

DATA STEWARDSHIP COMMITTEE

Policies Respecting the Disclosure of Information

Table of Contents

POLICIES	1
Policy Objective.....	1
Policy Foundation	1
Definitions	1
Policy Direction	3
Consideration of Requests	3
Funding	3
Conflict of Interest	4
Data Linkage.....	4
Disclosure of Data	4
Research Agreement.....	5
Data Access	5
Research Program	5
Student Research	6
Amendments.....	6
Extensions	7
Publication	7
Notification of material changes.....	8
Policy Review	8

POLICIES

Policy Objective

These policies, established by the Data Stewardship Committee (DSC), set out the foundational principles and rules to be applied by the DSC when considering requests for the disclosure of protected information for research purposes. The policy statements are intended to ensure that requests are evaluated in an objective and consistent manner that facilitates timely researcher access to data while appropriately addressing security and confidentiality considerations.

These policies fulfil the requirement in Section 13 (2) of the *E-Health (Personal Health Information Access and Protection of Privacy Act)* that stipulates that the DSC must establish policies and procedures respecting the disclosure of information from health information banks or PharmaNet for a health research purpose.

Policy Foundation

This policy is based on the DSC'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.

The above policy foundation governs the interpretation and application of this policy to all requests for access to protected information for a health research purpose.

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) as well as the Ministry of Health's *Access to Health Data for Research Policy* (September 2018).

Definitions

In this policy:

“conflict of interest” means circumstances that create a risk where professional judgments or actions regarding a primary interest may be unduly influenced by a secondary interest;

“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;

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

“health information bank” means a database containing personal health information that has been designated by the Minister of Health as a health information bank. As of January 2019, designated health information banks include the provincial laboratory information solution, the provider registry system, and the client registry system/electronic master patient index.

“individual 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;

“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;

"personal health information" means recorded information about an identifiable individual that is related to the individual's health or the provision of health services to the individual;

“PharmaNet” means the information management technology and associated databases operated by the Ministry of Health and prescribed under the Pharmaceutical Services Act.

"protected information" means personal health information, or information related to a health service provider, that is contained in a health information bank or ministry database;

“PopData BC” means the program of the University of British Columbia known as Population Data BC. PopData BC provides services to the Ministry of Health to, among other things, provide researchers access to protected information through PopData BC’s secure research environment (SRE) and the training researchers need to undertake approved research projects;

“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, the Natural Sciences and Engineering Research Council of Canada, or any other similar source, and process, approved by the Ministry of Health;

“record-level data” means data in which each record is related to a single individual;

“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 multiple projects that are shaped by broad objectives for the advancement of knowledge in a specified area of inquiry, though all 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

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

“request” means a data access request submitted to the DSC for the disclosure of protected information, from a health information bank or PharmaNet, for a health research purpose.

Policy Direction

Consideration of Requests

3. The DSC will only consider requests under the following conditions:
 - (a) the request has been submitted in the manner required by DSC;
 - (b) the request is complete and includes all information required by DSC for the purposes of evaluating the request;
 - (c) the research described in the request has been granted ethics approval;
 - (d) the research described in the request has received peer review satisfactory to the DSC; and
 - (e) each person identified as requiring access to the protected information requested is one of the following:
 - (i) a person who has an academic appointment at a university or college in Canada, or an institution deemed acceptable by the DSC¹; or
 - (ii) a graduate student enrolled in a university or college in Canada whose request has been approved in writing by the student’s academic supervisor; or
 - (iii) a health care professional who is employed by, or has privileges within, a Health Institution in Canada²; or
 - (iv) a person with other public research affiliations acceptable to the DSC.
4. A request to disclose protected information outside Canada will only be considered where there is express written consent to the disclosure from each person who is the subject of the protected information.

Funding

5. The sources of funding for research must be established to the satisfaction of the DSC, such that:
 - (a) the request must provide full transparency into all sources of funding related to the research, including documented evidence of any approved public funding,
 - (b) where any portion of the research funding is from a for-profit organization or individual:

¹ The institution can demonstrate, to the DSC’s satisfaction, that they do independent research and that they can ensure the integrity of the research process and outcomes.

² For example, BC Health Authorities or Ontario Local Health Integration Networks (LHINs)

- (i) the request must comply with the rest of this policy and must not involve market research; and
 - (ii) no for-profit organization or individual will have a direct contractual relationship with any member of the research team, have access to any protected information, have any role in the conduct of the research, attempt to influence the research, or have any role in the publication of research outcomes, including advance approval of publication.
 - (iii) The DSC may, at its sole discretion, request a written declaration of research independence from an identified for-profit funder.
6. The DSC must be notified if any additional sources of funding are added subsequent to DSC approval of a request.

Conflict of Interest

7. As part of a request, researchers and their affiliated organizations must declare any potential conflicts of interest.
8. Where conflicts of interest may exist:
- (a) the DSC will consider its response on a case by case basis, based on the policy foundations established in this policy; and
 - (b) the researcher may be required to submit a conflicts management plan to the satisfaction of the DSC.

Data Linkage

9. The DSC will approve requests that include linking personal information with other data only if the DSC determines that any proposed data linkage is not harmful to the individuals who are the subjects of the personal health information, and the benefits to be derived from the record linkage are clearly in the public interest.

