Perinatal Services BC
An agency of the Provincial Health Services Authority

SCHEDULE A – APPLICATION FOR ACCESS TO HEALTH DATA FOR RESEARCH PURPOSES (DATA ACCESS REQUEST – DAR)

Use this Application Form to request health data from the BC Perinatal Data Registry (BCPDR) administered by Perinatal Services BC (PSBC) for research purposes. Once this application has been approved, it becomes a legally enforceable agreement between the researcher and PSBC.

Submit this Application Form and attachments electronically to **psbc@phsa.ca**.

Contact PSBC with questions or concerns regarding:

Data Privacy Issues
Phone: 604.877.2121
Email: **psbc@phsa.ca**
Attn: Policy and Privacy Advisor

Research Review
Phone: 604.877.2121
Email: **psbc@phsa.ca**
Attn: Provincial Lead, Surveillance

Project Title

NOTE:

1. Applicants requesting PSBC data and data linkages from external data holdings (e.g., Vital Statistics Agency, WorkSafeBC, Medical Services Plan, Pharmacare, Discharge Abstract Database, etc) are requested to apply directly to Population Data BC at **www.popdata.bc.ca**.
2. Applicants are advised that a cost estimate will be provided after the data request has been approved and any changes to the study population *post* approval will incur a fee in addition to any previous estimates or costs paid.

For PSBC Use Only	
Project Title:	
Internal Project Number:	
Date of Receipt:	

Clear Form Print Form Submit Form

Definition of Terms used in this Application Form:

Researcher: A Researcher is a person who is engaged in research and is either:

(i) A student, teacher, or another individual enrolled, appointed or employed by any of the following:

1. A university, where the university status is defined under the BC University Act,
2. A college, university college or provincial institute as defined under the College and Institute Act, R.S.B.C. 1996, c. 52,
3. The Open Learning Agency as continued under the Open Learning Agency Act, R.S.B.C 1996, c. 341,
4. Royal Roads University continued under the Royal Roads University Act, R.S.B.C. 1996, c. 409,
5. Another equivalent educational institution in another jurisdiction outside of BC but within Canada; or

(ii) Any other person agreed to by PSBC.

Applicant: The Applicant is the Researcher who will hold primary responsibility for the data and conditions of the research project, and who will perform or oversee analysis and interpretation of the data that result from the request. This individual must be listed as the Principal Investigator or a Co-Investigator in the ethics board approval (or official waiver) from an accredited Research Ethics Board (REB).

The Applicant is legally and ethically responsible for the data and the person with whom PBSC will enter into a Data Sharing Agreement (DSA) if the project is approved. In the event of a breach, the Applicant will be held personally and professionally accountable to the DSA (of which the DAR is a schedule).

For student projects, the Applicant should be the student. All student Data Access Requests must be co-signed by the researcher who is acting as the project Supervisor. For student projects, the student Applicant and Supervisor will both be subject to the conditions and responsibilities outlined in the DSA.

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 project term outlined by the DSA. The Project Coordinator/Manager must be listed as a Project Member.

Project Member: All Project Members are Researcher(s), co-investigator(s) and/or other individuals specifically identified as requiring access to the data. All Project Members should also be listed on the REB documentation and grant documentation, if applicable.

Supervisor: The Supervisor is the Researcher who is acting as the primary supervisor for research projects contributing to a student thesis or dissertation.

Persons who will have access to the data: Identify ALL individuals who will have access to the requested data at any time. Please include any of the Applicant, Project Coordinator/Manager, Supervisor (student projects only) and other Project Members on this list if they will be accessing the research extract. The name, position, institutional affiliation and email address of each is required.

Each person on this list will be required to a sign a Confidentiality Pledge.

Clear Form Print Form Submit Form

This list should be kept up to date with PSBC. It may be necessary to amend the appropriate section of the ethics application to identify new individuals with data access throughout the duration of the project.

