Reproductive Care Program/Rh Program of Nova Scotia

Access to Data for Research or Health Care Planning from The Nova Scotia Atlee Perinatal Database or The Rh Program Database

Policy and Procedures

Table of Contents

Title: **Reproductive Care Program/Rh Program of Nova Scotia Access to Data for Research or Health Care Planning from the Nova Scotia Atlee Perinatal Database or the Rh Program Database: Policy and Procedures**

Effective Date: **April 1, 2006**
Authorization: **Reproductive Care Program of Nova Scotia Administration Group**[1]

Introduction & Purpose

The Reproductive Care Program/Rh Program of Nova Scotia (RCP/Rh) is a provincial program of the Nova Scotia Department of Health. RCP has a broad mandate to address health care needs across the perinatal continuum and Rh has a more specific role related to the care of pregnant women with Rh-negative blood or other antibodies. Both groups manage databases that are used for monitoring standards of care, performance reporting, clinical review/audit, and research. The RCP and the Rh Program recognize the important role of evidence-based research and administrative planning in improving maternal, fetal, and infant health, and demonstrate their support for these activities by considering requests for access to health data under specific conditions.

The Reproductive Care Program/Rh Program of Nova Scotia has the following data sources available:

1. The Nova Scotia Atlee Perinatal Database (managed by RCP)

2. The Rh Program Database

The purpose of this policy is to clearly define the principles and procedures that will be used by the RCP/Rh Program to guide decisions about granting access to the data for which the RCP and Rh Program are responsible.

This policy does not cover individuals requesting access to their own personal information. Such requests are covered under the Reproductive Care Program/Rh Program Privacy Policy.

[1] This policy is consistent with those developed by the Provincial Programs Privacy Group under the auspices of the Department of Health, Acute & Tertiary Care Branch

2. Legislative Requirements

Provincial legislation establishes minimum standards about data disclosure. In general, provincial legislation indicates the purpose for which personal data may be used, how it may be used, and the requirements that must be met to protect the personal privacy of the individual or entity to whom the information pertains and to ensure that confidentiality is maintained.

Currently, the provincial legislation governing the collection, use and disclosure of data from the RCP/Rh Program data sources is the *Freedom of Information and Protection of Privacy Act (FOIPOP Act)*. The *FOIPOP Act* establishes fundamental rules respecting protection of privacy and the basic framework for disclosure of personal information held by the Nova Scotia government.

Specifically, the RCP/Rh Program may disclose personal information for a research purpose, including statistical research, if:

1. The research purpose cannot reasonably be accomplished unless the information is provided in individually identifiable form,
2. Any record linkage is not harmful to individuals, and
3. The benefits to be derived from record linkage are clearly in the public interest.

Further, the RCP/Rh Program is required to approve conditions under which data are disclosed relating to:

1. Security and confidentiality;
2. The removal or destruction of individual identifiers at the earliest reasonable time; and
3. The prohibition of any subsequent use or disclosure of the information in individually identifiable form without express written permission.

Finally, the RCP/Rh Program is required to ensure that the person to whom personal information is disclosed has signed an agreement to comply with the approved conditions.

The *Hospitals Act* authorizes the hospitals to make patient records available to the RCP/Rh Program as authorized by law or, for the RCP/Rh Program, by the Minister of Health.

3. Definitions

Health Data
A broad term encompassing data of all types about health and health care, including personal health information, institution-identifiable information, and health expenditure information.

Personal Health Information
Information about an individual that:

- Identifies the individual; or
- May be used or manipulated by a reasonably foreseeable method to identify the individual, or may be linked by a reasonably foreseeable method to other information that identifies the individual and that may include information related to:
    - the physical or mental health of the individual;
    - the provision of health services to the individual;
    - the registration of the individual for the provision of health services;

- the donation of any body part or bodily substance of the individual, or is derived from the testing or examination of any such body part or bodily substance;
- payments or eligibility for health care;
- a number, symbol or particular assigned to an individual to uniquely identify the individual for health system purposes;
- information that is collected in the course of the provision of health services to the individual; or
- registration and practice information about a health professional.

