

Research Data Access Framework

Glossary

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| Data Access Request | An application for data held at Population Data BC. This request includes researcher and analyst information, project details, cohort details, fields and files requested, data protection plans, and supporting documents. It is this document that is reviewed by Data Stewards. If approved, a Research Agreement is entered into between the Public Body and researcher(s). |
| Data Preparation Fee Agreement | An agreement between the researcher and Population Data BC for cost recovery for the preparation of data for the approved Data Access Request. |
| Data Steward | The position that is responsible for the stewardship of a Public Body's data holdings, usually including approval of requests for access to data for research purposes. |
| Geomatics | The discipline of gathering, storing, processing, and delivery of geographic information, or spatially referenced information. |
| Identifiers | Information that identifies an individual or for which it is reasonably foreseeable in the circumstances of use that could be utilized, either alone or with other information, to identify an individual. |
| Information Sharing Agreements | For the purposes of Population Data BC, the agreement under the authority of the <i>Freedom of Information and Protection of Privacy Act</i> (i.e., a data contract) between the Public Body which is the steward of the data and the University of British Columbia that sets out the terms and conditions of data sharing and uses between those bodies. The ISA also includes provisions related to security controls and data linkages to ensure legislative compliance. |
| Privacy Impact Assessment | A requirement under the <i>Freedom of Information and Protection of Privacy Act</i> that provides a formal assessment of a new enactment, system, project or program to ensure compliance with Part 3 (Privacy) of the legislation . |
| Public Body | "Public Body" refers to an organizational entity, and is in contrast to private corporation or company. FIPPA defines Public Body as: (a) a ministry of the government of British Columbia, (b) an agency, board, commission, corporation, office or other body designated in, or added by regulation to, Schedule 2 of FIPPA, or (c) a local public body but does not include (d) the office of a person who is a member or officer of the Legislative |

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| | Assembly, or (e) the Court of Appeal, Supreme Court or Provincial Court. |
| Research Agreement | An agreement between a researcher and the Public Body responsible for the data that sets out the terms and conditions of access to information for research purposes, including specific conditions on use, disclosure, retention, and final disposition of the data pursuant to FIPPA section 35. |
| Research Extract | Data that are extracted and prepared by Population Data BC for the purpose of disclosure to a researcher for an approved research project. This requires the existence of an approved Research Agreement. |
| Secure Research Environment | A computer server for the storage of and secure remote access to approved Research Extracts, for purposes of data analysis. |

1. Introduction to Population Data BC

Population Data BC, a multi-university platform, is BC's first pan-provincial population data service. It is a nationally active and recognized data and education resource that facilitates interdisciplinary research and teaching on the determinants of human health, well-being and development.

Population Data BC acts as:

- A **research resource** in the form of data linkage, development, and access to what is expected to be the world's most comprehensive data source for population research, bringing in data sets from education, early childhood development, work place, health and the environment. Population Data BC will also support the integration and use of geomatics in population research
- A **space and place** which brings together researchers across disciplines and geographies to expand our understanding of what contributes to the health, well-being and development of a population, and
- A comprehensive **education and training service** on how to use population data

While respecting and adhering to legislation, policies, and protocols governing access to sensitive information and protecting individual privacy, Population Data BC's work will strive to facilitate and expedite:

- Researchers having timely access to data and training
- Researchers accessing data that address research questions on human health, well-being and development, and
- Research using data to inform policy-making that leads to healthier communities

Population Data BC values:

- Research conducted in the public interest
- The highest ethical standards and privacy sensitive practices
- Being responsive to the research community, policy makers, and changes in technology
- Adroit communications and transparency
- Commitment to timeliness and accuracy in data provision, and
- Active learning – constant improvement

2. Purpose of Research Data Access Framework

Population Data BC holds population-wide individual-level data to develop linkages among these data, and to support access to these data for approved research purposes. Population Data BC is authorized to receive, store, manage, manipulate and further disclose data through Information Sharing Agreements with the Public Bodies that provide the data, as outlined in Population Data BC's Privacy Impact Assessment. Population Data BC serves as a facilitating and coordinating third party for the creation of this resource for the research community.