Contact information: means information to enable an individual at a place of business to be contacted and includes the name, position name or title, business telephone number, business address, business email or business fax number of the individual. (ref: ***Freedom of Information and Protection of Privacy Act*** **(FIPPA)**)

Data Steward: refers to a public body that has ultimate responsibility for a given data source. In practice, an individual is typically named as having the authority to approve or reject research requests involving that data, typically called “the / a Data Steward.”

External Data: means any information, including Personal Information, that is provided by the Applicant and is in the custody or control of another data steward or stewards but the release of which is requested by the applicant.

Personal information: means recorded information about an identifiable individual other than contact information. (ref: FIPPA)

Clear Form Print Form Submit Form

TABLE OF CONTENTS

Clear Form Print Form Submit Form

APPLICATION SUBMISSION PROCESS

Please read the following carefully.

THE APPLICATION PROCESS REQUIRES THAT RESEARCHERS:

- Become familiar with all material outlining access requirements, data holdings, cohort definitions, and privacy considerations on the PSBC website **www.perinatalservicesbc.ca/DataAndSurveillance/DataRegistry.htm**
- Review the Frequently Asked Questions and other Data Access Request Documentation on the PSBC website: **www.perinatalservicesbc.ca/DataAndSurveillance/DataRegistry/data-requests/Research/default.htm**
- Ensure that the ethics and peer review requirements/documentation have been met.
- Complete this Application Form noting that the Applicant is the person who is listed as the Principal Investigator or Co-Investigator in the research ethics board approval or is the student carrying out the research as part of a thesis or dissertation project. Answer all questions and remember to include all documents to minimize confusion and avoid rejection of application forms.
- **Request only the variables that are necessary to answer your research question,** but do your best to request all that you need to avoid amendments. Ensure that the study population definition answers your research question.
- Review this Application Form thoroughly as only completed forms will be considered.
- Submit this Application Form and any relevant attachments electronically to **psbc@phsa.ca**
- Understand that both the Applicant and Supervisor (student projects only) must sign the DSA before data are released, as required by FIPPA.
- Understand that each person who will have access to the data must sign a Confidentiality Pledge and return it to PSBC prior to accessing the data extract.

YOUR APPLICATION WILL BE:

- Reviewed by the PSBC Research Review Committee. Only completed Application Forms will be reviewed.
- Reviewed for potential privacy concerns. A risk assessment will be conducted on the data requested. Data will be de-identified to the degree appropriate. Please consider carefully the data elements and cohort requested. The PSBC Research Review Committee will look for clear discussion and justification of your data needs.

COLLECTION, USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION

As an agency under the PHSA, PSBC is defined as a public body under Schedule 1 of the ***Freedom of Information and Protection of Privacy Act*** **(FIPPA)**. As such, PSBC is legislated and must comply with the FIPPA as well as other legislated Acts and rules of common law related to access and privacy of information.

Disclosure of personal information administered by PSBC is governed by the various Memorandum of Agreements and Partnership Accords between PSBC and the Health Authorities (the original collectors of Personal Health Information) as well as Sections 33 and 35 of the FIPPA.

Clear Form Print Form Submit Form

REQUIRED DOCUMENTATION CHECKLIST

Final, unconditional ethics approval certificates must be provided before data will be released. Electronic copies of all documents must be provided.

CHECK APPLICABLE BOXES

REQUIRED DOCUMENTATION: CONFIRM ATTACHMENT OF DOCUMENTS LISTED BELOW

ALL PROJECTS:

- ☐ Research protocol or thesis proposal
- ☐ Copy of application for ethics review, including all supporting documents
- ☐ Ethics certificate of approval

PEER-REVIEWED PROJECTS:

- ☐ Copy of proposal submitted for review and reviewers' comments

NON-PEER REVIEWED PROJECTS:

- ☐ Supervisor letter of review OR Applicant CV

FUNDED PROJECTS:

- ☐ Copy of funding application or contract proposal submitted
- ☐ Final funding approval letter or contract (removing financial information)

All of the above documents will become part of the DSA between the Applicant and PSBC.

