



Ministry of Health Policy Instrument

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ACCESS TO HEALTH DATA FOR RESEARCH

Note: The italicized text throughout the policy is intended to be explanatory.

POLICY OBJECTIVE

This policy's objective is to increase knowledge through research while appropriately protecting privacy. By assisting with the establishment of principles, facts and generalizable knowledge this policy will contribute to improvements in health care and health services, which can be expected to improve health outcomes for British Columbians. This policy at the same time provides for significant privacy protections in compliance with applicable legislative privacy requirements.

The Ministry will work collaboratively with other parties that the Ministry considers relevant to align this policy, and Ministry procedures, with other parties' policies and procedures for disclosure of data for research. Among others, the Ministry will work collaboratively with First Nations through the First Nations Health Authority to develop policies and procedures that respect First Nations data governance principles (e.g., OCAPtm) and processes in the disclosure of data for research and other purposes.

This policy acknowledges the mandate of the Data Stewardship Committee, which has a significant role in the approval of disclosure of certain data for research purposes. The Data Stewardship Committee establishes policies and procedures respecting those disclosures and the Ministry will work with the Data Stewardship Committee to align Ministry and Data Stewardship Committee policies and procedures, noting that consistency between their approaches is in the public interest.

POLICY FOUNDATION

This policy is based on the Ministry's recognition of and commitment to:

1. The significant public interest in scientific and other research and in improvements in health care, health services and health outcomes through scientific and other research;
2. Protection of privacy in relation to research, while at the same time facilitating research in a manner that is compliant with British Columbia law and consistent with accepted good practice.

This Ministry has determined that applying de-identification methods to data before disclosing data to researchers is an effective measure for protecting privacy. Because the risk of re-identification can never be entirely eliminated, the Ministry ensures that other necessary and desirable privacy-protection measures are implemented under this policy.

The above policy foundation governs the interpretation and application of this policy to all applications for access to health data for research.

This policy has been prepared in light of the *Policy on the Disclosure of Anonymized Information* published by the government's Corporate Information & Records Management Office.

This policy has been prepared in light of the guidance document *Access to Data for Health Research*, published by the Office of the Information and Privacy Commissioner for British Columbia (January 2018).

This affirms that the Ministry recognizes the public interest in research and is committed to research.

DEFINITIONS

In this policy:

“anonymization” is a de-identification process that removes or transforms all direct and indirect identifiers in a record for which there is a reasonable expectation that the identifiers could be used, either alone or with other information, to identify an individual;¹

“application” means an application to the Ministry for access to partially de-identified data or to personal information in the Ministry's custody or control for a research purpose;

“Chief Data Steward” means the individual designated as such by the Ministry or any successor in function to that role as designated by the Ministry;

“data analytics” means the use of computing technologies and techniques to discern patterns or linkages in large datasets to derive knowledge, including hypotheses;

“Data Stewardship Committee” means the data stewardship committee established under the *E-Health (Personal Health Information Access and Protection of Privacy Act)*;

“de-identification” means a process that removes, or transforms, direct and indirect identifiers in a record using methods that can include generalization, suppression, aggregation and randomization, and for unstructured data can include redacting or severing, with de-identification processes resulting in partial de-identification or anonymization;

“direct identifiers” means information that identifies an individual without additional information, with examples including an individual's name or a unique identifier such as a personal health number;

¹ An anonymized record no longer contains personal information; therefore, the privacy protection provisions contained in Part 3 of the *Freedom of Information and Protection of Privacy Act* or other applicable legislation no longer apply.

“ethics approval” means approval in writing of an application granted by the research ethics board or committee established at or recognized by a British Columbia university, hospital or health authority which has authority to provide that approval for that application;

“indirect identifiers” means information that is not a direct identifier but which may identify an individual when it is connected with other pieces of information to single out an individual, with indirect identifiers being considered personal information if they can be combined together to identify an individual, due to what is commonly referred to as the mosaic effect;

“market research” means activity conducted by or for the benefit of a for-profit organization to acquire knowledge about existing or potential customers for existing or potential products or services in an existing or new market;

“partial de-identification” means a de-identification process that removes direct identifiers and manages the indirect identifiers that could potentially be combined to identify an individual. Partially de-identified records contain personal information. Therefore, the disclosure of partially de-identified records would require appropriate authorization under Part 3 of *Freedom of Information and Protection of Privacy Act*;

“personal information” means recorded information about an identifiable individual;

