Policy: Data Disclosure for Data Requests for Women's Health Research Institute facilitated access to the British Columbia Perinatal Data Registry (BCPDR)

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Approved by: Women's Health Research Institute Data Access Committee for the British Columbia Perinatal Data Registry

Preamble:

Perinatal Services BC (PSBC) facilitates requests from researchers for data from the BC Perinatal Data Registry (PDR). The PDR has collected health data on nearly every birth in BC since 2000 and contains records for nearly 900,000 births and deliveries. PDR data are used for surveillance and research purposes and to support health care providers, researchers, health care leaders, and policy makers in their work to improve maternal, fetal, and neonatal health outcomes, as well as to enhance the delivery and quality of perinatal services in BC.

The Women's Health Research Institute (WHRI), a leading academic women's and newborn health research centre embedded within BC Women's Hospital & Health Centre, is devoted to improving health care of women and their families, and supporting an expanding provincial and national network of women's health researchers, policy makers and healthcare providers. The Women's Health Research Institute was established to enhance and galvanize the impact of women's health research conducted at BC Women's Hospital and throughout BC.

After several discussions between representatives from Perinatal Services BC, BC Women's Hospital & Health Centre, Women's Health Research Institute, and the Provincial Health Services Authority, a proposal was written with the aim of developing a pilot project that would streamline the Data Access Request process for researchers while keeping with Perinatal Service BC's commitment and vigilance towards the protection individuals in accordance with the Freedom of Information and Protection of Privacy Act (FIPPA) and other applicable legislation, ethical considerations, and best practices. The Women's Health Research Institute / Perinatal Service BC initiative will pilot the delegation of stewardship of the BC Perinatal Data Registry (PDR) data to the Women's Health Research Institute for unlinked and non-identifiable research data requests received from WHRI members.

Purpose:
The purpose of this document is to identify the parameters required when the Women's Health Research Institute (WHRI) releases and discloses British Columbia Perinatal Data Registry (BCPDR) data to research requestors. WHRI must comply with the *Freedom of Information and Protection of Privacy Act (FIPPA)* and the *Memorandum of Agreement* with Health Authorities (HAs) and the College of Midwives.

Scope:

This policy applies to WHRI member requests for access to unlinked or aggregate level data for research purposes from the BCPDR as facilitated by the WHRI.

Agreements:

Under the *Memorandum of Agreement* with HAs, Perinatal Services BC (PSBC) can use the data contained with the BCPDR for clinical review, research, planning, and evaluation purposes in accordance with the Agency's provincial role. PSBC has authorized delegate data stewardship of the BCPDR to the WHRI for requests from WHRI members, or student or trainee researchers who are under the supervision of WHRI members, which meet the risk criteria for "custodian approval" as defined by the PHSA proportionate governance model (Appendix B) and with criteria defined in the Data Steward Policies.

Statements:

1. WHRI handles all research data requests in compliance with FIPPA legislation. Sections 26 to 36 of FIPPA identify the conditions under which personal information can be collected, used and disclosed.
2. Requests will only be accepted from WHRI members, or student or trainee researchers under the supervision of WHRI members. Requests from researchers without WHRI membership will be referred to PSBC and will fall under the parameters outlined in P03 PSBC Data Disclosure for External Data Requests.
3. Requests from the general public regarding access to their personal patient records will be transferred to PSBC. WHRI is not the originator of data within its stewardship and will not be handling non-research requests for data.
4. Requests for perinatal data from a hospital or Health Authority should be made directly to PSBC; requests for single hospital or Health Authority perinatal data should be made directly to the Health Authority. WHRI does not provide this service.
5. Aggregate data requests from WHRI members can be made through the WHRI Analyst by completing an online Data Access Request form, found on the PSBC website (http://requests.perinatalservicesbc.ca/).
6. Applications for access to BCPDR data for research requests can be made by completing a pdf Data Access Request (DAR) form and BCPDR Data Field Checklist, found on the WHRI website and submitting completed application materials to the WHRI Data Analyst.
7. The Senior Research Manager, WHRI, in collaboration with the WHRI Data Analyst will review the request both before and after submission to:
    a. Determine the appropriateness of the request and the authority for making the request;
    b. Assess the clarity of the request;
    c. Classify the request as an Aggregate or Research request;
    d. Determine if the data disclosure is in accordance with the stated purpose;
    e. Confirm that the level of information requested is limited to the minimum amount reasonably required to meet the stated purpose (ensuring alignment with PSBC's commitment to a minimum rights data model);
    f. Determine that there is an appropriate knowledge translation plan; and
    g. Determine data steward approval and signed agreement requirements
8. Classification of requests:
    a. **Aggregate data** requests are for summary provincial and health authority-level data (e.g. total births, total caesarean sections, etc.) and do not include personal information or potential identifiers based on combination of variables and pose no potential harm to groups or individuals.