The purpose of this framework is to provide a transparent mechanism for enabling access to data for research purposes while preserving the integrity and confidentiality of the data and retaining the integrity of data stewardship of the Public Bodies. This framework outlines general considerations in the adjudication of Data Access Requests.

The principles that inform this framework are:

- Interest in supporting research and expanding the data sources available for research purposes,
- Access to and use of data must conform with legislative and policy requirements of the Public Bodies responsible for the data,
- All parties recognise their own and each other's obligations and responsibilities
- Access to and use of data must also conform to provisions of Information Sharing Agreements and Research Agreements,
- Clarity and transparency of the data access review process and procedures will benefit all those involved,
- The principle of proportionality as referred to in the Tri-Council Policy Statement¹ informs review of applications; in general, the level and extent of review should be proportionate to the sensitivity of data requested
- The framework will seek to be comprehensive and iterative in terms of requirements and restrictions for Data Access Requests,
- Any processes and procedures should be reasonable from the perspective of time and cost both for implementation and ongoing operations,
- The Research Data Access Framework will be treated as a "living document" and will benefit from the experiences of all Data Stewards, which will be incorporated as part of periodic reviews and revisions by the Data Stewards Working Group (at minimum on a bi-annual basis) and where new legislative or government policy requirements necessitate revisions.

3. History and Legislative Framework

The data access considerations contained herein build on data access documents from other local, national and international institutions, including the "Data Access Policy" that governed access to data from the BC Linked Health Database (BCLHD) from 1996 through 2009. The BCLHD was originally a cooperative venture between the British Columbia Ministry of Health Services and the Centre for Health Services and Policy Research, and later expanded to include the Vital Statistics Agency, BC Cancer Agency and WorkSafe BC.

¹ *"Proportionality is the key to ensuring that those who volunteer to participate in research are not exposed to unnecessary risks, while at the same time avoiding the creation of unnecessary barriers or delays to research."* Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 1998 (with 2000, 2002 and 2005 amendments).

Access to data from public bodies for research purposes is governed by a variety of legislation and supporting policies, including the BC's *Freedom of Information and Protection of Privacy Act* (FIPPA), initially proclaimed in 1993. This Act provides individuals with personal information privacy rights and, under specified circumstances, access to personal information that is collected or controlled by public bodies in British Columbia. Government ministries, provincial agencies, and universities are all considered public bodies. Population Data BC, as partnership within BC universities, is bound by the same provisions as its "parent" organizations, under the *Freedom of Information and Protection of Privacy Act*. The Information Sharing Agreements, such as the one between the University of British Columbia and the Ministry of Health Services, detail the authorities and legal terms and conditions for the collection, use, and disclosure of personal information between these two public bodies. Population Data BC is covered by these provisions.

In compliance with statutory requirements, Population Data BC has completed a Privacy Impact Assessment that outlines its privacy and security compliance, including detailing its risk management framework, consisting of accountability and advisory input, physical security, network security, and human resource controls.

4. Eligible Research

Access to data for research purposes under the *Freedom of Information and Protection of Privacy Act* is approved by the Data Steward of the Public Body responsible for the data. Each application is assessed on its own merits.

To be considered for approval by the Public Body, a Data Access Request must:

- Be for the time-limited purpose of addressing a specific set of research questions,
- Not involve use of data for administrative or any other non-research purpose, or for ongoing programs of research, unless specifically approved,
- Be in the public interest, for example, improves the welfare of the population,
- Not be proprietary research such as research done for commercial marketing purposes,
- Have scientific merit,
- Have approval from a recognized Research Ethics Board, as defined by the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*.

Scientific merit is met if the research is funded by a recognized granting agency, such as Social Sciences and Humanities Research Council of Canada, Canadian Institutes of Health Research, or Natural Sciences and Engineering Research Council of Canada. In the case of graduate students, a letter from the supervisor supporting the research must be provided and serves the purpose of proof of scientific merit. In the absence of peer review funding, the relevant Data Steward(s) can request a one-off peer review to determine eligibility, at its discretion.

