

Data Access Request Manual

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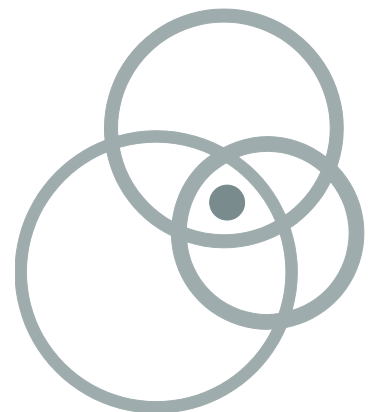


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The Data Access Request application form (“DAR”) has been developed and approved by the Data Stewards participating in Population Data BC. It is intended to be used to request data administered by Population Data BC as well as for data requests that involve linkage to **External Data**. (Definitions of this and other terms in bold typeface can be found at the end of this document.)

All requests for data are adjudicated by **Data Stewards** who in turn are bound by BC’s *Freedom of Information and Protection of Privacy Act* and other relevant laws and regulations of the Province, and ethical guidelines. Population Data BC works on behalf of Data Stewards and Researchers to help with the process, but has no role in the actual adjudication of requests. A **Research Data Access Framework** presents principles and responsibilities in the Data Access Request process. Researchers are encouraged to familiarize themselves with the **Research Data Access Framework** before submitting applications for data. See <http://www.popdata.bc.ca/dataaccess/rdaf> for complete document.

PLANNING AND COMPLETING A DATA ACCESS REQUEST

Why is a DAR form needed?

Data Stewards require specific information about your project in order to adjudicate it. Population Data BC staff also need specific information in order to prepare data, once a DAR is approved. The DAR is designed to collect and present this information in the most efficient manner possible.

A summary of the DAR Process

You may already have funding for your project and an ethics certificate. The data access request process is dependent on but separate from those pieces. Data access approval is not automatic and must be taken as seriously as those other steps. Completing a DAR takes time, planning, and attention to detail, as they are reviewed thoroughly.

The application process requires that researchers:

- Become familiar with all material outlining access requirements, data holdings, study population definitions, and privacy considerations, as presented on the Population Data BC website
- Ensure that the ethics and peer review requirements of the **Data Steward(s)** have been met
- If **external data** is to be used, ensure that the appropriate applications and approvals are sought, including linkage requirements
- Submit a completed DAR to Population Data BC, including all required attachments
- Work with Population Data BC to confirm that the technical definition section is reflective of the researcher’s planned study population.

Please visit Population Data BC's website FAQs sections for more information. Questions about the application process or any part of your application are to be directed to the PopData Researcher Liaison staff: rlu@popdata.bc.ca.

Once all necessary approvals are in place, a **Research Agreement** must be signed with the Applicant. This is a legal agreement between the public bodies that the **Data Steward(s)** represent and the **Applicant**. The DAR forms part of the **Research Agreement**.

How to complete the form

The DAR form has been setup as a PDF 'form-fill' application. Using the tab or arrow keys, the cursor will advance to the next input field, with the document text being protected from inadvertent changes. The DAR is divided into sections and the insertion point can be moved to the beginning of the next section by double clicking on the page/section area of the status bar (usually the lower left hand corner of the screen) and then selecting go to 'section' followed by either entering a specific section number or using the 'next' button. Checkboxes can be checked by clicking with a mouse, using the space bar, or entering an 'x'.

CONSENT AND SIGNATURE

Population Data BC would like to publish information about approved research projects whose data Population Data BC administers, including on the Population data BC website. The purpose of this documentation (such as researcher's name, project title and summary) is to provide information to the public and prospective researchers about the types of research projects Population Data BC facilitates. Please indicate on the form your consent for use of none, all or part of the described personal information collected on the application.

Please note that your participation is voluntary and you may withdraw your consent at any time for any reason by contacting Population Data BC.

Signature by Applicant must appear to acknowledge that application is complete and correct.

REQUIRED DOCUMENTATION CHECKLIST

The purpose of this section is twofold -- one, to assist Population Data BC and the Data Steward(s) in the content of the DAR package; and, two, to assist the applicant in organizing the different parts of the application.

For requests involving external data, special attention should be given to the required documentation. This documentation may include copies of other applications for the external data that the applicant wishes to link; and an approved copy of the informed consent letter that will be used for study recruitment.

If the applicant requires assistance or clarification regarding this checklist or completeness of the DAR, questions should be forwarded to the [Researcher Liaison Unit](#) (RLU) at Population Data BC.