Such potential identifiers might include Nova Scotia Health Card Number, hospital chart number, date of birth, postal code, health care facility number, physician specialty designation, or rare event or condition.

Data Types

The RCP/Rh Program data may be presented in five levels of anonymity, i.e. *aggregate, person-level, person-identifiable, health care provider-identifiable, and health care facility-identifiable.* The levels are defined as follows:

- *Aggregate data*: Data about groups of individuals. Data are grouped in a manner that does not permit residual disclosure (i.e. where there are fewer than 5 observations per cell, data are generally not released). Summary and other measures will not allow back-calculation to individual values;

- *Person-level data*[1]: Data about individuals from which identifying facts have been removed or encrypted; and

- *Person-identifiable data*[2]: Data about individuals that includes individual identifiers such as name, date of birth, address, or personal health card number.

- *Health care provider-identifiable*: Data about individual care providers that includes individual identifiers such, address, postal code, age, care provider group in combination with other information (e.g. pediatrician in a specific community), unique identifier related to a health provider.

- *Health care facility-identifiable*: Data contains institution identifiers such as address, facility name, District Health Authority (DHA) name (most DHAs have only one facility with an active maternity service), and facility code.

---

[1] **Indirect identifiers.** Referred to as person-level data in this policy, these are variables such as date of birth, sex, marital status, area of residence, occupation, type of business, etc. that, in combination, could be used to identify an individual (adapted from Statistics Canada).

[2] **Direct identifiers**. Referred to as person-identifiable data in this policy, these are variables such as name and address, health insurance number, etc., that provide an explicit link to a respondent (adapted from Statistics Canada).

4. Principles for the Release of RCP/Rh Program Data

The RCP/Rh Program is authorized by the Nova Scotia Department of Health to decide whether and under what circumstances and conditions perinatal data may be disclosed. The following principles are the foundation on which the RCP/Rh Program Data Access Policy and Procedures are based. The principles are based on the Principles in Summary of the Canadian Standards Association's *Model Code for the Protection of Personal Information*.

4.1 Accountability

4.1.1 The Coordinator of the RCP is accountable for the RCP/Rh Program's adherence to these principles. Members of the RCP Data Access Committee, the Joint Perinatal Epidemiology Research Unit-Population Health Research Unit-Reproductive Care Program Data Access Committee, and the RCP Obstetrical and Neonatal Co-directors support the Coordinator in this activity.

4.1.2 The RCP/Rh Program recognizes that it is responsible for all of the personal data in its possession, even when those data have been transferred to a third party for processing. RCP/Rh requires data use agreements with third parties to ensure that data are provided with a comparable level of protection while being processed or analyzed by a third party.

4.2 Limiting Use of Data

Data access requests will only be granted when:

4.2.1. Use of the data directly supports research or administrative planning that will contribute to perinatal health or health care. Priority will be given to primary or collaborating requesters/researchers from Nova Scotia.

4.2.2. In the case of research, the proposed research is scientifically valid and is proposed by parties with a demonstrated capacity to undertake scientifically valid research;

4.2.3. In the case of research, the project has received ethics approval from a recognized university or health care facility ethics approval board;

4.2.4. In the case of administrative planning, the proposed use of the data is consistent with health system goals established by the Nova Scotia Department of Health, and in the case of facility or district-specific data, consistent with the goals of the District Health Authority from which the request originated or the IWK Health Centre;

4.2.5. The proposed use of the data will not harm the individuals that the information is about and the benefits to be derived are clearly in the public interest; and

4.2.6. The data are at the highest possible level of anonymity.

4.3 Limiting Retention

4.3.1. Researchers, health care managers, clinicians and health care planners who receive access to the data may only use the data for the originally stated purpose. Use of the data for additional purposes requires a new data access request.

4.3.2. When the data are no longer required to fulfill the identified purpose, the data will be returned to the RCP/Rh Program, which may maintain the data on behalf of the requester for up to five years. The researcher will destroy all working files containing the data in any form.

