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

General Information

These guidelines are to be used in conjunction with the application "Request for Access to Personal Health Information Held by the Government of Manitoba" ("the application"). The application has been developed and approved by the Health Information Privacy Committee (HIPC) and is intended to be used to request Personal Health Information held by the Government of Manitoba for research.

Applicants are required to email one (1) copy of the application to HIPC@gov.mb.ca and deliver ten (10) hard copies to the HIPC Coordinator at the following address:

HIPC Coordinator
Manitoba Health, Seniors and Active Living
4043 - 300 Carlton Street
Winnipeg, MB R3B 3M9

Applications should be collated so that they can be easily sent to the individual HIPC members. See Appendix 1 for a complete list of the required documents for the submission package. Submissions must be received no later than two weeks before the scheduled HIPC meeting. Meeting dates and submission requirements are posted online at: http://www.gov.mb.ca/health/hipc/index.html

Complete ALL questions on the application. Applications that are not completed in full will not be reviewed by the HIPC. Referencing the protocol and/or attachments is not acceptable as an alternative to completing each section of the application. The application can be used to request data for an individual Research Project or to create a Program of Research (please see definitions below). Please contact the HIPC Coordinator before submitting an application for a program of research.

It is the responsibility of the applicant to provide the HIPC with a submission package that is complete, clear and concise. Please use simple, non-technical terms and try to avoid medical jargon and acronyms. The HIPC is made up of members with expertise across a range of areas and includes representatives from the public. 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: 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**.

The HIPC Coordinator can be consulted during the development of this application. **It is recommended that a copy of the application be submitted to the HIPC Coordinator for review and feedback at least one week prior to the 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).

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

Program of Research: A sustained research endeavor that includes one or more projects and is generally shaped by broad objectives. Research proposals for a Program of Research (the 'Program') usually describe an area of research rather than a discrete, time-limited project. The HIPC will consider applications for a Program with the understanding that individual projects within the Program must be listed in the application and 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 and other data providers 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 by the HIPC 'in principle' only.

Please consult the HIPC Coordinator for additional advice on how to complete this application for a new Program of Research.

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. Co-investigators

Enter the name and primary affiliation of the project's co-investigators. 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 there are more co-investigators than the space allows, please attach the complete list of co-investigators and their roles and access levels to the application.

If the research team will consist of individuals based outside of the province of Manitoba, they will not be allowed access to Line-level Data unless they travel to this province. Only aggregated data is allowed to leave the province.

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 the HIPC before they can access Line-Level Data.

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?

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 a 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 HIPC 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 HIPC members with a general idea of the length of the project.

(b) Is this project part of a Program of Research?

If the application is for a research project that is part of an approved Program of Research recognized by the HIPC and defined above, specify the HIPC file number of the Program and briefly summarize the Program.

If the application is for a new Program of Research, please provide a description of the program in this area and include a list of projects that will be individually submitted.

(c) 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. If this application is for a Program of Research, please list and describe the planned research projects within the Program. Any publications arising from the project need to relate back to the objectives in the application.

(d) 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 HIPC members will not review these documents.

(e) 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). Ten (10) copies 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.

(f) Will the study involve correspondence with potential participants that is mailed out?

Please indicate whether the study will involve correspondence with potential participants that is mailed out. If so, specify whether Manitoba Health, Seniors and Active Living (MHSAL) will be asked to facilitate the planned mail-out.

The HIPC Coordinator should be made aware of any request for MHSAL to facilitate a mail-out before the application is submitted to the HIPC.

V. Specific Data Required

(a) Please attach a Data Extraction Form

Using the data extraction form template in the application, indicate **all** databases and/or registries to be accessed, the 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.

The HIPC will not approve access to data beyond the current year. Requests for information into the future must be submitted as a protocol amendment to the HIPC when the data become available. MHSAL administrative data is generally organized according to fiscal years beginning April 1st through March 31st. Please mention the specific 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.

If the application is for a Program of Research, the databases and registries that will be accessed by individual projects must still be identified here. Subsequent applications for research projects within the Program can further refine these data requests.

(b) 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 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, a letter 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.

(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)?

Describe any and all planned linkages of government data with other data sources including linkages to data held by other government departments. Describe the process for linking data from varied sources.

If the external databases that are being linked to government health data contain Line-Level Data, permission from each trustee is required and a copy of the trustee's approval must be provided to the HIPC. The HIPC will not provide full approval for the project if there are any missing approvals from other trustees.

