Instructions for Completing an Application for Access to Data from the RCP Nova Scotia Atlee Perinatal Database

Data Access Committees

Your request for data from the Nova Scotia Atlee Perinatal Database will be reviewed by one of two Data Access Committees, depending on the type of request. All applications should be sent to the Reproductive Care Program of Nova Scotia who will forward them to the appropriate committee.

For projects requiring a linkage between the Nova Scotia Atlee Perinatal Database and one or more other data sets, applications are reviewed by the **Joint Data Access Committee (JDAC)** which is a partnership of the Perinatal Epidemiology Research Unit (PERU), Health Data Nova Scotia (HDNS), and the Reproductive Care Program of Nova Scotia (RCP).

For projects that require data from the Nova Scotia Atlee Perinatal Database ONLY (as long as the data set remains in Nova Scotia), applications are reviewed by the **RCP Data Access Committee (RCPDAC)**.

The Data Access Committees have two main roles:

1. To determine that the data being sought from the NSAPD by the investigator(s) are appropriate and pertinent to the project proposal under consideration and

2. To ensure to the extent possible that the data are released to investigator(s) under conditions that protect the privacy and confidentiality of patients, care-providers, institutions, and vulnerable sub-populations contained in the NSAPD, within the bounds of permission given to the investigator(s).

Data requests may be made for a variety of reasons; including:

- Data quality/audit processes
- Care planning
- Research

Both Data Access Committees meet on a regular (usually monthly) basis to consider requests. You will be offered the opportunity to attend a meeting to review your application with members of the Committee. If your request for access to data is approved, you will be required to sign appropriate contractual agreements that outline the specific conditions under which the data will be released.

If you have any questions regarding your application, please feel free to contact:

For linkage projects:

Dr. Alexander Allen
Chair, Joint Data Access Committee
Perinatal Epidemiology Research Unit
Dalhousie University
IWK Health Centre
5980 University Avenue
Halifax, Nova Scotia
Canada B3K 6R8
E-Mail: alexander.allen@dal.ca
(902) 470-6681

For data requests to NSAPD only:

John Fahey or Irene Gagnon
Co-Chair, RCP Data Access Committee
Reproductive Care Program of Nova Scotia
5991 Spring Garden Road
Suite 700
Halifax, Nova Scotia
Canada B3H 1Y6
E-Mail: rcp@iwk.nshealth.ca
(902) 470-6798

Acronyms

CIHI	Canadian Institute for Health Information
DHW	Nova Scotia Department of Health & Wellness
HDNS	Health Data Nova Scotia
JDAC	Joint Data Access Committee
MSI	Medical Services Insurance
NSAPD	Nova Scotia Atlee Perinatal Database
PERU	Perinatal Epidemiology Research Unit
PHIA	Personal Health Information Act
RCP	Reproductive Care Program of Nova Scotia
REB	Research Ethics Board
RCPDAC	RCP Data Access Committee

Research Ethics Board

Please note: Any project calling for the release of data involving patients treated at the IWK Health Centre requires that the project be reviewed and approved by the IWK Health Centre Research Ethics Board. It is the responsibility of the investigator(s) to submit an application to Research Ethics.

Privacy

In Nova Scotia the *Personal Health Information Act (PHIA)* governs the collection, use, disclosure, retention, disposal and destruction of personal health information. *PHIA* recognizes both the right of individuals to protect their personal health information and the need for custodians to collect, use and disclose personal health information to provide, support and manage health care. Data for the Nova Scotia Atlee Perinatal Database is collected by RCP/the Department of Health & Wellness (DHW) without expressed consent. When record-level data are provided for research purposes, the investigator is required to address the impracticability clause in *PHIA*, which requires investigators to seek consent unless doing so is impracticable.

In keeping with the principle that privacy of individuals will be protected as a top priority, investigators are not permitted to release data from cells containing fewer than 5 individuals. If such information is important to the outcomes of the study and the risk of identifying individuals in such cells is low, then it is possible for the investigator to apply for a variance to this rule in a specific case. If this is the case in a specific project, the principal investigator must notify the Chair of the Joint Data Access Committee or the Chair of the RCP Data Access Committee in writing, by e-mail, or by phone that he/she will be requesting permission to publish tables having less than 5 individuals in a cell. The principal investigator must then submit the specific request in writing together with the rationale for the variance to the Chair of the Joint Data Access Committee. Notification of the decision will be sent to all investigators and to the pertinent REB.

