PHSA Online Data Access Request Instructions

OVERVIEW

In order to obtain data access for Research, Quality Improvement projects, or Operation/Strategic requests from the Provincial Health Services Authority's (PHSA) Data Registries, requestors must complete a Data Access Request (DAR) Form and provide applicable supporting documentation. This document contains important information you will need to submit a Data Access Request, as well as an overview of how the Data Access process works, definitions, and detailed steps for completing and submitting your request.

All requests for data are managed in accordance with the requirements of the Freedom of Information and Protection of Privacy Act (FIPPA) of British Columbia as well as PHSA data access policies and guidelines.

Acronyms

DAR - Data Access Request

PSBC – Perinatal Services BC

REB – Research Ethics Board

MoH – Ministry of Health

PHSA - Provincial Health Services Authority

COMPLETING AND SUBMITTING THE DATA ACCESS REQUEST ONLINE

Why is an online DAR form needed?

PHSA Data Registries require specific information about your project in order to adjudicate on it. The DAR is designed to collect and provide this information in the most efficient manner possible for adjudication.

How to complete the online DAR form?

The information you provide in the DAR form will be used to evaluate your request. Data access approval is not automatic and must be taken as seriously as an application for funding or ethical review. Please note that the DAR process is dependent on but separate from the funding and ethics approval process. You may be contacted if additional information is needed.

List of documents may be required for completing the DAR form (for Research Requests)

- Study Protocol
- Copy of the Ethics Application
- Current Ethics Approval Certificate
- Supervisor Letter of Review or Curriculum Vitae (Non-peer reviewed projects)

- Data files for data extract, if applicable
- Peer review, if applicable (Copy of proposal submitted for review and reviewers' comments)
- Copy of Funding Application and Funding Approval Letter, if applicable

If you have any queries regarding the REDCap DAR form, please contact PHSA Research and Administration at: researchadministration@phsa.ca

Before filling out the form, please ensure that the type and purpose of your request is clear as this will determine the route of the intake process. Please see the definitions below for clarification.

Inquiry Form: Use this form if you need to inquire whether the PHSA registry has the data available and/or to assess your data needs prior to completing the full online DAR form.

Full Request: This form is to be completed when you know your data needs and have all the required documents ready to upload.

Research: "Research" means a systematic investigation designed to establish principles or other generalizable knowledge, and includes the development, testing and assessment of research. (Link: https://www2.gov.bc.ca/assets/gov/health/conducting-health-research/data-access/access-to-health-data-for-research.pdf)

Quality Improvement: Quality improvement is a framework to improve service systematically. The framework includes processes that can be measured, analyzed, improved, and controlled. For more information, visit: http://2pod.phsa.ca/quality-safety/quality-improvement/Pages/default.aspx

Operations/ Strategies: You must be a PHSA employee and this must be part of your regular daily job at PHSA; this must be essential data for you to do your job (e.g., department head needs x all the time, new department head gets X automatically).

Aggregate:

Requested aggregate data are typically used for quality improvement, evaluation, or planning purposes by health authorities and other governmental agencies.

Summary provincial and sub-provincial data do not include personal information or potential identifiers based on combination of variables and pose no potential harm to groups or individuals.

Turnaround time is dependent on available staff resources, so please submit requests with as much advance notice as possible. In circumstances where the request is time sensitive, PHSA will try to accommodate if resources are available.

Aggregate data will not be released if any risk of re-identification of an individual (e.g., small cell sizes, small geographic areas) is perceived by PHSA or if release is not authorized by a health authority(s). Counts between one and four and rates based on numerators between one and four are not typically disclosed.