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 the HIPC.

VI. Level of Intrusion

(a) 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, 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.

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, the HIPC 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

(b) 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.

(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 MHSAL for review of confidentiality, privacy, and consistency with the HIPC approved protocol. The following timelines should be adhered to:

- An intended publication must be submitted at least **thirty (30)** calendar days prior to submission for publication in learned journals;

- Presentation material or posters must be submitted at least **ten (10)** calendar days prior to any oral presentation where such presentation material will be physically released or distributed, or posted on a website.

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

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 HIPC, a letter of support for alternative funding must be attached.

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.

For research that is funded in any way by a private industry, MHSAL has clear requirements that must be adhered to before access to personal health information will be provided. MHSAL has created guidelines for this requirement and they are available upon request from the HIPC Coordinator. The guidelines provide an arm's-length approach, in which the sponsor is not permitted to control the direction, content or outcomes of the research, and ensures that the goal of private profit is mitigated and the knowledge gained as a result of the research is to the benefit of the general public.

The Manitoba Centre for Health Policy (MCHP) has also created guidelines for private industry-sponsored research, which are consistent with MHSAL's guidelines. PIs that are conducting their projects at the MCHP must follow these guidelines, which can be found on the MCHP website:

http://umanitoba.ca/faculties/health_sciences/medicine/units/community_health_sciences/departmental_units/mchp/

Research Ethics Board (REB) approval or indication that the project has been submitted to a REB is required. The HIPC will not fully approve a project until REB approval has been provided.

If the application is for a research project within a Program of Research, a new REB approval may not be required. Please contact the HIPC Coordinator to determine if a new REB approval is required for each project within the Program.

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.

Organization or Institutional Research Review Committee approval is required from all trustees that data is being requested from (including government departments other than MHSAL and non-government organizations). For example, if linkages to a clinical patient registry are being proposed, the hospital or institution maintaining the registry must approve the linkage and/or access to the registry. Each trustee that you are seeking approval from must be indicated.

Attach a copy of all approvals to the application.

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 MHSAL.

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.

Appendix 1: Required Documents to Include in New Submissions to the HIPC	
HIPC Application Complete all questions in the application. Applications that are not completed in full will not be reviewed by the HIPC. Referencing the protocol and/or attachments is not acceptable as an alternative to completing each section of the HIPC application. All information must be typewritten. Do not use a font size smaller than 10 points. Please use simple, non-technical terms and try to avoid medical jargon and acronyms. The HIPC is made up of members with expertise across a range of areas, including public representatives. 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.	10 copies + 1 emailed copy
Data Extraction Form - List the specific information/variables that will be extracted and collected from each administrative database.	10 copies + 1 emailed copy
Conflict of Interest Disclosure Form – Only required if a research team member is aware of a conflict of interest	1 copy
Proof of Funding - Submit a copy of a letter of support from the granting agency. If grant funding has not been awarded at the time of submission to the HIPC, a letter of support for alternative funding must be attached. E.g. if internal department funds will be used in lieu of grant funding, a letter of support from the department head is required.	1 copy
Ethics Approval - Submit a copy of all research ethics board approvals. Note that a submission to a research ethics board may be made concurrently with a submission to the HIPC; however, projects will not receive final approval until the appropriate documentation is received by the HIPC Coordinator.	1 copy
Project Protocol - The HIPC requires that the information provided in the project protocol is captured in the appropriate sections of the HIPC application. In the case of discrepancy between the project protocol and the information provided in the HIPC application, the latter will prevail.	1 copy
Other Approval(s) (WRHA, CCMB, etc.) - It is the responsibility of the researcher to obtain all necessary and applicable approvals from the trustees of data that will be linked/merged with data held by the Government of MB.	1 copy
Manitoba First Nations – Health Information Research Governance Committee or Other Appropriate First Nations, Métis or Inuit Letter of Support (if applicable) - Stratification of analysis or outcomes according to First Nations, Métis or Inuit populations requires a letter of support from an appropriate First Nations, Métis or Inuit partner.	1 copy
Participant Information and Consent Form(s) (if applicable).	10 copies + 1 emailed copy
Letter(s) of Invitation to Participate - (if applicable).	10 copies + 1 emailed copy
Questionnaires and Other Material(s) to be given to participants (if applicable).	10 copies + 1 emailed copy
Other Supporting Documents	Consult the HIPC Coordinator