Even though direct identifiers are not released, certain types of data (e.g., place of residence and birth date, birth date and time, obstetrician or paediatrician and place of practice) can be used to

identify individuals. Investigators given permission to use these data must commit to establishing secure systems of data management and analysis so that no individual patient, care-provider, person or institution will be identified. Investigators must also commit to the RCP Data Access Committee's or Joint Data Access Committee's policies of pre-submission review of publications to ensure that confidentiality and privacy have been maintained.

Completing and Submitting the Application

The information you supply on the Application Form will be used to evaluate your request for access to the Nova Scotia Atlee Perinatal Database. Please download the Application Form from the RCP website, complete all applicable sections of the form and provide any additional information that is requested.

1) Before finalizing your project application, familiarize yourself with the variables in the Databases that you are applying to access.

2) It is strongly recommended that you discuss with the custodians of each of the Databases the feasibility of addressing the questions in your project and the guidelines and limitations for the data in each field that you plan to use.

3) Provide a detailed description of the project including the reason(s) for data access (e.g., care planning, quality review or research) in the Proposal Summary section on page 5 of the Application Form. If this is a request for a research project, attach the full study protocol as **Appendix 1**.

4) For linkage projects, attach a full listing of all database variables that will be used in the linkage procedure as **Appendix 2**. Organize these linkage variables by database. Although protecting privacy and confidentiality is a key consideration in the project review, linkage rates are improved with the number of linkage variables available.

   Note: All linkage projects must be discussed with the Chair of JDAC or designate <u>prior to</u> submitting the application.

5) Attach a full listing of all database variables that you are requesting to be included in the "Analysis File" as **Appendix 3**. Organize these variables by source database.

6) If requesting person-identifiable, health-provider identifiable or institution-identifiable variables, detailed justification for their use must be provided in **Appendix 4**.

7) For research projects, please attach a copy of the *Curriculum vitae* of the principal investigator(s) as **Appendix 5** if an up-to-date version of it is not on file in IWK Research Services.

8) Fully describe your plans for maintaining the security and confidentiality of the data in the "Analysis File" on pages 6, 7 and 8 of the Application Form.

9) Review Attachments A, B and C pertaining to data management and data access. Confirm your agreement and commitment to abide by the principles stated in these documents by

having all investigators print, initial and sign a copy of page 9 of the Application Form. *Note: Attachment A is the Process for Requesting Individual-Level Data from the Nova Scotia Atlee Perinatal Database. Attachment B is the RCP/DHW Data Use Agreement. Attachment C is the RCP Data Management Principles.*

10) If your project is a linkage project and involves access to the Provincial Health Administrative Databases managed by Health Data Nova Scotia (HDNS), there will be additional documents to review and an additional application to complete.

11) Send the completed Application Form, including the appropriate Appendices 1 through 5, by e-mail to the Reproductive Care Program at RCPDAC_JDAC@iwk.nshealth.ca

    It is <u>not</u> necessary to send Attachments A through C with your completed Application. You will be asked to complete Attachment B, the Data Use Agreement, when you receive your analysis file.

12) The signature page (page 9) must be printed separately, initialed and signed. All investigators must print, initial and sign a copy of page 9 and submit the page to the office of Janet Slaunwhite at the IWK Health Centre. Investigators must use one of the following submission methods:
    a) hand deliver or mail the form to Janet Slaunwhite, Room G7108, Women's Site, IWK Health Centre
    b) scan the form **<u>with the investigator's original signature</u>** (an electronically generated signature will not be accepted) and e-mail it to janet.slaunwhite@iwk.nshealth.ca
    c) fax the form **<u>with the investigator's original signature</u>** (an electronically generated signature will not be accepted) to Janet Slaunwhite at 902-470-7190.

13) You are encouraged to attend the Joint Data Access Committee or RCP Data Access Committee meeting at the time of review to answer questions raised during the Committee discussion. If it is not possible for the principal investigator(s) to attend the meeting, a co-investigator with knowledge about the project would be helpful in addressing such questions during the Committee Review.

Once your application has been reviewed and fully approved (i.e., all clarifications and questions have been answered) your data request will be entered into the data request queue. Data requests from the RCP Nova Scotia Atlee Perinatal Database typically take 2-6 weeks, depending on the complexity of the project. Data requests requiring linkages can take longer. We recommend that investigators begin the data request process as early as possible to limit delays in obtaining data.

Definitions

Impracticable[1]
Impracticable means a degree of difficulty higher than inconvenience or impracticality but lower than impossibility.

Privacy and Confidentiality[2]
Privacy means the right of individuals to determine when, how and to what extent they share information about themselves with others.

Confidentiality means the obligation of an organization or custodian to protect the information entrusted to it and not misuse or wrongfully disclose it.