Type of data requested (definitions)

Non-identifiable data: Summed or categorized data (e.g., total number of visits to the Emergency Department in the last year). The data have been compiled from record-level data to a summary level that ensures the identities of individuals or groups cannot be determined by a reasonably foreseeable method (Source: PHSA Performance Measurement & Reporting (PMR) glossary).
Aggregate data is typically used for the purposes of reporting or statistical analysis. It is important to note that aggregate data is not synonymous with de-identified data (Source: Information from the Ministry of Health (MoH)).
Potentially Identifiable: Data that can identify an individual indirectly. Data that can help connect pieces of information to single out an individual (e.g., date of birth, place of residence, or unique personal characteristic). As an example, Canadians have a high risk of re-identification using only their date of birth and postal code. While indirect identifiers individually may not be personal information, they are considered personal information if they can be combined together to single out an individual (Source: MoH and additions from reviewers).
Identifiable: Data elements that identify an individual without additional information (e.g., name, address, telephone numbers). Direct identifiers are considered personal information (Source: MoH) Information that identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number (PHN), medical record number (MRN)) (Source: TCPS2 (2014) with additions from reviewers).
More information:
http://www.phsa.ca/research/Documents/PHSA%20Research%20Privacy%20Tip%20Sheet%20and%20Data%20Terms_2017Nov29.pdf

Other Definitions:

Research Team Member means any individual(s) including a co-investigator, student, trainee, collaborator, employee, or consultant working for or with the Principal Investigator in connection with this Research Project.

Data Administrator means the data administrator or his/her delegate responsible for the PHSA Registry Database.

Data Steward means the person or group of persons designated by the PHSA program as data steward with responsibility and accountability for oversight of the Registry Database, including compliance with applicable privacy and security policies with respect to collection, use, access to and disclosure and disposal of data.

Personal Identifiers means any recorded information that could, either by itself or in combination with other information, be used to link or associate Personal Information to a particular individual. In the BCTR Database, the following are considered Personal Identifiers:

- Name
- Birth date
- PHN
- MRN
- Home address

- Home postal code

Other unique identifying number, characteristic, or code (except a code to permit re-identification of the de-identified data).

Personal Information means recorded information about an identifiable patient that is obtained, collected, created, stored, maintained or accessed by the BC Trauma Registry.

INSTRUCTIONS TO COMPLETE THE ONLINE DAR FOR RESEARCH PURPOSES:

General Project Details:

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 online DAR, for example, the ethics review or the funding application/peer review.

Previously Approved Applications: If the current request is related to a previously approved data release or data access request from PHSA Data Registry please indicate it in this section. Please explain the relationship to the previously approved study.

Requestor Information:

This section outlining the requestor information should match the approved Research Ethics Board (REB) application for the project exactly.

The Applicant, as well as the PI (if different from the Applicant), is legally and ethically responsible for the data (Please see PHSA Data Access Use Terms for more information)

Applicant:

- Can only be a single individual. Although he/ she may be one of a number of Investigators

on a grant/ethics application, one must be selected to be the Applicant.

- Can appoint another person to be the primary contact for the duration of the project.

Primary Contact:

Is the person with whom PHSA Data Registries will communicate during the application and approval process?

Principal Investigator:

The Principal Investigator is an individual who either has a faculty appointment (Clinical Assistant Professor, Clinical Associate Professor, Clinical Professor, Assistant Professor, Associate Professor, Professor or BCCA Investigator) or is deemed a PI by an affiliated institution or by a Dean. This individual bears the overall responsibility for the conduct of the study, including the activities of the Co-Investigators, who are assumed to be acting under the delegated authority of the PI, and is required to act within the requirements of the Tri-Council Policy Statement (TCPS).

The Principal Investigator must also be the Principal Investigator listed on ethics approval or waiver and in approvals for use of other data.

The PI, as well as the Applicant, is legally and ethically responsible for the data and the person with whom the PHSA Data Registries will communicate in order to adjudicate online DAR application. In the event of a breach, the PI will be held personally and professionally accountable to the Research Agreement.

External Peer Review and Funding

External peer review: Please indicate if you project has been peer reviewed and by whom.

If a project has not been peer- reviewed, the Applicant must attach a complete CV to prove that the Applicant has the expertise to meet the objectives of the project

Funding: Identify all the funding sources, including the funder and the expiry date of funding. A copy of funding application or contract proposal submitted and the final funding approval letter or contract (removing financial information), should be submitted with DAR application

Ethical Review

Applicants MUST indicate the organization, certificate number and expiry date of the research project's ethical review by an REB, Institutional Review Board, or other institutional ethics review committee, and provide the necessary documents as indicated. You are also required to upload a copy of the completed ethics application for and a current ethical approval.