It should be noted that the above requirements are necessary for review, but may not be sufficient, in and of themselves, for approval by the Data Steward of the Public Body. Additional requirements may arise that are project specific, and this framework may be updated with such requirements as they become relevant and routine.

5. Eligible Researchers

A researcher is:

- Either a student, teacher, or other individual enrolled, appointed or employed by any of the following:
 - a university, where the university status is defined under the *BC University Act*,
 - a college, university college or provincial institute as defined under the *Colleges and Institute Act* R.S.B.C. 1996, c. 52,
 - the Open Learning Agency as continued under the *Open Learning Agency Act* R.S.B.C. 1996, c. 34,
 - Royal Roads University continued under the *Royal Roads University Act* R.S.B.C. 1996, c. 409,
 - another equivalent educational institution in another jurisdiction outside B.C. but within Canada.
- Any other individual agreed to by the relevant Data Steward of the Public Body.

6. Coordination and Intake of Data Access Requests

Population Data BC is a central entry point for access to research data administered by Population Data BC. Population Data BC's specific activities in support of Data Access Requests include:

- Providing information and coordination support to facilitate researchers preparing Data Access Requests, such as guidance on data sets, years, fields, and development of the cohort definition,
- Confirming research team composition and ensuring all have completed confidentiality undertakings,
- Undertaking preliminary review of Data Access Requests to ensure that applications include all required documentation and information (e.g., ethics review is current and relevant to the project requesting data, investigators are consistently identified, etc.),
- Forwarding Data Access Requests to the relevant Data Steward(s) for full review and approval,
- Facilitating communications and additional requirements as necessary and appropriate and to enable timely responses.

7. Data Access Request Adjudication Process

Population Data BC supports the Data Access Request process by facilitating the submission of completed Data Access Requests to the appropriate Data Steward(s).

Data Access Requests are assessed on their individual merits.

Among the criteria considered by public bodies when reviewing a request for research Data Access Request are those established under Section 35 of the *Freedom of Information and Protection of Privacy Act*, such as:

- Demonstrated reasonable need for the requested data to answer the specified research question(s),
- The record linkage and/or use of data is not harmful to the individuals that the information is about,
- The proposed research and the benefits of record linkage are clearly in the public interest,
- Scientific merit (peer- or merit-reviewed), and
- Ethical considerations
- The suitability of any consent documents

Applications for linkage of Data not administered by Population Data BC

A Researcher may request linkage to data not administered by Population Data BC. There are two likely types of data sources to which a Researcher would seek linkage: a) data from a Public Body which is not covered by an Information Sharing Agreement with Population Data BC b) Researcher-collected data.

Data from a Public Body which is not covered by an Information Sharing Agreement with Population Data BC

For linking to data from a Public Body, the review process would be substantially similar to that established for data administered by Population Data BC, with Data Stewards performing their adjudication function, and the Researcher Liaison Unit coordinating the application and review process. Population Data BC would additionally require an Information Sharing Agreement which may be limited to the single research project in order to have data transmitted to Population Data BC.

Researcher-collected data

For linkage to Researcher-collected Data, there will be additional requirements for review:

- Compliance with relevant legislation(s) for Researcher-collected data must be considered prior to application. For example, data originally collected from a physician who is not employed by a public body will need to be in compliance with the *Personal Information Protection Act (PIPA)*, in addition to meeting the requirements of FIPPA, upon approval from the public body for data linkage.
- Assessment of privacy risks related to linkage of Researcher-collected Data to additional data: the Researcher will need to describe the potential privacy risks in performing the proposed linkage. This will be done through an appendix to the Data Access Request which includes items common in a Privacy Impact Assessment.
- Informed consent or its waiver: The Researcher will need to provide evidence of written, informed consent to link the researcher-collected data for the specified research

purposes. If consent has not been obtained, the Researcher will need to provide an explanation and a justification for why consent should be viewed as impracticable.