Personal Health Information1[3]

"Personal health information means identifying information about an individual, whether living or deceased, and in both recorded and unrecorded forms, if the information

> (i) relates to the physical or mental health of the individual, including information that consists of the health history of the individual's family,
>
> (ii) relates to the application, assessment, eligibility and provision of health care to the individual, including the identification of a person as a provider of health care to the individual,
>
> (iii) relates to payments or eligibility for health care in respect of the individual,
>
> (iv) relates to the donation by the individual 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,
>
> (v) is the individual's registration information, including the individual's health-card number, or
>
> (vi) identifies an individual's substitute decision-maker"

Personal Information[4]

"Personal Information means recorded information about an identifiable individual, including:
a) the individual's name, address or telephone,
b) the individual's race, national or ethnic origin, color, or religious or political beliefs or associations,

[1] Source: Personal Health Information Act
[2] Source: The Pan-Canadian Health Information Privacy & Confidentiality Framework
[3] Source: Personal Health Information Act
[4] Source: Nova Scotia Freedom of Information and Protection of Privacy Act.

c) the individual's age, sex, sexual orientation, marital status or family status,
d) an identifying number, symbol or other particular assigned to the individual,
e) the individual's fingerprints, blood type or inheritable characteristics,
f) information about the individual's health care history, including a physical or mental disability,
g) information about the individual's educational, financial, criminal or employment history,
h) anyone else's opinions about the individual, and
i) the individual's personal views or opinion, except if they are about someone else."

Types of Information

Identifiable information – Information that may reasonably be expected to identify an individual, alone or in combination with other available information.[5]

Directly identifying information – The information identifies a specific individual through direct identifiers (e.g. name, social insurance number, personal health number).[4]

Indirectly identifying information – The information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence, or unique personal characteristic).[4]

Coded information – Direct identifiers are removed from the information and replaced with a code. Depending on access to the code, it may be possible to re-identify specific participants.[4]

Anonymized information – The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.[4]

Anonymous information – The information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low.[4]

Identifying information means information that identifies an individual or, where it is reasonably foreseeable in the circumstances, could be utilized, either alone or with other information, to identify an individual[6]

De-identified information is information that has had all identifiers removed that

(i) identify the individual, or
(ii) where it is reasonably foreseeable in the circumstances, could be utilized, either alone or with other information, to identify the individual[5]

Levels of Identifiability

a) Aggregate: Data that cannot be linked to individuals. For data release purposes, this term generally refers to data that has been grouped with all cells having 5 or more individual

[5] Source: Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
[6] Source: Personal Health Information Act

patients or subjects. In addition, presentation of data must ensure that summary and other measures cannot allow back-calculations to individual values. Aggregate data for distinct population or specific communities may still be identifiable or sensitive enough that additional measures to protect privacy and confidentiality may be required prior to release of data tables.

b) **Person-Level (De-identified):** Individual level data that has had all direct and indirect identifiers removed. Direct identifiers are those that are specific to the individual patient or subject and include such variables as name or health card number. Indirect identifiers are those that could be used alone or in combination to identify an individual patient or subject, such as birth date or full address. For data release purposes, individual data are "coded" as per the definition above. That is, direct identifiers are removed from each patient/subject record in the analysis file and replaced with a unique identifier that is specific to the approved project. RCP retains the key in case re-identification is required. Indirect identifiers are modified to reduce the risk of re-identification. Examples include replacing birth date with maternal age and replacing a full address with the forward sortation area (first 3 digits) of the postal code.

c) **Person-Identifiable:** Individual level data that contains direct or indirect identifiers. For data release purposes, patient/subject consent is usually required. Occasionally an indirect identifier is required to complete a project. The researcher must provide a strong argument for including an indirect identifier in the analysis file. *Note: For any linkage project, direct identifiers will be required to perform the linkage. These identifiers will be used to link the files required for the approved project then the file will be coded as described in the Person-Level (De-identified) section above. The data in the analysis file is then considered person-level (de-identified).*

d) **Health Care Provider-Identifiable:** Individual care providers can be identified by name, practice number, specialty, practice parameters, or location of practice. (e.g., obstetrician practicing in XX County when there is only one obstetrician in that county). For data release purposes, caregiver consent is usually required. The researcher must provide a strong argument for including health care provider-identifiable data in the analysis file.

e) **Institution-Identifiable:** Health care facilities can be identified by name or location (e.g. the health care facility in XX District Health Authority when there is only one facility with an active maternal and newborn service in the District). For data release purposes, institutions are usually categorized as tertiary, regional or community hospitals. The researcher must provide a strong argument for including Institution-Identifiable data in the analysis file and may be required to seek approval from the facilities as part of the project approval process.

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