As stated on the online DAR, only non-profit ethics review committees, such as those at universities, are acceptable. PHSA Data Registries 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 submitted to the PHSA Data Registries.

Research Project Description

Description of the project: Provide a brief description of the project including its purpose and background. This should include an introduction to the project and a relationship to any other study program of research or to other on-going studies.

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.

Research Questions and Hypothesis: Indicate ALL predicted research objectives and questions and 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.

The PHSA Data Registry assesses 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.

Methodology: Summarize the study design and methodology including all statistical procedures within the analysis plan. Also, summarise the techniques and the methodologies that will be used and provide clear rationales.

Achieving research objectives: As per FIPPA section 35, the Data Steward(s) 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 necessary to identify each data file being requested, including external data files, and describe why each file is necessary to achieve the research objectives).

Database used for Extract

Internal data - Checklist: Please complete the appropriate data file checklist (s) and select the fields used for analysis. It is necessary to state the time period start and end date) for which data is being requested.

Researcher collected data: Provide description of researcher collected data in this section. Please ensure to include the source of data, the purpose of collection and the collection method (survey, questionnaire, focus group, interview etc.). Provide any other relevant information that will give assist PHSA Data Registry to better understand the source of data, including a plain language list of fields

that are available in the researcher-collected data file. If applicable, on this list please identify fields that will be used for linkage only and fields that will be retained for analysis.

NOTE: Please be aware that data stewards reserves the right to request informed consent of research participants as a requirement under applicable law and/ or government policies and procedure. If requested, 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 REB.

Data linkage

The PDR can also be linked to some individual level data source(s); however data linkages to the data requested from PHSA and performed by the requestor is prohibited.

Data security and Access

Data Transmission: Please indicate all the parties who will receive the requested data and select preferred method of data delivery. Data and derived information, other than aggregated information such as statistical output, must be transferred using a Secure File Transfer Protocol (sFTP) as approved by the PHSA Data Registries. E-mail, regular mail and fax are NOT acceptable transfer methods at any time.

Physical Location and Security of Data: 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.

Network Security and Backups: 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 describe in detail the network security measures in place.

Personal Computer Security and backups: 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 unless have written authorization by the data steward. If there is a legitimate business need to store data on a portable storage device (e.g. external hard drives and USBs) the information must be stored for the absolute minimum time required, and securely deleted after usage. Confidential or Personal Information must be encrypted on all the portable storage devices.

Final Submission/ Declarations

Legal terms and conditions: In order to confirm that the Applicant, have read and understood the above section on Data Security and Access, please select the check box. Data Access and Use terms can also be found here: http://www.phsa.ca/researcher/data-access-privacy/requesting-data/phsa-data-access-use-terms

Checklist(s)

Please complete the appropriate data file checklist (s) and select the fields used for analysis. It is necessary to state the time period start and end date) for which data is being requested. If you have any questions on checklist, please contact the PHSA Data Registry directly.

ADDITIONAL INSTRUCTIONS TO COMPLETE ONLINE DAR FOR QI AND OPERATIONS

Data output format (QI, Operations)

Project description (QI): same as research project description

Institutional review (QI): Provide details if your project has been reviewed by any institution reviewing committee. However, it is not mandatory that your project has been reviewed but recommended.

Project Sorting Tool (QI): Please complete the questionnaire and upload a copy of certificate generated at the end of the project sorting tool.

The PHSA Project Sorting Tool is intended to help differentiate between research and non-research projects and direct them to the relevant review bodies (as applicable) within PHSA. Questions also reference the BC Centre for Disease Control's Panorama Data Governance Framework and the tool authored by Mike Catchpole et al. and included in the Field Epidemiology Manual.[1] As explained in Article 2.5 of the Tri-Council Policy Statement (TCPS),[2] quality assurance and quality improvement studies, program evaluation activities, and performance reviews…do not constitute research for the purposes of TCPS2 and do not fall within the scope of Research Ethics Board (REB) review. The TCPS2 Interpretations go on to explain that activities that are conducted in support of a public health program or under the jurisdiction of a public health authority and that does not have research as a primary goal, do not fall within the TCPS2 definition of research and do not require REB review.