        WHRI provides aggregate data services to WHRI members or those under the supervision of WHRI members for the purposes of research planning.

All reports will have the following suppression rule applied:

Counts between one and four, rates based on numerators between one and four, and combinations of fields that may infer identification will not be disclosed.

The WHRI prepares and reviews all aggregate reports prior to disclosure to ensure that the information cannot reasonably be used in ways, whether alone or in combination with other data sources, to identify an individual.

Once review is completed, aggregate reports will be sent to the requestor using the IMITS Secure File Transfer service.

b. **Research data** requests are bona fide research requests that involve record-level data from the BCPDR.
    - WHRI is authorized to release research requests that are in alignment with PSBC's commitment to a minimum rights data model; only the minimum amount of data required to carry out an approved research project will be provided to the researcher. To be considered for approval by WHRI, research requests for data must meet the following criteria:
        - The request must be from a bona fide researcher with WHRI membership or from student or trainee researchers under the supervision of a WHRI member.
        - The request must be for the time-limited purpose of addressing a specific set of research questions.
        - The request must pertain to an identified research project that has received current ethics approval from a recognized Research Ethics Board, as defined by the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, at an academic institution.
        - The request must be for an unlinked BCPDR dataset only and must not be linked to any other data.
        - The requested data must not be used to identify individuals for developing a registry or for data pooling.
        - The request must not involve use of data for administrative or any other non-research purpose.
        - The request must not involve the use of data for ongoing programs of research, defined as a sustained research enterprise that includes one or more projects, is shaped by broad overarching research objectives and often evolves or adds on new projects.

- The request must be in the public interest, for example, the stated aims set out to improve the welfare of the population.
- The request must not be proprietary research such as research done for commercial marketing purposes.
- The request must have scientific merit.

Research extracts of the BCPDR are prepared by the WHRI Data Analyst through PSBC's data warehouse and accessed within PHSA's secure network. Dates included in the research extract will be restricted to month and year only.

Research outputs will be stored and accessible within a secure PHSA network folder and/or within vetted privacy and security controls within BC.

9. All project documentation for individual research projects will be provided to PSBC for auditing and recording purposes.
10. When the data are ready for release, the Senior Research Manager, WHRI, the PSBC delegated data steward, is notified. The Senior Research Manager, WHRI has the responsibility for reviewing all aggregate reports and unlinked datasets prior to disclosure to ensure that the information cannot reasonably be used in ways, whether alone or in combination with other data sources, to identify an individual.
11. Once review is completed, the WHRI Data Analyst will send the report/data to the requestor.
12. All outputs must cite Perinatal Services BC – Perinatal Data Registry as the source of the data (i.e. written documents, PowerPoint slides, Excel spreadsheets, etc.) using the following format:
13. Perinatal Services BC. British Columbia Perinatal Data Registry. Years Provided: (YYYY to YYYY). Resource Type: (Extract or tabulated data). Data provided on (YYYY).