4.4 Accuracy

The RCP/Rh Program will endeavor to ensure the quality, accuracy and reliability of records under its control, whether in written, electronic or other form, as is necessary to fulfill the Program's identified purposes.

4.5 Security

The RCP/Rh Program shall establish and require from employees and contractors a high level of physical and electronic security for all data in the Nova Scotia Atlee Perinatal Database or Rh Program Database.

4.6 Openness

Upon request, RCP/Rh will make available specific information about its policies and practices relating to the management of data in the Nova Scotia Atlee Perinatal Database or Rh Program Database.

5. Access to Aggregate Data

Release of aggregate data is subject to the following conditions:

5.1. Once published by the RCP/Rh Program, files and reports based on aggregate data may be accessed without review or approval.

5.2. Requests for unpublished aggregate data must be made in writing to the Coordinator of the RCP, who has the authority to review the request in accordance with the Data Request Review Criteria established in section 8, and to deny or grant access to the data.

5.3. Requests for unpublished aggregate data for commercial or income-generating purposes may not be granted. These requests will be assessed for potential contributions to perinatal health or health care.

6. Access to Person-Level or Person-Identifiable Data

Release of person-level or person-identifiable data is subject to stringent conditions, which are outlined below:

6.1. The RCP/Rh Program may release person-level or person-identifiable data to authorized personnel of the Nova Scotia Department of Health for administrative planning purposes, on the basis of a written request to the RCP Coordinator, signed by the Minister of Health.

6.2. Requests for person-level or person-identifiable data by any party other than the Nova Scotia Department of Health must be made using the process outlined in section 11. Either the RCP Data Access Committee, or the Joint Data Access Committee will review the request, using review criteria outlined in section 8.

6.3. Requests for person-level or person-identifiable data must fully disclose the intended use of the data.

6.4. Requests for person-level or person-identifiable data will not be granted in pursuit of any commercial or income-generating purposes.

6.5. Researchers, health care managers, or health care planners requesting access to person-level or person-identifiable data must sign a data use agreement with RCP or the Rh Program that outlines the conditions of access. The requester will be required to verify compliance with required data security measures and capacity to use the data in a manner that is consistent with the RCP/Rh Program's principles of data use.

6.6. Access to person-identifiable data for research purposes will be granted only after the proposed research has received ethics approval from a recognized university, district health authority, or health care facility ethics approval board. **Ethics approval from more than one agency may be required based on DHA or health care facility policy.**

6.7. Access to de-identified person-level data for research purposes will be granted only after the proposed research has received ethics approval from a recognized university, district health authority, or health care facility ethics approval board.

6.8. Anyone who is granted access to person-level or person-identifiable data who violates the conditions of access outlined in the contract, will be subject to sanctions that may include:

6.8.1 a written complaint to the sponsoring organization,
6.8.2 refusal of future access to data,
6.8.3 seizure of any data released by the RCP/Rh Program, and/or
6.8.4 legal action.

7. Access to Health Care Provider or Health Care Facility-Identifiable Data

Release of health care provider-identifiable or health care facility-identifiable data is subject to stringent conditions, which are outlined below:

7.1 The RCP/Rh Program may release health care provider-level or health care provider-identifiable data to authorized personnel of the Nova Scotia Department of Health for administrative planning purposes, on the basis of a written request to the RCP Coordinator, signed by the Minister of Health and after the providers in question have approved the request.

7.2 Requests for health care provider or health care facility-level or health care provider or health care facility-identifiable data by any party other than the Nova Scotia Department of Health must be made using the process outlined in section 11 and must be approved by the provider(s) or DHA(s)/facilitiy(ies). Using review criteria outlined in section 8, either the RCP Data Access Committee or the Joint Data Access Committee will review the request and may assist the requester with making application for approval to DHAs/facilities as requested.

7.3 Requests for health care provider or health care facility-level, or health care provider or health care facility-identifiable data must fully disclose the intended use of the data.