However, the Panel on Research Ethics is also clear in its TCPS Interpretations that where in doubt about the applicability of TCPS2 or the requirement for REB review of a particular research project, the researcher should consult the REB. This tool does not replace proper consultations with your REB or other relevant review bodies.

Useful definitions:

TCPS defines research as an undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.

TCPS defines public health surveillance as the systematic collection, analysis and interpretation of health-related data for the planning, implementation and evaluation of public health practice. The primary intent of the public health project activities is to improve a program or service by:

- identifying patterns or behaviours associated with increased health risks
- measuring the burden of disease
- measuring the effectiveness of public health interventions and services
- preventing or controlling disease or injury and improving health, or

- improving disease reporting

The American Academy of Family Physicians defines quality improvement (QI) as a systematic, formal approach to the analysis of practice performance and efforts to improve performance.

Summary of intended use of data: Describe how you intend to use, share and/or publish the results of your project.

Approvals (QI, Operations): For all operations/strategy related and online QI DAR request, you must have an Approval from your Manager – level or above. Approver will be copied on this request.

Link with PHSA Strategies: Indicate if your research project aligns with any of the PHSA strategies. This will support PHSA to shape the integrated approach to data access streamlining and strategies.

SPECIFIC INFORMATION ON SOME PHSA DATA REGISTRIES

Women's Health Research Institute & BC Perinatal Data Registry Specific Questions:

- WHRI members may request access to unlinked BCPDR data via a free of charge expedited process through the WHRI:
  Link to membership page: http://whri.org/become-a-member/
- A Knowledge Translation Plan should be submitted in the online DAR: Summarize your Knowledge Translation (KT) plan. Please include 1) the KT goals of the project; 2) the Knowledge Users or target audience; 3) your KT strategies and 4) your project team and collaborators. A detailed guide is available in the online DAR

Trauma Services BC (Definitions):

"BCTR Database" means the provincial Trauma Registry Database that contains Personal Information on patients meeting determined criteria for inclusion in the BC Trauma Registry and/or BC Burn Registry.

WHAT HAPPENS NEXT?

Once your application has been reviewed (i.e., all clarifications and questions have been answered) by the Data Access Coordinator and you have received confirmation that your application package is complete, your data request will be sent to the Approver/Review Committee for adjudication. It should also be noted that the Data Access Coordinator may contact you for further clarification on your online DAR application as requested by the Approver/Review Committee.

If approved by the Approver/ Review Committee, the request will be entered into the Registry's work queue. Please note that it may take several months before the data are ready for release, depending on the complexity of the request and current workload of the Registry's team. Data requests require linkages can take longer; therefore we recommend that applicants begin the data request process as early as possible to limit delays in obtaining data.

You will be contacted once your requested data extract is ready.

Amendments to the online DAR

Note that amendments must be changes **within the scope of the original request**. Changes such as adding new questions that are related to (but not included in) the original application; or modifications to data collection methods or populations of focus, **must be submitted as a new DAR for review and approval.**

- A detailed description outlining the reason for the amendment is required.
- The amendment(s) must not result in significant changes to the data extract. (New study questions must be submitted as a new DAR.)
- Changes such as additional variables, addition/removal of Project Members, or a change to the requested data retention date must be submitted as Amendments.

Publication Requirements

Any Output intended for publication must be reviewed and approved prior to publication; researchers may not submit a manuscript for publication until the PHSA Registry has provided written approval to proceed. We request the opportunity to review materials such as manuscripts and reports **at least 45 days** prior to submission for publication. We understand that abstracts, oral presentations, and conference posters may require a shorter turnaround time. Therefore, we will do our best to provide feedback for these expedited materials as quickly as possible.

In all Outputs, the applicant is asked to appropriately reference PHSA Data Registry and include the following disclaimer:

"All inferences, opinions, and conclusions drawn in this publication are those of the authors and do not reflect the opinions or policies of any PHSA Data Registry.