It is recommended that Researchers submit the aforementioned additional requirements to Population Data BC prior to Data collection or pursuit of the research project, so that Population Data BC together with the Data Stewards can ensure the relevant information is collected according to a suitable process for subsequent Data Access Requests.

If consents and relevant legislation allows, and the data are of sufficient interest, in the above cases Population Data BC may choose to initiate discussions with the Public Body or the Researcher in order to support these data to being made available for access by other Researchers via Population Data BC. This would involve negotiation of Information Sharing Agreement(s).

8. Approval and Receipt of Data by Researchers

Once a Data Access Request is approved by the Data Steward, researchers enter into a Research Agreement with each relevant Public Body and a Data Preparation Agreement with Population Data BC. Data preparation is the process of finalizing the data for the study population/cohort(s) of interest as well as extracting the data for these population(s) in accordance with the approved Data Access Request, including setting up any needed documentation.

With limited exceptions as approved by the public bodies, the Research Extracts will be stored on the Secure Research Environment provided by Population Data BC. Access to these data will be provided only via encrypted Virtual Private Network-type services, through a firewall and use of a SecurID token for authentication. The Secure Research Environment will provide storage and back up of data while in use for the approved purposes, as well as analytical software necessary for the research process.

9. Expectations and Responsibilities of Researchers

Through the Research Agreement and Data Preparation Agreement, the researcher agrees to all conditions of use set by the public bodies that retain stewardship of the data, which may include (but are not limited to) the following:

- Data are to be used only for the research questions approved by the Data Steward in the Research Agreement,
- Data will be retained for a limited time, normally set at an initial two years, with the possibility of extension with approval of the public bodies,
- Any requested changes to the research question(s), researcher(s) or time frames are submitted to Population Data BC for review by the public bodies,
- Research Ethics Board approval certificates must remain current throughout this data retention period,

- Data are to be accessed only by named staff who have signed pledges of confidentiality, and who have undertaken privacy training provided by Population Data BC,
- All Pre-publication materials must be submitted for review by public bodies prior to seeking publication, the Public Bodies commit to review within 45 calendar days. Researchers are eligible to proceed with publication if there is no response within the given time frame,
- Researchers will be asked to participate in the Population Data BC library and bibliography, to be accessed via Population Data BC's website, and participate in Population Data BC's data documentation efforts by contributing data analysis concepts and related code fragments, which will also be made available to the public bodies, and
- Researchers will provide timely payment of the specified cost-recovery charges for data preparation and corresponding data services.

10. Expectations and Responsibilities of Population Data BC under this framework

Population Data BC will undertake the following broad responsibilities:

- Adhere to the Population Data BC Privacy Impact Assessment,
- Adhere to all requirements of all bilateral Information Sharing Agreements,
- Support the research community by supporting access to linkable data in a privacy sensitive manner,
- Provide access to approved Research Extracts as authorized,
- Provide timely service to the research community, and
- Collaborate with participating Data Stewards and public bodies, as required.

If Population Data BC learns of or suspects non-compliance with a Research Agreement, Population Data BC will immediately notify all relevant public bodies that are responsible for the response. Examples of possible responses may include any or all of the following, plus other remedies available under the terms of Research Agreements or under law, at the discretion of the public bodies:

- Immediate termination of access to the Secure Research Environment,
- Suspension and / or revocation of data access approval,
- Denial of any further access to Population Data BC's data holdings or other data holdings of the Public Body,
- Reporting of non-compliance to the researcher's home institution,
- Reporting of non-compliance to the Research Ethics Board that provided approval for the project,
- Reporting of non-compliance to all agencies that provided funding for the project.
- Reporting of non-compliance to any organizations who have published findings from the study.

11. Expectations and Responsibilities of Public Bodies

The role of the public bodies in relation to Population Data BC, will be to:

- Maintain stewardship and control of the data,
- Provide data to Population Data BC as outlined in the relevant Information Sharing Agreements,
- Commit to timely review of Data Access Requests,
- Communicate and discuss the development of policies, guidelines, or processes for access to data, through the Data Stewards Working Group, and
- Ensure Population Data BC's policies, processes and practices support the needs of the Public Body.