Appendix A: Terminology definitions

Term	Acronym	Description
Contact information		FIPPA defines “contact information” as 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.
Freedom of Information and Protection of Privacy Act	FOIPPA or FIPPA	The Freedom of Information and Protection of Privacy Act sets out the access and privacy rights of individuals as they relate to the public sector. FIPPA establishes an individual's right to access records - this includes access to a person's own "personal information" as well as records in the custody or control of a "public body" – see Schedule 2 and Schedule 3 for a list of public bodies that are covered by FIPPA. There are certain exceptions to accessing records- for example, a public body cannot disclose information that is deemed to be harmful to law enforcement, personal privacy or public safety. Policy advice and legal advice are also excluded. These exceptions are spelled out in sections 12 to 22. In addition to establishing an individual's right to access records, FIPPA also sets out the terms under which a public body can collect, use and disclose the "personal information" of individuals. Public bodies are held accountable for their information practices -- FIPPA requires that they take reasonable steps to protect the privacy of personal information they hold.

		(https://www.oipc.bc.ca/about/legislation) FIPPA outlines the authority and conditions for collecting, using and disclosing personal information under Part 3.
Personal information	PI	FIPPA defines "personal information" to mean recorded information about an identifiable individual other than contact information.
Personal identity information	PII	FIPPA defines "personal identity information" to mean any personal information of a type that is commonly used, alone or in combination with other information, to identify or purport to identify an individual.

Appendix B: Proportional governance model

Data Access Risk Assessment Framework – For Research Requests (Secondary Use) Version 1.4 Revised: 14-June-17

DOMAIN	SPECTRUM OF RISK			
	LOW	MEDIUM	HIGH	VERY HIGH
For Data Custodian Use – Note requests for Sensitive Data undergo an additional assessment				
DATA DELIVERED TO REQUESTOR	Aggregated data *OR* Anonymized record-level data	Record-level data: • De-identified data *(as defined by the Data Steward's policies and procedures)* • Data de-identified by trusted third party *(e.g., linked and de-identified by another HA, MoH, or PopData)* • Identified data and prior consent from patient *(linking file provided with coded data)*	Record-level data: • De-identified data with reasonable risk of identifiability • Identified data for chart pull with REB Waiver of Informed Consent *(identifiers sent to HIM for use)* • Identified data provided to contact individuals and requestor has no relationship with patient and already approved by the OIPC required • Identified data provided to contact individuals; requestor has relationship with patient (circle of care) or PHSA to facilitate contact	Record-level data: • Identified data to be linked further by the requestor • Identified data to be used as a base to develop a registry or data pooling
ENVIRONMENT WHERE DATA WILL BE STORED Including: • Physical sites • Networks and servers • Portable devices	Secure Research Environment (i.e. Population Data BC SRE) *OR* PHSA sites and secure networks only	Within BC, environment with vetted privacy and security controls, including: • BC Health Authorities • BC Ministry of Health • BCCHR REDCap • Portable devices compliant with IMITS/BCCHR/GSC/CRC security standards	Within Canada, new environment with unvetted privacy and security controls, including: • Portable devices with unknown security standards	Outside of Canada
PEOPLE	Non-industry + research team has collective experience to meet the study objectives	Non-industry + research team does not have collective experience to meet the study objectives		Industry

DOMAIN	SPECTRUM OF RISK			
	LOW	MEDIUM	HIGH	VERY HIGH
CUSTODIAN APPROVE or ESCALATION* based on assessment OUTCOME (Data + Environment + People)	Data: LOW + Environment: LOW or MEDIUM + People: LOW or MEDIUM = CUSTODIAN APPROVE** *OTHER COMBINATIONS = ESCALATION*	Data: MEDIUM + Environment: LOW or MEDIUM+ People: LOW or MEDIUM = CUSTODIAN APPROVE** *OTHER COMBINATIONS = ESCALATION*	Data: HIGH + Environment: LOW + People: LOW or MEDIUM = CUSTODIAN APPROVE** *OTHER COMBINATIONS = ESCALATION*	Data: VERY HIGH + Environment: ANY + People: ANY = ESCALATION

*Data Domain has the most weight and guides the outcomes

** Custodian approval is contingent on completion of applicable documents (e.g. ISA)