Applications that are not complete will not be forwarded to Data Stewards for review.

SECTION I: APPLICANT INFORMATION

Applicant information

The Applicant is the individual legally and ethically responsible for the data and the person with whom the Data Steward(s) will enter into a Research Agreement (RA.)

The Applicant:

- Can only be a single individual. Although he/ she may be one of a number of Investigators on a grant, one must be selected to be the Applicant
- Must be the same individual who has obtained Ethics Approval (or official waiver) from an accredited Ethics Review Board (REB), such as at a University or Hospital, as well as the same person listed in any grants used as peer review for the Data Access Request
- Is the person who will be held personally and professionally accountable in the case of breaches to the **Research Agreement** (of which the DAR is a part)
- Can appoint another person to be the primary contact for the duration of the project
- Is the person with whom Population Data BC will communicate during the application and approval process, unless otherwise delegated

Principal Investigator

The Principal Investigator must also be the Principal Investigator listed on Ethics Approval or waiver and on any grants used as peer review for the purposes of the Request. This is used when the application is made by someone other than the Principal Investigator.

Project Coordinator / Manager

A Project Coordinator / Manager may be appointed by the Applicant. This designate will be considered to be the primary contact person for the duration of the Agreement. The project coordinator will receive copies of all correspondence.

Co-Investigators

The name, position, and institutional affiliation of each Investigator on the research project must be provided. This is expected to mirror the Investigator list on the grant, if grant funding is in place.

Persons who will have access to the data

ALL INDIVIDUALS, including faculty, students, research staff, and supervisors who will have access to the study data must be specified. The name, position, and institutional affiliation of each is requested.

In cases where access via the Secure Research Environment (SRE) is requested, this list will indicate those who will receive SecurIDs.

Each person on this list will be required to 1) sign a confidentiality undertaking, and 2) complete Population Data BC privacy training prior to release of data.

This list should be kept up to date with Population Data BC. Adding or deleting individuals from this list is permitted. New individuals must meet the aforementioned requirements. Data Stewards are kept informed about all changes.

Please note that not using the SRE imposes additional requirements as outlined on the DAR. These requirements are in place because not using the SRE means that Population Data BC can exercise less administrative control over data security and access on behalf of the Data Stewards. We recommend that researchers take advantage of the SRE.

Thesis / dissertation supervisors

If a graduate student is applying for access to data, the student, NOT the academic supervisor, should be identified as the Applicant. Use this section to identify the graduate student's academic supervisor. Please ensure that if this individual will have access to data, that they are also listed in the section entitled Section I Applicant Information.

Note on student use of existing research project data

Students may request access to and use of an existing research extract. For example, their supervisor may have an approved DAR and RA, and the student may have even been working on the data as a listed research assistant. However, use for their own thesis MAY constitute a new research question and thus a new DAR. Please contact the RLU for assistance on all student applications.

SECTION II: RESEARCH PROJECT DESCRIPTION

Question 1: Project title

The Applicant must indicate the complete title of the research project in the field provided. This should be the same title used on ALL other supporting documents attached to the DAR, e.g. the ethics review or the funding application / peer review.

Question 2: Explanation of title discrepancy

If there is disparity amongst titles, the Applicant must state the reasons for this in the box provided.

Question 3: Project objectives, research questions and hypotheses

The Data Steward(s) assess research questions in accordance with current provincial and national laws, regulations, and ethical standards. Research questions are reviewed for public interest value and compliance with legislation and policy - particularly the BC *Freedom of Information and Protection of Privacy Act* (FIPPA), and the Tri-Council Policy Statement for guidelines involving ethical research on humans.

Applicants must list ALL anticipated research objectives and questions, and should be as specific as possible. Consideration should be given to 'preliminary' research questions; re-workings of any hypotheses; and any theoretically 'predictable' outcomes of the analysis when designing the set of research questions.

Remember, upon approval and receipt of data, all analyses need to be restricted to those needed to answer these stipulated research questions. Any change in direction or scope of the question needs to be brought back for Data Steward review, and may constitute a new project (requiring a new application and new data extract.)

Question 4: Project description

The Applicant must provide a brief description of the project. The Applicant must provide details for any relationship to other on-going studies; the involvement of linkages to external databases; intent to apply using the "phased approach" (e.g. may intend to link to PharmaNet once preliminary analysis is complete). A general description of an area of investigation such as "to create a database on the health of health care workers" is not permissible.