CONSENT FOR PSBC TO PUBLISH PROJECT INFORMATION

PSBC would like the opportunity to publish details about your project, including on the PSBC website. By completing this application, you are granting PSBC permission to publish the following project information upon project approval: applicant and supervisor (student projects only) names, institution, project title, funding agency, research objectives, approved data sets, and publication information.

Clear Form Print Form Submit Form

SECTION I: APPLICANT INFORMATION

APPLICANT (If the project is a thesis or dissertation, this must be the student)

Last Name	First Name	Title
Street		
City	Province	
Country	Postal code	
Phone	Fax	
Email		
Position		

INSTITUTION ADDRESS (If different from Applicant address)

Institution Name	
Street	
City	Province
Country	Postal code
Phone	Fax
Email	

SUPERVISOR (student projects only)

Last Name	First Name	Title
Street		
City	Province	
Country	Postal code	
Phone	Fax	
Email		
Position		
Institution Name		

Clear Form Print Form Submit Form

PROJECT COORDINATOR/ MANAGER (Primary contact person for correspondence, etc.)

Last Name	First Name	Title
Institution		
Position		
Street		
City	Province	
Country	Postal code	
Phone	Fax	
Email		

PROJECT MEMBERS
(excluding Applicant, Supervisor and Project Coordinator/Manager, if applicable)

Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	

Clear Form Print Form Submit Form

PERSONS WHO WILL HAVE ACCESS TO THE DATA (attach a separate sheet if necessary)

Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	
Name	Position
Institution	

Clear Form Print Form Submit Form

SECTION II: FUNDING AND ETHICS BOARD APPROVAL

1. WHO IS FUNDING YOUR RESEARCH PROJECT?

Identify ALL funding, commissioning and contracting sources, including those requested but not yet confirmed.

- ☐ Canadian Institutes of Health Research — Expiry Date:
- ☐ Canadian Health Services Research Foundation — Expiry Date:
- ☐ Social Sciences and Humanities Research Council — Expiry Date:
- ☐ Michael Smith Foundation for Health Research — Expiry Date:
- ☐ WorkSafeBC — Expiry Date:
- ☐ In-kind donations *(source)*: — Expiry Date:

- ☐ Other funds donated by researchers involved or their academic departments *(describe)*: — Expiry Date:

- ☐ Funds provided by private industry *(describe source(s))*: — Expiry Date:

- ☐ If the project is wholly or partly funded by contract, attach a copy of the confirmation letter.
- ☐ No funding. Explain why.

Clear Form Print Form Submit Form

CONFLICT OF INTEREST

If you the Applicant and/or Applicant's spouse, domestic partner or child has an association or connection of any kind, whether financial or non-financial, with any sponsor of the project or the manufacturer or owner of any drug, device, program, or method being evaluated in the project, please attach details. Examples of financial interests include ownership of stocks, bonds, options, patent or royalty interests, receipt of consulting, honoraria, or speaking fees, salary, subject accrual rewards or penalties, loans, lectureships, memberships on boards of directors or scientific advisory boards. Examples of non-financial relationships include previous research collaborations, student/teacher relationships, other personal or professional relationships, professional differences, or any other connection that might lead to the perception of influence on the study.

☐ ATTACHED ☐ NOT APPLICABLE

2. EXTERNAL PEER REVIEW OF YOUR RESEARCH PROJECT

☐ My project has been reviewed by an external peer committee, such as a grant funding agency.
Attach a copy of the following documents:
a) Project proposal from application
b) Final funding letter, if funded

☐ My project is a **thesis or dissertation** and has been reviewed by my supervisory committee.
Attach a copy of the following documents:
a) Description of the project/thesis proposal submitted for review
b) Letter from supervisory committee indicating the proposal has been approved

☐ My project has not been peer reviewed.
Attach a Supervisor letter of review or Applicant CV.

3. ETHICAL REVIEW OF YOUR RESEARCH PROJECT

Attach a copy of current ethics application and approval. Projects must have current ethics approval to be considered by the PSBC Research Review Committee.