“Pop Data BC” means the program of the University of British Columbia known as Population Data BC;²

“public funding” means funding from a source of public funds that includes a peer review process, with examples including the Social Sciences and Humanities Research Council of Canada, Canadian Institutes of Health Research or the Natural Sciences and Engineering Research Council of Canada, or any other similar source, and process, approved by the Ministry;

“research” means a systematic investigation designed to establish principles or other generalizable knowledge, and includes the development, testing and assessment of research;

“research program” means a sustained research enterprise that has the following features:

- (a) it comprises one or more projects that are shaped by broad objectives for the advancement of knowledge in a specified area of inquiry, though projects may not be defined at the outset, and, even if they are, they may evolve over the research period;
- (b) the projects have related research themes but may have differing data access needs, including as to data elements and time periods;
- (c) specific research approaches and methods are advanced, adopted and modified as the research proceeds and as findings are made; and

² Pop Data BC provides services to the Ministry to, among other things, ensure that researchers have timely access to de-identified Ministry data through Pop Data BC’s secure research environment and the training researchers need to undertake approved research projects.

- (d) the research enterprise has a specified maximum time limit.

SCOPE

The Ministry is responsible for applying this policy and will do so in collaboration with stakeholders and with partners as appropriate, including Pop Data BC, health authorities and the Data Stewardship Committee.

This policy applies to any proposed disclosure of Ministry data (personal information) for research purposes, but it does not apply to the disclosure for non-research purposes of personal information or partially de-identified data under an information sharing agreement or similar arrangement, or under an internal Ministry data request. Those disclosures are subject to other Ministry policies, which also will be interpreted and applied in light of the above policy foundation.

This policy does not apply to applications referred to the Data Stewardship Committee as required under applicable laws.

This paragraph clarifies that the policy does not apply to disclosure of personal information, or data, under the General Health Information Sharing Agreement or under information-sharing agreements with other organizations.

POLICY DIRECTION

Chief Data Steward's role—general

1. The Chief Data Steward:
 - (a) has the sole delegated authority to approve applications to the Ministry, but not in relation to applications that under certain applicable laws require the approval of the Data Stewardship Committee;
 - (b) has the sole delegated authority to enter into research agreements for the Ministry;
 - (c) exercises all other authority that this policy gives to the Chief Data Steward;
 - (d) is the sole authoritative source of interpretation of this policy in all cases;
 - (e) may, with the approval of the Ministry, establish policies and procedures, and forms of documents, to implement this policy;
 - (f) may give directions to Ministry employees regarding the implementation of this policy.

This section acknowledges that the Chief Data Steward's authority to approve applications under this policy does not extend to applications that must be approved by the Data Stewardship Committee approval under certain of the applicable laws.

General application of this policy

2. This policy applies in all circumstances, subject to the following:

- (a) where this policy expressly authorizes a variation from this policy, that can only be done by the Chief Data Steward where he or she considers that there is clear justification in the circumstances, as an exceptional matter;
- (b) the Chief Data Steward may add a requirement that is not expressly provided for in this policy where she or he considers it necessary or desirable in the circumstances.

The reason for this is obvious, but it also helps align this policy, in practice, with other policies and procedures for access to Ministry data. An example is where this policy provides that the Ministry may accept an application in another form or through another process, which can accommodate disclosure to another public body or public agency not otherwise covered below.

Disclosure of data

- 3. The Ministry will disclose data from which direct identifiers have been removed, and will disclose personal information, only on the conditions set out in this policy.

This underscores the fact that the policy is aimed at the vast majority of data access requests, which are for “data” provisioned through Pop Data BC, from which direct identifiers have been removed. The discretion of the Chief Data Steward to approve access to fully-identifiable personal information recognizes that in some cases access to fully-identifiable personal information may be warranted, subject to compliance with the other conditions set out in this policy. This section does not affect the discretion of the Data Stewardship Committee under certain of the applicable laws to approve access to fully-identifiable personal information.

Application requirements—general

- 4. An application must be made in a form approved by the Ministry. In the case of an application for access to partially de-identified data, the application must make use of the data checklists approved by the Ministry and published on Pop Data BC’s website. The Ministry will not consider an application unless the application is complete in accordance with the Ministry’s requirements, or the Chief Data Steward has approved disclosure pursuant to an application made in another form or through another process approved by the Chief Data Steward.