Please note that FIPPA requires that Data Steward(s) approve access to data on a “need to know” basis for specific purposes only. As such, the research objective(s) will always be measured against the specific data requested.

Question 5: Public interest / benefit

The Data Steward(s) readily support high-quality research on human health, well-being and the development of British Columbians and welcome research proposals aiming to inform policy-making that leads to healthier BC communities. As stipulated in FIPPA, the Data Steward(s) will assess projects with an eye for public interest value, and relevant legislation.

Question 6: Data justification

Under FIPPA section 35, the Data Steward(s) and in turn Population Data BC are permitted to release only those data that are necessary to achieve a specific research objective. It is the responsibility of the Applicant to draw this connection. Reviewers expect to see solid rationales outlining the relationship between the question(s) and the data requested. This section is expected to be fairly detailed in nature. It is recommended that this be filled out as one of the last sections, after the Study Population and checklists are complete.

SECTION III: DATA LINKAGES

1. Data sources

Identify all Data sources that you propose to have linked, including those requested from within Population Data BC and those from other sources including geographic data. “External data” refer to data not administered by Population Data BC i.e. data for which a checklist has not been provided. Unless otherwise stated, it is assumed that linkage will happen at Population Data BC.

2(a). External data requests

This question is for Researchers using or linking to data that is not “in-house” at Population Data BC and therefore not currently covered by an Information Sharing Agreement between Population Data BC and the Data Provider. We do not have checklists for these data.

Check all External Data Identifier fields to be used for linkage. Please note these will be removed from your extract unless identified in 2B.

2(b). External data requests

A researcher can request some identifier fields (e.g. sex) to be retained for analysis. Please identify and provide a detailed rationale for such a request and ensure that these fields are checked.

3. Requests for linkages to happen in a location other than Population Data BC

If linkage is expected to happen outside of Population Data BC, a separate attachment is required to describe how this linkage will occur, any steps that have been, or will be, taken to minimize the privacy risks including timeline for destruction of linkage data. For assistance in creating this linkage strategy please contact your researcher liaison.

The application(s) and approval(s) for external data must be attached to your DAR.

4. Informed consent for external data

If an external data source is to be linked to the Population Data BC data, consent may be required (e.g. when the external data is a survey data set collected by the Applicant). In cases where it is required, the consent form must be included, and needs to include consent to link data for the specified research purposes. This should be the same consent approved by the Research Ethics Board.

If consent has not been obtained, the Applicant will need to provide an explanation and a justification for why consent should be viewed as impracticable. If other methods have been used to obtain consent (e.g., oral consent), these need to be described.

SECTION IV: FUNDING, AFFILIATIONS, AND REVIEWS

1. Who is funding

Researchers applying for data must identify ALL funding, commissioning and contracting sources, including those requested but not yet confirmed. Please include the funder and the expiry date of funding.

If the project is funded by contract, researchers must attach a copy of the contract, removing financial information.

Please be advised of requirement that if a researcher is funded by a for-profit organization, the industry sponsor must not influence the study direction or analysis, or be given access to the data except in the final published results. Furthermore, no employees, contractors or agents of the sponsor may be on the researcher's project team, or work on the research project in any other way. Be aware of these rules if you negotiate a contract with an industry sponsor for a research project that requires access to data

administered by Population Data BC. Receiving funding that is considered a conflict of interest for the Data Providers involved in your Request may mean your DAR will be denied.

2. External Peer Review

Researchers must indicate the type of external peer review, and provide the necessary documents as indicated.

3. Ethical Review

Researchers must indicate the status of the research project's ethical review by a Research Ethics Board, Institutional Review Board, or other institutional ethics review committee, and provide the necessary documents as indicated.

As stated on the DAR, only non-profit ethics review committees, such as those at universities, are acceptable. The Data Steward(s) reserve the right to decide the acceptability of ethics review committees. If the project has not been approved or submitted for review by an acceptable ethics review committee, the application will not be considered.

Ethical reviews are updated periodically. It is the responsibility of the Applicant to ensure that any updates to ethical review are provided to Population Data BC who will in turn share them with the Data Steward(s).

SECTION V: DATA SECURITY AND ACCESS

1. Use of Secure Research Environment at Population Data BC

Data for approved research projects will be housed on Population Data BC's Secure Research Environment (SRE) unless otherwise authorized. The SRE is a computer server accessible via Virtual Private Network (VPN) using a SecurID token for authentication. The security and privacy policies and process for the SRE have been audited by an external consultant whose report was approved by all Data Stewards.