Organization	Certificate Number	Expiry Date

NOTE: Only non-profit ethics review committees, such as those at universities, are acceptable. PSBC reserves the right to decide the acceptability of ethics review committees in its sole and absolute discretion.

Clear Form Print Form Submit Form

SECTION III: RESEARCH PROJECT DESCRIPTION

PROJECT TITLE

TITLE DIFFERENCE

If this project has a different title from the one that appears on funding approvals or ethics review documentation, indicate the reason for the discrepancy.

PUBLIC INTEREST VALUE / PUBLIC BENEFIT OF PROJECT

SMALL CELL SIZE

Please describe measures that will be taken to protect confidentiality (identification of an individual) during analysis and in any publication of results when dealing with small cell size (e.g., < 5).

Clear Form Print Form Submit Form

DESCRIPTION OF PROJECT

Describe the project including its purpose and background. Include an introduction to the project and if relevant, its relationship to any other program of research (e.g., phased or existing studies).

Clear Form Print Form Submit Form

PROJECT OBJECTIVES: RESEARCH QUESTIONS AND HYPOTHESIS

1) List research questions and 2) Identify hypotheses

Clear Form Print Form Submit Form

METHODOLOGY

Summarize the study design and methodology. Please include a description of your planned analysis.

Clear Form Print Form Submit Form

ACHIEVING RESEARCH OBJECTIVES AND JUSTIFICATION OF REQUESTED DATA ELEMENTS

Describe how data used to define cohort AND all data requested from PSBC are necessary to achieve research objectives. See list of fields in **APPENDIX A**. Please demonstrate that you have considered how the requested data elements will fit into your analysis. Justification of individual variables is not necessary. However, each requested variable must at least fit within a group described in your application. For example, “breastfeeding practices” could include any/ all of the breastfeeding variables in the BCPDR. **The exception is potentially identifiable variables (indicated by ** i**n Appendix A); **these must be justified on an individual basis in Section IV, 4. JUSTIFICATION FOR PARTIALLY IDENTIFIABLE DATA** on page 18**.**

Clear Form Print Form Submit Form

SECTION IV: DEFINING YOUR STUDY POPULATION

A **study population** is the group of subjects that researchers want to include in their analyses. The study population may include a cohort as well as one or more comparison group(s). Applicants must clearly define their study groups below and use as much detail as possible.

IMPORTANT: A clear, explicit rationale is required for the inclusion of all proposed individuals in the study population. The rationale must be clearly related to the research question and methods.

Applicants are advised that any changes to the study population after approval may require an amendment, further review and adjudication by the PSBC Research Review Committee, and will incur a fee in addition to any previous estimates or costs paid.

1. STUDY POPULATION

a) The study population will be defined using data from the following sources, check all that apply:

- ☐ Data from PSBC (see **APPENDIX A**)
- ☐ Data from External Organizations
- ☐ Researcher-collected data
- ☐ Other (specify):

b) Applicants who want to use data that requires linking to other data sources in order to define the project-specific study population are required to complete the table(s) in **SECTION V: DATA LINKAGES TO EXTERNAL DATA** on page 19.

2. TEXT DESCRIPTION

Please describe the Study Population, and as relevant, include a description of the study cohort or comparison group(s). This description should include as much detail as possible, such as health condition(s), age groups, date ranges or geographic areas, as well as specifications for sampling or matching, as required for your comparison group(s). Include a sample size calculation and any specific exclusion criteria if relevant. If known, please include an estimate of the anticipated size of the cohort(s) to facilitate an accurate estimate of data extract costs.

Clear Form Print Form Submit Form

3. RATIONALE FOR STUDY POPULATION IN RELATION TO RESEARCH OBJECTIVES

Applicants must clearly illustrate how the study population is designed to meet the stated research objectives. If requesting a population-based cohort, please explain why your research objectives cannot be met by sampling or by using a sub-set of the population.