This reflects long-standing Ministry policy and practice. However, this gives the Chief Data Steward discretion to allow another form of application, outside the Pop Data BC and Ministry process, in exceptional cases. The Chief Data Steward has been designated to ensure that only one senior official in the field has this role. This ensures that relevant expertise and experience are applied, and that there is consistency (although few of these exceptions are likely).

Application requirements—specific

- 5. Unless an alternative application has been approved by the Chief Data Steward under section 4, an application must meet all the following conditions to be approved:

- (a) the applicant must be one of the following:
 - (i) an individual who has an academic appointment at a university or college in Canada;
 - (ii) a graduate student enrolled in a university or college in Canada whose application has been approved in writing by the student's academic supervisor;
 - (iii) a health care professional who is employed by, or has privileges within, a British Columbia health authority;
- (b) the research described in the application must have been granted ethics approval;
- (c) the research described in the application must either have been granted public funding approval in writing or otherwise be publicly funded as established to the Ministry's satisfaction, or meet the requirements in paragraph (d) of this section;

These provisions reflect long-standing Ministry practice. They provide assurance that proposed research has merit. Requiring ethics approval is consistent with the requirement by public funding agencies such as the Canadian Institutes of Health Research for ethics approval, noting that a university will generally require ethics approval for research proposed by an academic at the university.

At the same time, the Ministry does not assess the scientific merit of an application. It does not assess the merits of the research methodology. It does not assess whether the research is in the public interest. They are also consistent with best practices elsewhere in Canada.

- (d) despite paragraph (c) of this section, if the research has received funding approval in writing from a for-profit organization, the Chief Data Steward may approve the application if:
 - (i) the application complies with the rest of this policy and does not involve market research;
 - (ii) no for-profit organization will: have access to any Ministry data; have any role in the conduct of the research; attempt to influence, or have any role in, publication of research outcomes, including advance approval of publication;
 - (iii) the applicant has entered into an agreement in writing with the Ministry requiring that the results of the research be made publicly available, including by publication in an academic journal or by the Ministry making the results publicly available, on terms acceptable to the Ministry in its sole discretion;
 - (iv) the requirements of clauses (i) and (ii) of this paragraph are secured to the Ministry's satisfaction, including by an agreement in writing with the funding for-profit organization or another organization, or, where the Chief Data Steward requires it, with a public body with which the applicant is affiliated or that employs the applicant, or any combination of the foregoing; and

- (v) if the Ministry requires it, the research described in the application has received peer review satisfactory to the Ministry.

The Ministry approves industry-funded research where the other conditions in this policy are met. This paragraph, and the definition of “market research” set out above, clarify how and when this is done.

Disclosure of data

6. The Ministry is not required to approve disclosure of data or of personal information, but may do so in accordance with the following provisions, as applicable:
 - (a) in the case of data from which direct identifiers have been removed, the Ministry will only approve disclosure of the data that are reasonably necessary to conduct the proposed research, and, in assessing whether the requested data are reasonably necessary, the Ministry will:
 - (i) consider the significant public interest in research and the privacy protections that will be put in place under this policy, and that exist under applicable laws;
 - (ii) consider the characteristics of “research” and “research program”, as defined in this policy, as considerations in the assessment of what is reasonably necessary;
 - (iii) consider whether the requested data are sufficiently relevant and proportional to the research as to be reasonably conducive to its successful conduct;
 - (b) in the case of personal information that contains direct identifiers, the Ministry will only approve disclosure where the research cannot reasonably be accomplished without disclosure of personal information, and then will only approve disclosure of the personal information that is reasonably necessary, determined in accordance with paragraph (a) of this section, and in compliance with the rest of this policy.

*This paragraph ensures that the Ministry’s decision as to what data are “necessary” for an application does **not** require the applicant to demonstrate that each data element is indispensable to the proposed research. Such a strict approach is not required by the applicable laws and it is not Ministry policy. Nor does core government policy require such a strict approach. This has been confirmed by the central government agency responsible for privacy matters. This policy is consistent with practices elsewhere in Canada.*

Further, this policy recognizes that, under this policy, researchers only have access to data from which direct identifiers have been removed, subject to exceptions approved by the Chief Data Steward under this policy. In addition, the other protections implemented under this policy guard against inappropriate actions by researchers. These include use of the secure research environment at Pop Data BC, the requirement for a research agreement, required privacy training, and the fact that approval is generally limited to academic research (with public funding and ethics approval).