7.4 Requests for health care provider or health care facility-level or health care provider or health care facility-identifiable data will not be granted in pursuit of any commercial or income-generating purposes.

7.5 Researchers or health planners requesting access to health care provider or health care facility-level or health care provider or health care facility-identifiable data must sign a data use agreement with RCP or the Rh Program that outlines the conditions of access. The researchers or health planner will be required to verify their compliance with required data security measures and their capacity to use the data in a manner that is consistent with the RCP/Rh Program's principles of data use.

7.6 Access to health care provider or health care facility-level, or health care provider or health care facility-identifiable data for research purposes will be granted only after the proposed research has received ethics approval from a recognized university, District Health Authority, or health care facility ethics approval board. **Ethics approval from more than one agency may be required based on DHA or health care facility policy.**

7.7 Anyone who is granted access to health care provider or health care facility-level or health care provider or health care facility-identifiable data who violates the conditions of access outlined in the contract, will be subject to sanctions that may include:

- 7.7.1 a written complaint to the sponsoring organization,
- 7.7.2 refusal of future access to data,
- 7.7.3 seizure of any data released by the RCP/Rh Program, and/or
- 7.7.4 legal action.

8. Reproductive Care Program (RCP) Data Request Review Criteria

The RCP Data Access Committee uses the following criteria to guide the review of requests for access to person-level, person-identifiable, health care provider-identifiable, health care facility-identifiable data. The RCP Data Access Committee's decision to approve or deny requests for data access will be based on these criteria.

8.1 Ethical Review and Approval

All research projects requiring the use of person-level, person-identifiable, health care provider-identifiable or health care facility-identifiable data must undergo an ethics review. Researchers must obtain ethics approval from a recognized university or health care facility ethics approval board, and if applicable, from all groups or organizations participating in the research.

Non-research projects requiring the use of health care provider-identifiable or health care facility-identifiable data require approval of all individuals or agencies participating in the project and may require ethics review, depending on the nature of the project. *Note: Ethics approval is always required if person-level or person-identifiable data are required, regardless of the project purpose.*

8.2 Qualifications

The principal investigator and the research team must possess the requisite clinical and research experience to complete successfully the proposed project or study. The research team should include health care providers with the appropriate clinical background as well as individuals with the appropriate methodological and analysis skills.

8.3 Data Appropriateness

The requested data elements must directly support achievement of the research or project purpose.

8.4 Level of Anonymity

The proposed data analysis methodology must support the need for person-level, person-identifiable, health care provider-identifiable, or health care facility-identifiable data.

8.5 Technical Merit

The data analysis methodology must be sufficiently detailed to evaluate the completeness and quality of the requested data. The RCP Data Access Committee reserves the right to request a technical/scientific review of the research proposal at the researcher's expense.

8.6 Resource Capacity

The requester must have access to the necessary computer hardware, software and data analysis personnel to complete the proposed analysis. The requester must have the funding to pay all of the costs associated with the proposed research or project.

8.7 Nova Scotia Participation

The research team must include a collaborator from Nova Scotia, preferably in a Principal Investigator or Co-Principal Investigator role. The purposes of this requirement are to ensure appropriate interpretation of local data and to facilitate research capacity in Nova Scotia.

8.8 Administrative, Physical and Technical Safeguards

The requester must identify reasonable steps that will be taken to maintain administrative, technical and physical safeguards that will protect the integrity and confidentiality of the information (e.g. agreeing not to copy database files to a hard drive or shared network, password protection on computer, locked cabinet, encryption – see RCP/Rh Program Application for Access to Data). Safeguards must protect against:

- 8.8.1 Any reasonably anticipated threats or hazards to the security or integrity of the data,
- 8.8.2 Loss of the data, and
- 8.8.3 Unauthorized access, use, modification or disclosure of the data.

8.9 Significance

The project or research must have the potential to improve the health status of Nova Scotians and/or improve the performance of the health system in Nova Scotia.

