**Combined Joint Data Access Committee (JDAC), Reproductive Care Program of**

**Nova Scotia (RCP), and Health Data Nova Scotia (HDNS) Data Access Request Form**

Information contained on this form will be used to evaluate your request for access to Nova Scotia Atlee Perinatal Database (NSAPD) [hyperlink] and/or Health Data Nova Scotia (HDNS) [hyperlink] data. Complete all sections of the form, including the Submission Checklist. Incomplete forms will be returned to the applicant.

Project Title:

Principal Applicant:

Original Submission Date:

Request for Data Access from (check all that apply):

□ Reproductive Care Program of Nova Scotia Data Access Committee (RCP DAC)

□ Joint Data Access Committee (JDAC)

□ Health Data Nova Scotia Data Access Committee (HDNS DAC)

□ Department of Health and Wellness (DHW)

**SUBMISSION CHECKLIST**

□ Completed Data Access Request form (this document)

□ Appendix 1 - Project proposal, protocol and/or research plan

□ Appendix 2 - Table of linkage variables and detailed flow diagram of the data linkage process

□ Data linkage process not applicable

□ Appendix 3 - Table of variables to be included in the Data Analysis File, including case definitions/diagnostic/procedure codes /inclusion & exclusion criteria required

□ Appendix 4 - List of all project team members

□ Appendix 5 - Completed REB application & supporting documents (such as REB waiver of consent), for review by the Data Access Committee(s) – *This requirement is Data Access Committee-specific - please check with the relevant Data Access Committee*

 □ Waiver of consent not applicable

 □ REB application not applicable

□ Appendix 6 - Abbreviated CVs of Principal Applicant, Academic Supervisor (if applicable), and any project team members requesting individual-level data access; CV is not required if a recent version (within two years) is on file.

□ Appendix 7 - For proposals that are not funded:

- Letters of support from Academic Supervisor (if Principal Applicant is a student), and from the Research Director, Division Head, Department Head or Manager (for proposals that have not been peer-reviewed)

 □ Letters of support not applicable

 □ Letters of support included in the attached REB application

- The investigators should provide the reviewers’ comments and reasonable response to the comments

 □ Proposal has not been peer reviewed – not applicable

□ Appendix 8 - Letters of feasibility from Database Custodian/Agent/Manager for requested data

□ Appendix 9 - Participant introduction letter

 □ Participant introduction letter not applicable

□ Appendix 10 - Participant consent form

□ Participant consent form not applicable

**Combined Joint Data Access Committee (JDAC), Reproductive Care Program of**

**Nova Scotia (RCP), and Health Data Nova Scotia (HDNS) Data Access Request Form**

1. Before you begin, read the Frequently Asked Questions document, the Definitions document and the Data Management Principles document [insert hyperlink] on the RCP website, and the Guide to HDNS Services and the HDNS Data Access Form Instructions document [inset hyperlink] on the HDNS website. These documents convey important information you will need to ensure a successful data request, including an overview of how the Data Access Committees work, how to contact the Committee Chairs, privacy requirements and definitions and detailed steps for completing and submitting your application.
2. Download the Application Form (this file) and save it on your computer. Open it and complete all sections. Save the document. Create a separate document(s) to use for adding Appendices 1 through 10 (if applicable) and save it as MS-Word, Rich Text Format (rtf) or PDF.
3. Prior to submitting your application to SharePoint, [insert hyperlink with instructions] save the completed Application Form and Appendices for your records.

**ADMINISTRATIVE INFORMATION**

Project Title:

Original Submission Date:

Amendment Date and Version (if applicable):

*Every new amendment needs a new Amendment Form submitted and an updated application (Data Access Request—DAR).*

(Internal use only): Project ID:

 Amendment ID:

 AmendmentDate Received:

**Project Funding Information:**

**Has funding been obtained for this project?**

□ No □ Yes

If “yes”, please identify the funding source(s):

**Total award amount:**

**At which institution is this funding being held?**

□ Dalhousie University □ NSHA □ IWK Health Centre

□ Other (please specify):

Is this research being conducted on behalf of, or with the support of, any other person or organization other than its funder(s)?