4. JUSTIFICATION FOR PARTIALLY IDENTIFIABLE DATA

When selecting fields from **APPENDIX A** for your study purposes, please note that fields bolded and designated with asterisks (**) are considered partially identifiable and will require additional justification for release. Please list partially identifiable data individually below and provide justification.

Clear Form Print Form Submit Form

SECTION V: DATA LINKAGES TO EXTERNAL DATA

Please complete this section only if your research project involves linkage of PSBC data to External Data.

Applicants should be aware that a 100% match of any study population between databases is not expected, regardless of the linking variables used.

Please note that projects involving data linkage may be ultimately requested to go through Population Data BC (PopDataBC). This includes linkages to data holdings of PopDataBC, primary research data, or any other external data source.

1. DATA SOURCES TO BE LINKED

Please list all of the databases to be linked. For all data sources to be used in your project, please provide approval letters from the designated Data Steward(s). For those rare occasions where the applicant is also a Data Steward for a data source to be used, please have the approval letter signed by one signature above (i.e., a person one step higher in authority). NOTE: the approvals must fully disclose ALL proposed linkages.

2. LINKAGE VARIABLES

Please indicate all BCPDR variables to be used in the linkage. NOTE: PHN alone is usually not sufficient for linkage between databases.

Check	Mother
	Personal Health Number (PHN)
	Surname(s)
	Given name(s)
	Alias(es)
	Date of birth
	Postal code
	Institution ID

Check	Baby
	Personal Health Number (PHN)
	Surname(s)
	Given name(s)
	Alias(es)
	Date of birth
	Postal code
	Institution ID

	Other (specify):

Clear Form Print Form Submit Form

3. IF RESEARCHER-COLLECTED DATA ARE TO BE USED

a) Please include a text description of the researcher-collected data in the space provided. Please include the source of the data, the purpose of collection, and whether data are collected in the form of a survey/questionnaire, interviews, focus groups, or another method.

b) Typically, Informed Consent is required of Researcher Collected Data that contains personal health information in individually identifiable form. PSBC *reserves the right* to request Informed Consent of research participants as a requirement under applicable law and/or government policy and procedure.

If you are requesting linkage of PSBC data to Researcher Collected Data, written informed consent to use and link the collected data for the specified research purpose(s) must be obtained. The consent documents should explicitly identify the proposed linkages and the data involved. Each individual member of the cohort will be required to complete the consent form in full.

☐ Attach a blank copy of the informed consent form and any attachments provided to participants, as approved by the research ethics review board.

If other methods other than written, informed consent have been used to obtain consent to access this information (e.g., oral consent), please describe:

c) Provide the name of the appropriate Data Steward who has authorized use of the data that will be linked to data administered by PSBC. Please provide an approval letter(s) from the designated Data Steward(s). For those rare occasions where the applicant is also a Data Steward for a data source to be used, please have the approval letter signed by one signature above (i.e., a person one step higher in authority). NOTE: the approval(s) must fully disclose ALL proposed linkages.

Clear Form Print Form Submit Form

SECTION VI: DATA SECURITY AND ACCESS

1. PHYSICAL LOCATION AND SECURITY OF DATA

NOTE: All physical locations housing data must be locked, except when an individual authorized to access the data is present.

We require all researchers to have, at a minimum, the following software installed on their workstations:

- firewalls,
- antivirus,
- antispyware and adware,
- file encryption.

Data may not be stored on laptops, hand-held devices and other portable devices (e.g., external memory), under any circumstances.

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.

Location 1		
Room Number	Building Name or Number	
Street		
City	Province	Postal Code
Country		
Physical security measures: ☐ Locked file cabinet ☐ Door keypad		
☐ Other (specify):		

Location 2		
Room Number	Building Name or Number	
Street		
City	Province	Postal Code
Country		
Physical security measures: ☐ Locked file cabinet ☐ Door keypad		
☐ Other (specify):		

Clear Form Print Form Submit Form

2. NETWORK SECURITY AND BACKUPS

NOTE: You may need to contact your IMIT service provider to assist you with this section.