9. Cost Recovery

The Nova Scotia Atlee Perinatal Database is a provincial resource. Data extraction and production services are provided to Nova Scotia researchers, health care providers and health care planners at the lowest cost possible. If investigators are applying for funds to carry out their projects, costs for data extraction and production services should be included in the budget. Costs should include direct and indirect costs i.e. time for administration, data extraction, production, and if applicable, storage. Estimates will be provided by the RCP Coordinator, in consultation with RCP staff, as part of initial discussions about proposed projects.

10. Publication of Information Using RCP or Rh Program Data

10.1 Pre-publication Notification

Pre-publication/presentation review is available at any time and is encouraged for novice researchers or for those unfamiliar with perinatal care in Nova Scotia. Under certain circumstances (e.g. particularly sensitive topics), pre-publication review may be required.

Final copies of all abstracts, posters, presentations or publications that include RCP/Rh Program data should be submitted to the RCP/Rh Program for information purposes only. Information obtained from these documents will not be used or disclosed without the written consent of the authors.

10.2 Acknowledgement of the Nova Scotia Atlee Perinatal Database and RCP or the Rh Program Database

All publications that include data from either the Nova Scotia Atlee Perinatal Database or the RCP/Rh Program Database must contain the following acknowledgement:

"The authors acknowledge the Nova Scotia Atlee Perinatal Database, managed by the Reproductive Care Program of Nova Scotia (RCP) for the contribution of data used in this research. Any opinions expressed by the authors do not necessarily reflect the opinion of the RCP/Rh Program of Nova Scotia."

or

"The authors acknowledge the Rh Program of Nova Scotia for the contribution of data used in this research. Any opinions expressed by the authors do not necessarily reflect the opinion of the RCP/Rh Program of Nova Scotia."

11. Procedures for Accessing RCP or Rh Program Data

The following section describes the procedures for accessing RCP/Rh Program data. Requesters unfamiliar with the Nova Scotia Atlee Perinatal Database or the Rh Program Database should contact the RCP prior to initiating a request. It is recommended that researchers contact the RCP Coordinator as early as possible in the research design process.

11.1 Discussion about Project or Research Design

Requesters should initiate this step in the data access process as early in the research design or project planning phase as possible. The following steps are required as part of this phase in the process:

11.1.1 The requester initiates contact with the RCP Coordinator or designate from RCP, the RCP Data Access Committee, or the Perinatal Epidemiology Research Unit via telephone, e-mail or in person to hold a preliminary discussion about the feasibility of the proposed project, to obtain a description of the appropriate data sets, and to obtain an electronic copy of *the RCP/Rh Program of Nova Scotia Application for Access to Data* (Appendix A, also available on the RCP website).

11.1.2 The requester submits to the RCP Coordinator the following information using the appropriate portions of the *RCP/Rh Program of Nova Scotia Application for Access to Data*:

1. Name of the requester/principal investigator who is submitting the request. If the requester is a student, the name of the student's supervisor must also be included.
2. Requester's/ principal investigator's organizational affiliation, position, and contact information.
3. Title of project,
4. Purpose and objectives of the project.
5. Description of analysis capacity
6. Budget (if applicable) and time schedule

7. Proposed methodology
8. Data required, including population of interest (births to Nova Scotia residents versus births in Nova Scotia), level of anonymity, data elements, months/years for which the data are required.
9. Dissemination plans
10. Data security practices.

11.1.3 The RCP Coordinator reviews the data request regarding data availability and the required level of anonymity to fulfill the purpose of the project. The purpose of the review is to determine any additional items or issues concerning use of RCP/Rh Program data that should be reflected in the *Application for Access to Data.*

11.1.4. The RCP Coordinator prepares a preliminary cost estimate if applicable. Note: The estimate may be adjusted once the data elements and research design have been finalized.

11.1.5 The RCP Coordinator and the requester agree upon the data requirements. The RCP Coordinator may consult with staff members, members of the RCP Data Access Committee or the Perinatal Epidemiology Research Unit regarding the preliminary research design or request that the researcher seek additional consultation about the proposed methodology.