The SRE provides researchers with secure storage and back up of data, and access to various software programs for analyzing the data. See the SRE Guide for further details.

In some exceptional circumstances researchers may be granted permission to access their data using another method. To request such permission, researchers need to provide a written rationale in the space provided on the DAR, and complete questions 2, 3, 4, 5 and 6 in this section. Please work with and External Data Providers to decide on the use of the SRE before completing your DAR.

2. Physical location and security of personal computer

[To be completed by non-SRE users only]

Please indicate the physical location(s) where research data will be used or accessed, including research sites and storage sites (if different). Indicate all general physical security measures in place at each location. Include measures taken to protect workstations, hard copy and source media.

3. Network security and backups

[To be completed by non-SRE users only]

If data will be stored on a network or system to which individuals other than identified project personnel have access, or on a system connected to a public network (the Internet), please indicate, and if appropriate describe, the network security measures in place.

4. Personal computer security and backups

[To be completed by non-SRE users only]

If data will be accessed or stored on the hard drive of a personal computer, identify all security measures taken to protect data residing on the PC.

NOTE: Access and storage of record level data on laptop, notebook, handheld devices and other portable devices (e.g. external memory) is NOT ACCEPTABLE without PRIOR WRITTEN AUTHORIZATION from the Data Steward(s). Please contact the RLU at Population Data BC for more information on requesting authorization.

5. Data transfer security

[To be completed by non-SRE users only]

Data and derived information, other than aggregated information such as statistical output, must be transferred by one of: courier; in person by someone named above as having access to the data; or secure file transfer as approved by the Data Steward(s). E-mail, regular mail and fax are not acceptable transfer methods at any time.

6. Data destruction security

[To be completed by non-SRE users only]

All data and related materials containing data from Population Data BC holdings or linked records generated with data from Population Data BC, such as derived data, duplicated data, analysis table, working files, backups files, data on server, temporary files, etc need to be destroyed.

Please note that paper records should be destroyed in a manner that leaves no possibility for reconstruction of information. The accepted method for destroying paper records is cross-cut shredding.

For more detailed information, please refer to Population Data BC’s Project Closure Manual. Written notice of data destruction is to be provided, as outlined in the Research Agreement and Project Closure Manual.

SECTION VI: DEFINING YOUR STUDY POPULATION

Each Applicant must collaborate with Population Data BC on this section of the DAR before formal submission to the Data Stewards. Applicants are advised that any changes to the study population post approval will incur a fee in addition to any previous estimates or costs paid. Changes will also require a new Data Steward review.

To reiterate from the DAR, a study population is the group of subjects that a researcher wants to include in their analyses. The study population may include a cohort as well as one or more comparison group(s). The cohort(s) or comparison group(s) for the study can be defined by data from Population Data BC and/or by External Data (from an External Data Provider or Researcher-Collected Data). Please indicate the specifics of this in the checkboxes provided. This provides the Data Stewards with a quick context for their review of the Study Population section.

In order to clarify what is meant by Study Population, the table below provides a few examples of study populations, and how these relate to cohort(s), comparison group(s) and the data extract that you might request for your analyses.

Study Population	Cohort	Comparison Group(s)	Data Extract
All women who gave birth in a BC hospital between 1993 and 2000, and their babies	Women who gave birth between 1993 and 2000 who are residents of Greater Vancouver	Women who gave birth between 1993 and 2000 who are residents of other parts of BC	<i>All MSP Services, hospital separations and deaths data for mothers, from one year before to two years after birth. Births data for the babies, plus all MSP Services, hospital separations and deaths data for two years after birth.</i>

Study Population	Cohort	Comparison Group(s)	Data Extract
All children for whom there are <i>Early Development Instrument</i> scores in 1999-2002 and 2007-2008	Kids with <i>EDI</i> scores above the median	Kids with <i>EDI</i> scores below the median	<i>Foundation Skills Assessment</i> scores, other <i>Education</i> information, and <i>hospitalizations</i> for 1999 to 2008.
All individuals aged 65 and over who spent at least one night in a residential care facility between 1 April 1998 and 31 March 2008, plus a 10% random sample of other individuals aged 65+	Individuals 65 and over who spent at least one night in a residential care facility between 1 April 1998 and 31 March 2008.	A 10% random sample of individuals who did not spend a night in a residential care facility but who were 65+ and resident in BC at some point between 1 April 1998 and 31 March 2008.	<i>Home and Community Care, MSP Services, and Hospital Separations</i> data for 1998/99 to 2007/08.