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), indicate and describe, the network security measures in place.

Location 1
☐ Firewall
☐ Password changed every days
☐ Password rules (minimum length, complexity)
☐ Drives or folders with access restricted to specified research group
☐ File encryption
☐ Other (specify):
☐ Security audit
☐ Access tracking
Describe how, and from where, any regular maintenance and backups of your network are conducted, where backup material are stored, and backup retention schedule:

Location 2
☐ Firewall
☐ Password changed every days
☐ Password rules (minimum length, complexity)
☐ Drives or folders with access restricted to specified research group
☐ File encryption
☐ Other (specify):
☐ Security audit
☐ Access tracking
Describe how, and from where, any regular maintenance and backups of your network are conducted, where backup material are stored, and backup retention schedule:

Clear Form Print Form Submit Form

3. DATA TRANSFER SECURITY

NOTE: Data and derived information, other than aggregated information such as statistical output, must be transferred by courier, in person by someone named above as having access to the data, or by secure file transfer. PSBC may request secure file transfer through PopDataBC.

E-MAIL, REGULAR MAIL, AND FAX ARE NOT ACCEPTABLE TRANSFER METHODS AT ANY TIME.

4. DATA DESTRUCTION SECURITY

Upon project completion or two years after receipt of the data, the Researcher agrees either to destroy the data and any copies or return it to PSBC. PSBC and/or other agencies will normally grant approval for initial retention of the data for a period of up to two years. Beyond this date, PSBC may approve extensions through a formal Amendment. See **Section VII: 2. EXTENSIONS** on page 24.

As per Section 13.0 of the **Data Sharing Agreement**, upon expiry or termination of the project, the data and any copies must be destroyed using a method of destruction that will render the data unreadable through the use of an appropriate mechanical, physical or electronic process and converted into such a form that cannot be reconstructed in whole or in part. Written notice of such destruction is to be provided to PSBC.

☐ **The Applicant declares the above section on data security and access requirements has been read and understood.**

The Applicant is requested to complete a **Project Closure Form** on completion of the project.

Clear Form Print Form Submit Form

SECTION VII: AMENDMENTS / EXTENSIONS TO DATA REQUEST

1. AMENDMENTS

- Amendments to previously approved applications will be assessed for additional costs to the researcher.
- PSBC reserves the right to limit the number of amendments per research project.
- A detailed description outlining the reason for the amendment is required.
- The amendment(s) must not result in significant changes to the data extract. For example, new study questions must be submitted as a new DAR.
- Amendments to studies should be changes within the scope of the original study. Changes such as additional variables, addition/removal of Project Members, or a change to the requested data retention date must be submitted as Amendments. New research questions that are related to (but not included in) the original study should be submitted as a new DAR. Also, projects that undergo changes to data collection methods or study populations should be submitted in a new DAR for review and approval.
- The appropriate amendment request form must be completed and approved by PSBC. Please refer to **Amendment to Application for Access to Health Data for Research Purposes** form.

2. EXTENSIONS

- Extension of data retention may be requested in one-year increments. Two-year increments may be considered with appropriate justification. To request an extension to complete the research project for the purpose set out in the original application, including publication and/or presentation, please submit an **Amendment to Application for Access to Health Data for Research Purposes** form. Please indicate the reasons(s) and the proposed duration of the required extension.

Clear Form Print Form Submit Form

SECTION VIII: SIGNATURE AND DECLARATION

NOTE: Once this DAR is approved, the Applicant, as well as the Supervisor, if applicable, will need to enter into a **Data Sharing Agreement**. This application will become a schedule to the Data Sharing Agreement.

APPLICANT:
I declare that all information provided in this application is complete and correct.

Name of Applicant	Signature	Date
Name of Witness	**Signature**	**Date**

SUPERVISOR *(student projects only)*:
I declare that all information provided in this application is complete and correct.

Name of Supervisor	Signature	Date
Name of Witness	**Signature**	**Date**

Clear Form Print Form Submit Form