11.2 Review and Approval of the Request

The following steps outline the RCP/Rh Program request review process:

11.2.1 The RCP Coordinator acknowledges receipt of the *Application for Access to Data* , and identifies any omissions in required information. The researcher forwards materials that address the omissions to the RCP Coordinator before the review proceeds.

11.2.2 The RCP Coordinator reviews requests for aggregate data. Review of all data access applications uses the review criteria described in section 8. Reviews of requests for aggregate data will normally be completed within 2 weeks of submission to the RCP Coordinator.

11.2.3 The RCP Data Access Committee reviews requests for person-level, person-identifiable, care provider-level, care provider-identifiable, health care facility-level, or health care facility-identifiable data from the Nova Scotia Atlee Perinatal Database. Requests that require a linkage between the Nova Scotia Atlee Perinatal Database or the Rh Program Database and any other database or data set are reviewed through the Joint Perinatal Epidemiology Research Unit-Population Health Research Unit-RCP Data Access Committee. Reviews of all data access applications use the review criteria described in section 8. Review will normally be completed within 4-6 weeks of submission to the RCP Co-ordinator. However, unforeseen circumstances may delay processing. **Note: All requests described in 8.1 require approval by the IWK Health Centre Research Ethics Board (application forms available from**

IWK Research Services). Requests for health care provider-identifiable or health care facility-identifiable data usually require approval by all the providers or all the DHAs/facilities involved (application forms available from each DHA/facility REB). This process may take several months. Data retrieval will not take place until verification of all required approvals has been forwarded to RCP.

11.2.4 Approval of requests for aggregate data may be verbal or in writing. For requests requiring person-level, person-identifiable, care provider-level, care provider identifiable, health care facility-level, or health care facility-identifiable data, including linkage projects, the researcher will receive a written report outlining approval or denial of the request and any stipulations or conditions for data use.

11.3 Data Use Agreement

For approved requests, other than those for aggregate data, the RCP Co-ordinator forwards the Data Use Agreement (sample agreement in Appendix B) to the researcher. The researcher reviews, signs, and returns the contractual agreement to the RCP Coordinator.

11.4 Data Preparation

11.4.1 An RCP analyst prepares the data for the researcher in the format specified in the data request.

11.4.2 The RCP Coordinator or designate sends the data to the researcher using a secure transmission method such as a bonded courier or an electronic system with the appropriate level of encryption and security.

11.4.3 Within two weeks of receipt of the data, the researcher confirms with the RCP Coordinator or designate that the data meets the agreed upon specifications for the request.

11.4.4. The RCP Coordinator or designate sends an invoice to the researcher for the amount specified in the contractual agreement.

11.5 Publication/Presentation Submission

The researcher provides final copies of all abstracts, posters, presentations, or publications that include RCP/Rh data to the RCP/Rh Program. Pre-publication/presentation review is available at any time and is encouraged for novice researchers or for those unfamiliar with perinatal care in Nova Scotia. Pre-publication/presentation review may be required as a condition of data access in situations where the area of study may be sensitive or contentious.

11.6 Return of Data and Destruction of Working Files

The researcher returns the data to the RCP Co-ordinator at the end of the research project (a mutually agreed upon date stipulated in the Data Use Agreement). The researcher destroys *working files* and sends a written notice to the RCP Coordinator confirming destruction of the files in accordance with the contractual agreement. In the case of electronic media either physical destruction or non-recoverable deletion of data is required. Use of the data for any

purposes other than those stated in the *Application for Data Access for Research Purposes* is prohibited.

The RCP/Rh Program will hold the researcher's data for up to five years after project completion, upon a written request from the researcher. If the researcher wishes the RCP/Rh Program to hold a copy of his or her data for a period of time, the researcher is responsible for ensuring that the data to be held is transferred to the RCP/Rh Program via secure means, prior to the destruction of the researcher's working files.

12. Evaluation of Policy and Procedures

The RCP Administration Group, in consultation with the RCP Data Access Committee, will review these policies and procedures at least every two years or as new standards for data access, management, or use become available provincially or nationally.