Although you may have identified more than one cohort and/or comparison group in order to answer your research question, your Data Extract will contain the data covering the entire Study Population you defined earlier. This will ensure that you have all the data necessary to look at your cohort and comparison groups.

Text description

Applicants must define their Study Population in text and use as much detail as possible. These details should include any information to assist Population Data BC in creating the study population. At this point, descriptions of cohort(s) and comparison group(s) are helpful.

Rationale

As in Section I, a rationale or justification for the data requested must be provided. In this section, the focus is ONLY on the Study Population. In particular, justification of the breadth or specificity required to complete the research questions and objectives.

It is acceptable if some of this is repeated from the last question of Section I.

Technical definition

Once the DAR has been completed in draft form, it needs to be passed to Population Data BC to complete this section. Based on the information provided, Population Data BC will identify the technical details for the study population required for your research. This section needs to be confirmed by the Applicant prior to DAR submission.

IMPORTANT TO NOTE: The variables described in the definition are not necessarily the variables that will be provided in the data extract. The years of data and variables required for your data extract are listed in the Checklists in Section VII.

External data for study population

Many Applicants want to use data from **outside** Population Data BC to define the project-specific study population. Examples of External Data include survey data, a clinical data set, or some other outside source. Population Data BC requires linkage variables to link the study population to the research data for these projects. More specifically, Population Data BC requires the Applicant to indicate the linkage variables available for the external data to facilitate linkage. Applicants should be aware that regardless of the linking variables used, a 100% match of any study population to data at Population Data BC is not always possible.

Applicants must also complete and submit any necessary protocols for requesting and linking External Data. Copies of applications and final approvals to use and link data from an external source must be submitted as part of the application package.

SECTION VII: DATA FIELD EXTRACT CHECKLISTS

Researchers must download and complete the appropriate data file checklist(s) and select the fields to be used for analysis.

Researchers need to request the data for their **extract** and not the data required to construct a **study population** when filling out the data file checklists.

The Data Steward(s) will assess each and every field to determine how each field pertains to the project objective. Justification for the fields should be provided by the Applicant in Section I of the DAR.

Applicants are encouraged to use all available resources such as information provided on the Population Data BC web site, discussions with RLU staff, and consultations with other successful Applicants.

Neither the Data Steward(s) nor Population Data BC will be held responsible for data selection oversights. The onus is on the Applicant to research data holdings prior to submitting an application for data.

How much data to request

Researchers should only request as much data as is required to complete a research project. According to the principles of the BC *Freedom of Information and Protection of Privacy Act*, only those data necessary to complete the research questions can be released. Applications requesting more data than needed could be delayed due to modifications and revision of the data requested.

IN CLOSING

Project communications

Once the DAR has been received by the Population Data BC, the project will be issued a project number for tracking purposes. The assignment of the tracking number does not necessarily mean the review process has been activated. While every DAR will receive a tracking number, not every DAR will be approved.

Please use the title that appears on the DAR and the Population Data BC-assigned project number on all future correspondence with Population Data BC.

As Population Data BC facilitates communications and additional requirements, it needs to be copied on all direct communications/consultation with relevant Data Steward(s).

Questions and help

Population Data BC's Researcher Liaison staff are available to help researchers with the DAR process. That said, staff time is a finite resource. Population Data BC is working to move many of the support related functions to the web in order to maintain high levels of support for applications. Prior to contact with the RLU, please do check to see if there are answers to your questions on the web. If you cannot find them do not hesitate to write or call.

DEFINITIONS

Applicant - is the individual legally and ethically responsible for the data and the person with whom the Data Steward(s) will enter into a Research Agreement (RA).

DAR - refers to the formal Data Access Request application document for data through Population Data BC. Components of this application form include information on the researchers, the research questions, the proposed methodology, and details of the proposed cohort and data requested.

RA - refers to a Research Agreement between a Researcher and Data Steward(s) for the use of specific fields of data for specific research projects and outlining obligations associated with that access.

External data - refers to data not administered by Population Data BC and for which a checklist has not been provided.

SRE - refers to a study-specific space on a central server (Secure Research Environment) at Population Data BC, where Research Extracts are stored and analyses can be done remotely using Virtual Private Networking.

FIPPA - refers to British Columbia's *Freedom of Information and Protection of Privacy Act* [RSBC 1996].

Study population - refers to the group of subjects that a researcher wants to include in their analyses. The study population may include a cohort as well as one or more comparison group(s).