

Guidelines for Completing A Request for Access to Health Information Held by the Government of Manitoba

General Information:

- Applicants are required to **submit the original plus 10 copies** of the completed application form as well as 10 copies of all supporting documentation. *Applications must be received at least two weeks before the scheduled Health Information Privacy Committee (HIPC) meeting.* Meeting dates are posted online at: <http://www.gov.mb.ca/health/hipc/index.html>.
- This application can be used to request data for either a **program of research** or an individual **research project** (please see definitions below).
- Filling out the form in MSWord: 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'.

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 publication with cell sizes of at least five (5) or more (smaller rates of occurrence or cell sizes must be suppressed).

Line-level Data: Data at the individual level. This is considered Personal Health Information as defined in *The Personal Health Information Act* (C.C.S.M. c. P33.5):

“**Personal Health Information** 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
 - (e) 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; “

Program of Research: A sustained research endeavor that includes (or is likely to include) one or more projects and which is generally shaped by broad objectives. Research proposals for a program of research usually describe an area of research rather than a discrete, time limited project. The HIPC will consider applications for Programs of Research (the ‘Program’) with the understanding that individual projects within the Program must be reviewed on a project by project basis. However, individual projects within the Program will not necessarily require separate and distinct approvals from an ethics board if (1) the individual projects are well described in the original ethics approval for the Program, and; (2) there are no changes to the protocol originally approved by the ethics board. Programs of Research are approved ‘in-principle’ only.

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, enter the name and address of the student's primary academic advisor.

II. Co-investigators

Enter the name and primary affiliation of the project co-investigators. Indicate their primary role in the project (e.g. data analyst, statistical consultant, etc.) and indicate whether or not this individual will have access to the line-level data. Note that all individuals (other than the PI) who will be accessing line-level data must be identified. If it is anticipated that a co-investigator will be the lead author on any publications or reports resulting from this project, the co-investigator must be identified here and it should be indicated that he/she will have access to the line-level data.

III. Description of the Research Project

(a) If this application applies to a research project within a Program of Research, please specify the HIPC file number of the original program.

(b) Please provide a general description of the research project, including its purpose and the proposed methodology. A protocol summary or research proposal may be added as an attachment.

(c) Please list and describe the specific research questions, objectives, and/or hypotheses that will be tested. If this application is for a program of research, please list and describe the planned research projects within the program.

(d) Please indicate if the study requires direct access to potential study participants. This includes contact through a mail-out survey/questionnaire or interview (in person or via telephone). A 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.

IV. Specific Data Required

(a) Using the drop-down list in the table provided, indicate the databases and/or registries to be accessed, the years of data required, and the fields of interest. Note that the Personal Health Information Act requires that only the minimum information necessary to accomplish the purpose of the research project be released to researchers.

Note: If this application is for a program of research, the databases and registries that will be accessed must still be identified here. *Subsequent applications for research projects within the program can further refine these data requests.*

Note: Manitoba Health administrative data is organized according to fiscal years beginning April 1st through March 31st.

(b) If there are specific inclusion or exclusion criteria outlined in the research protocol, please describe.

(c) Indicate if a control group is required and describe the matching criteria to be applied.

(d) Describe any and all planned linkages of Manitoba Health and Healthy Living data with other data sources including linkages to data held by other government departments.

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

Note: If the external database is a clinical patient registry, informed consent from the patient must be obtained. If informed consent was not obtained, please provide rationale.

V. Level of Intrusion

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, the Health Information Privacy Committee must determine that the research is of sufficient importance to outweigh the necessary intrusion into privacy from the disclosure of personal health information.

Using the guidelines below, indicate the highest level of intrusion associated with the proposed research project. Provide a rationale for your choice and discuss the importance of this research in relation to the level of intrusion.

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 data, which create no potential for the identification of individuals;

2b. multiple linkage or specificity of use within Manitoba Health data which may create the potential for identification of individuals;

2c. linkage of Manitoba Health data files to other publicly available and aggregate level data sources (e.g. neighbourhood-level data from the census) where all individual identifiers have been removed or modified;

2d. linkage of Manitoba Health 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 (eg National Population Health Survey from Statistics Canada). *(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. *(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 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. *(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, First Nations, etc.) or where the nature of the information is highly personal and sensitive (e.g. persons with mental disabilities, sexually transmitted diseases, etc).

VI. Data Security

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 proposed by the researcher to minimize the probability and implications of disclosure.

In the space provided, indicate where the data will reside (address and 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. 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.

VII. Publication of Study Results

(a) Identify those individuals or organizations that will be receiving study results. This includes 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) Indicate whether or not the results of the analysis(es) will be published and/or disseminated. This includes public reports, articles in scientific journals, or presentations at conferences and/or meeting.

Note: All publication material resulting from the analyses must be submitted to Manitoba Health (Health Information Privacy Committee Coordinator, Health Information Management Branch, 300 Carlton Street, Winnipeg, MB, R3B 3M9; or via email (see the HIPC website)) for review of confidentiality, privacy, and consistency with the HIPC approved protocol. The following timelines should be adhered to:

- Publications in learned journals or thesis presentation: At least 30 days prior to submission.
- Conference/Meeting Presentation: At least 10 days prior to the conference.

A final copy (in .pdf form) must be sent to the HIPC Coordinator upon acceptance by the publishing journal.

Note: If the study results will be presented to the media (in the form of a press release or otherwise), the PI must inform the Health Information Privacy Committee Coordinator prior to the media release, regardless of prior notification to the HIPC of journal publications.

VIII. Other Information

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

IX. Attachments

i. Proof of Ethics Committee approval must be attached to all applications.

Note: If this application is for a research project within a program of research, a new Ethics Committee approval may not be required. Please contact the HIPC Coordinator to determine if a new Ethics Committee approval is required for each project within the program.

ii. Proof of research funding must be attached all applications.

Note: If this application is for a research project within a program of research, proof of funding for the research project may not be required if it was included in the original program of research application. Please contact the HIPC Coordinator to determine if proof of funding is required for each project within the program.

iii. Institutional Research Review Board approval is required for those projects proposing to link data held by a non-government department. For example, if linkages with clinical patient registries are proposed, the hospital or institution maintaining the registry must approve linkage and/or access to the registry.

iv. Assembly of Manitoba Chiefs – Health Information Research and Governance Committee (HIRGC). Programs of research and/or projects whose specific focus is the health of First Nations people of Manitoba, must seek approval from the AMC-HIRGC.

v. Other institutional or research review board approvals. If additional approvals from other government departments (e.g. Department of Education), external data trustees, or institutional review boards were sought, please indicate. Attach a copy of all approvals to the application

X. Declaration

The Principal Investigator (PI) must read and sign this declaration. If the PI is a student, the student's advisor must also sign the declaration.