Disclosure of Data

10. The DSC will only consider the disclosure of record-level data under the following circumstances:
- (a) where the research cannot reasonably be conducted using aggregated data, or through access to data from sources other than health information banks or PharmaNet.
 - (b) if the data is contained in a health information bank, the disclosure is authorized under the terms of a designation order.
11. Where a requirement for record-level data has been established to the satisfaction of the DSC, the DSC will, by default, approve the disclosure of record-level data that has been de-identified;
12. The DSC will only consider the disclosure of record-level data that includes individual identifiers on an exception basis, under the following conditions:

- (a) the research cannot reasonably be conducted using record-level data that has been de-identified;
 - (b) the individual identifiers must be removed or destroyed at the earliest reasonable time; and
 - (c) the data cannot be used to contact a person to participate in the research, unless approved by the Information and Privacy Commissioner for BC.
13. In assessing whether requested data are reasonably necessary, the DSC will:
- (a) 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;
 - (b) consider the characteristics of “research” and “research program”, as defined in this policy, as considerations in the assessment of what is reasonably necessary;
 - (c) consider whether the requested data are sufficiently relevant and proportional to the research as to be reasonably conducive to its successful conduct.

Research Agreement

14. Where the DSC has approved a request, the data will only be disclosed where the requestor has entered into a Research Agreement as required by the Chief Data Steward.

Data Access

15. Where the DSC has approved a request and the researcher has entered into a Research Agreement, the requestor will be provided access to data via a secure environment designated by the DSC, unless otherwise permitted under sections 16 and 17 below.
16. The DSC will only consider exceptions where:
- (a) rationale has been provided detailing why the research cannot reasonably be conducted using the environment designated by the DSC; and
 - (b) it can be established to the satisfaction of the DSC that it is in the public interest to allow access outside of the environment designated by the DSC.
17. Where the DSC approves the disclosure of data outside of the environment designated by the DSC, the manner of access must be acceptable to the Ministry of Health and must be detailed in an approved Research Agreement.

Research Program

18. The DSC will consider requests in support of a research program under the following conditions:
- (a) The requestor has demonstrated their ability to fulfill data stewardship responsibilities regarding sensitive data by successfully completing one or more research projects using data provisioned by the DSC;

- (b) the requestor has committed to perform the role of “Principal Investigator”, responsible for determining the overall direction of the program of research and all component projects;
 - (c) the requestor has defined a minimum of two projects under the research program;
 - (d) the request complies with all the other requirements of this policy, and any other requirements of the Ministry of Health; and
 - (e) all component projects have:
 - (i) related research themes leading to the advancement of knowledge in a specified area of inquiry;
 - (ii) generally similar data requirements such that the research program may be conducted using a common data set;
 - (iii) ethics approval;
 - (iv) sufficient funding for the duration of the project; and
 - (v) received peer review satisfactory to the DSC.
19. DSC approval for research programs will have a maximum duration of 60 months, unless extended under this policy. The DSC will conduct a full review of any research program prior to considering the approval of an extension.

Student Research

20. Requests for data access for student research will only be considered by the DSC if the request is submitted by the student’s supervisor:
- (a) A student’s supervisor must submit a request on behalf of the student; or
 - (b) Where the student’s supervisor has an existing approved request, the supervisor can submit an amendment request to the DSC for approval to provide the student access to the data. However, if the proposed student research is inconsistent with the objectives of the original approved request, the supervisor must submit a new request.
21. Any change to a student’s supervisor requires the submission of an amendment request to the DSC.

Amendments

22. The DSC may approve an amendment to an approved project where the researcher wishes to:
- (a) access different data than originally approved; or
 - (b) access additional data to the data originally approved (e.g. additional years of data); or
 - (c) include additional research questions not set out in the original request.
23. The DSC will approve an amendment to an approved project only where the proposed changes:
- (a) are described in sufficient detail to enable the DSC to conduct an informed evaluation;

- (b) will provide clear public value;
- (c) are consistent with the original objectives of the research;
- (d) do not require a replacement of the original research cohort;
- (e) can be sustained using existing funds; and
- (f) comply with the rest of this policy.

24. The DSC may, at its sole discretion, require the submission of a new request.

Extensions

25. The DSC may grant only **one** extension to a previously-approved request for access, for a period up to the original approved data retention period, not to exceed five years. Requests for extensions may be approved where:

- (a) there is clear public value from the extension;
- (b) demonstrated progress towards the research objectives has been made;
- (c) funding for the period of the extension is in place;
- (d) the goals of the extension are clearly consistent with the original objectives of the research; and
- (e) it is reasonable to believe that outstanding project activities will be completed within the extension period.

Publication

26. Where the DSC approves a request, upon the completion of the project the DSC requires the researcher to:

- (a) submit a publication to a peer reviewed journal, and provide a copy of the acceptance or rejection letter to the DSC; and
- (b) submit to the DSC a final summary report of the outcome of the research for publishing on a website designated by the DSC for that purpose. This could be in the form of a report submitted to the funding agency; or
- (c) where (a) and (b) are not possible, the researcher must submit a letter to the DSC that explains how the research was in the public interest, and why they were not able to publish the research outcomes.

27. Where the publication requirements of this policy have not been satisfied to the satisfaction of the DSC, the DSC may, at its sole discretion, deny future requests submitted by members of the research team.

Notification of material changes

28. The requestor is required to notify the DSC of any changes to the members of the researcher team, persons who will access the data, funding sources, and conflicts of interest, that may arise during the course of the data retention period.

Policy Review

The policy will be reviewed within three years of the approval date.

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