will only be done for projects that have current approvals from the data providers and appropriate committees. Restoration requires both physical access to the backup media as well as administrative system access.

Data and programming files are destroyed at the end of the project by deletion, the act of deleting a file in the server environment destroys the allocation information. There is no 'trash can' or restore function – the location of the file is destroyed. There is no way for a user to recover data files; it would not be reasonably possible to recover deleted files.

Physical storage media is destroyed by shredding or physical destruction of the media either by UofM IST staff or using a commercial shredding service (e.g. ShredIt)..

(c) Will the data be accessed remotely? Yes ☐ No ☐

If yes, by whom?

Where is the remote terminal located? <Ask MCHP if you are unsure of the exact room location of the Remote Access Site (RAS) terminal you will be using>

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

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

<For Remote Access Sites (RAS): Physical measures include restricted, alarm protected access to the facility. Electronic measures include multiple levels of passwords, electronic firewalls, encryption of transmitted information, and other security measures. Each terminal is secure in that they do not permit copying, transferring, storing, and printing of any content.>

VIII. Publication of Study Results

(a) Who will be receiving the study results?

e.g. The results will be shared with the participating clinics and physicians, MHHLS, and the Manitoba Centre for Health Policy. Academic papers may also be written for publication in journals.

(b) Will there be any publication of the study results? Yes ☐ No ☐

If yes, a copy must be sent to Manitoba Health, Seniors and Active Living for review prior to publication. <A notification must also be sent to all non-health data providers on the project>

Note: At least thirty (30) calendar days prior notice is required for every intended publication in learned journals or thesis presentation; at least ten (10) calendar days prior notice is

required for every poster or oral presentation where such presentation material will be released.

IX. Other Information

Please describe any other information relevant to this application.

X. Attachments

<If approvals for data access are being sought from non-MHHLS agencies, it should be specified here- e.g. Social Services data, Vital Statistics data, Education data, Aboriginal Health data. “Pending” will typically be checked since submissions for approvals are all done around the same time (HIPC, HREB, other agencies)>

The following documentation is attached:

☐ **Proof of research funding**

**** Required for every HIPC submission.*

Please specify funding source:

**** 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** ☐

**** If the study is funded by Private Industry, please review the guidelines on Private Industry-Sponsored Research by Manitoba Health, Seniors and Active Living. These Guidelines are available upon request from the HIPC Coordinator.*

☐ **Research Ethics Board approval** <refers to UM Health Research Ethics Board>

Pending ☐

**** Required for every HIPC submission.*

☐ **Letter of Support from the Manitoba First Nations Health Information Research Governance Committee and/or other First Nations, Métis or Inuit partners as appropriate**

Pending ☐

☐ **Organization or Institutional Research Review Committee approval (please specify):**

<ex. Vital Statistics>

Pending ☐

☐ **Organization or Institutional Research Review Committee approval (please specify):**

<ex. Manitoba Jobs and the Economy>

Pending ☐

☐ **Organization or Institutional Research Review Committee approval (please specify):**

Pending ☐

☐ **Organization or Institutional Research Review Committee approval (please specify):**

Pending ☐

Note: Projects will not receive full approval until all the appropriate documentation is received by the HIPC Coordinator.

<Please ensure to provide MCHP with one copy of each document sent to and requested by HIPC prior to Final Approval being issued>

XI. Declaration

I declare that:

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

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

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

d) 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.

e) All reports, publications, and presentations resulting from this project will be submitted to the Information Management and Analytics Branch of Manitoba Health, Seniors and Active Living for review prior to distribution or publication (in accordance with the timelines described in the Guidelines), to assure that the anonymity of the study cohort is preserved and that any references to Manitoba Health, Seniors and Active Living or other trustees, are factually correct.

f) A copy of all published reports and articles will be provided to the Information Management and Analytics Branch of Manitoba Health, Seniors and Active Living for its records.

Date _____ **Signature of Principal Investigator** _____

An MCHP co-investigator can sign on behalf of a non-UM Principle Investigator*

***Please print name*:** _____

Date _____ **Signature of Academic Advisor** _____

(if PI is a student)

***Please print name*:** _____

*The Researcher Agreement must, however, be signed by the PI**.***

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.

Date _____ **Signature of Principal Investigator** _____

Please print name: _____