Approval of research programs

7. The Ministry may approve an application for disclosure of partially de-identified data for the purposes of a research program, but unless extended under this policy the maximum life of the approval is 60 months after the approval date. The application must comply with all the other requirements of this policy, and any other requirements of the Ministry or of Pop Data BC, or both, as well as these requirements:
 - (a) relating to notice in writing to the Ministry, in reasonable detail, about each project comprised in the research program before the project proceeds;
 - (b) relating to any possible application to extend the maximum life of the approval;
 - (c) approval of any requested changes to the research program or to projects within it, or both.

The advantage of this policy is that it enables better use of the Ministry's rich trove of data, using data analytics, to create knowledge that will lead to further research. The other protections under this policy continue to apply. This policy is consistent with the policy of CIHR and Statistics Canada to approve research programs.

Research agreement is required

8. The Ministry will not permit disclosure to an applicant until the applicant has entered into a research agreement with the Ministry in a form required by the Ministry. The Ministry may require others, including other researchers involved in the research, to agree to be bound by the research agreement.

*This is a long-standing Ministry policy and is legislatively required where the Ministry discloses personal information for a research purpose. The Ministry's template research agreement **includes** the following provisions: all research team members must have completed privacy training satisfactory to the Ministry; prohibition from contacting individuals whose information has been disclosed; any attempt to identify or re-identify individuals using the Ministry's data, alone or in combination with other information, is prohibited; requirement to destroy individual identifiers, if any, at the earliest practicable opportunity; any subsequent use or disclosure of information in individually-identifiable form is prohibited; a requirement to implement reasonable security measures to protect the information; publication of any information derived from, or disclosing, the data in cell sizes less than prescribed in the agreement is prohibited.*

How data are accessed

9. The Ministry will not disclose partially de-identified data to an applicant by giving the applicant a copy. The applicant will instead be required to access the partially de-identified data, and perform the research, using a secure analysis environment acceptable to the Ministry (including the secure research environment maintained and operated by Pop Data BC), and to comply with any requirements associated with the use of the designated environment and with any requirements that the Ministry may direct.

However, the Chief Data Steward may permit disclosure of a copy of partially de-identified data, subject to such conditions (including as to technical and administrative security) as the Chief Data Steward may require. Further, for clarity, this policy does not apply to disclosure of personal information or data for a research purpose when the disclosure is to a public body or public agency under an information-sharing agreement, information sharing plan, or any other method approved by the Chief Data Steward.

In almost all cases, researchers are required to access the approved data only through Pop Data BC's secure research environment. In exceptional cases where data are disclosed to the researcher, the other protections under this policy apply and the Chief Data Steward may impose other requirements. The last sentence of this section clarifies that where data are disclosed to health authorities or other public agencies for research-related purposes, or planning and evaluation purposes, this is done under an information-sharing agreement or information sharing plan.

Applications to amend approvals

10. The Ministry may approve an application for amendment of an approved research application where the applicant wishes to obtain different data or to obtain the same data for different periods. The amendment application must describe the proposed changes in reasonable detail. The Ministry will approve the amendment application only if it complies with the rest of this policy and it involves no other changes to the original approved application. The Chief Data Steward may permit other changes. For clarity, this section applies to applications to extend the maximum time limit of a research program.

MONITORING AND EVALUATION

The performance indicators for implementation are as follows:

1. The target for Ministry approval of an application is a maximum of 30 days from the date on which the Ministry receives it.
2. The target for Ministry approval of an amendment application is a maximum of 10 days from the date on which the Ministry receives it.
3. The Ministry will work with Pop Data BC to attempt to provide researchers with access to data through Pop Data BC in as timely a manner as is reasonably practicable after the date on which the Ministry approves an application, and will work with Pop Data BC to establish service level parameters in this regard. For clarity, this section creates no legal or other duty or obligation on the part of the Ministry or Pop Data BC.

The Ministry will track performance against the above indicators, and the time it takes for the Ministry to approve an application, measured from the date of submission to the date of the Ministry's approval, and publish them on a calendar quarter and calendar basis. The Ministry also will work collaboratively with stakeholders and partners as appropriate, including the Data Stewardship Committee, Pop Data BC, health authorities and researchers, to create other meaningful performance indicators and to track performance and publish the results.

REVIEW & QUALITY IMPROVEMENT

1. This policy will be refreshed as needed and reviewed two years from the 1st of August, 2018.
2. This policy may also be reviewed as determined through consultation between the Ministry and external stakeholders.