□ No □ Yes

If yes, please explain:

If no, has this project been peer-reviewed (for example: funding committee, thesis committee, peer-reviewed journal review of study protocol)?

□ No □ Yes

If yes, by whom?

If no, please attach a letter of support from your Academic Supervisor (if a student); a letter of support must also be received from one of the following: Research Director, Division Head, Department Head or Manager. The letter(s) of support will indicate that a review of the project has been done and that it is worthwhile (attach as Appendix 7).

Purpose of Project: (check each that is appropriate)

□ Research □ Educational Materials

□ Health Service Assessment/Planning and Management of Health Care

□ Other (specify):

Estimated Project End Date: Month\_\_\_\_\_\_\_\_\_ Year\_\_\_\_\_\_\_\_\_\_\_

Dissemination and Use of Study Results:

□ Presentation □ Publication □ Policy Development

□ Other (specify):

Research Ethics Board(s) Approving/Waiving the Project:

□ Dalhousie □ IWK □ NSHA □ N/A □ Other (specify):

If N/A, please explain:

**PROJECT TEAM**

Principal Applicant:

Position:

Institution:

Email Address:

Phone Number:

Street Address:

City:

Province:

Postal Code:

Is the Principal Applicant requesting access to person-level data? □ No □ Yes

If yes:

 Provide rationale:

 Summarize qualifications:

Project Contact Person (if different from Principal Applicant):

Position:

Institution:

Email Address:

Phone Number:

Street Address:

City:

Province:

Postal Code:

Is the Project Contact Person requesting access to person-level data? □ No □ Yes

If yes:

 Provide rationale:

 Summarize qualifications:

Academic Supervisor (if Principal Applicant is a student):

Position:

Institution:

Email Address:

Phone Number:

Street Address:

City:

Province:

Postal Code:

Is the Academic Supervisor requesting access to person-level data? □ No □ Yes

If yes:

 Provide rationale:

 Summarize qualifications:

Include a listing of all the project team members, including their names, affiliations, and roles in the project, and request for access to person-level data, attached as Appendix 4 (include CVs as part of Appendix 6). Please see below an example of a Table listing all the project team members.

If an amendment to the project is submitted to the Data Access Committees with changes to the data requested, or with a different plan to analyze the requested data associated with risk of re-identification, applicants having access to person-level data must confirm that they understand these changes with a new original signature on the Data Sharing Agreement with the relevant Data Access Committee.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name** | **Position** | **Institution** | **Role on Project** | **Requesting access to person-level data (Yes, No).** **If Yes, provide rationale.** | **Email address** |
| *e.g. Jane Smith* | *e.g. Associate Professor* | *e.g. Dalhousie University* | *e.g. Principal applicant* | *e.g. Yes. Confirmation of relevant data and Interpretation of data analysis* |  |
| *e.g. John Doe* | *e.g. Statistician*  | *e.g. MSSU* | *e.g. Co-Applicant* | *e.g. Yes. Data analysis* |  |
| *e.g. Jane Doe* | *e.g. Medical Student* | *e.g. Dalhousie University* | *e.g. Co-Applicant* | *No*  |  |

**PROJECT DETAILS**

**ATTACHED AS APPENDIX 1**

1. Please provide asummary of the research project (attach the complete project proposal/protocol/research plan as Appendix 1) in plain language, avoiding technical terms wherever possible. Maximum 2000 characters.
2. List all project objectives and/or research questions. Maximum 2000 characters.
3. Please provide a summary of the plan to analyze the requested data, including but not limited to, study cohort/population, study timeframe, data sources, and the study variables (listed as general categories, since the detailed list is included in Appendix 3) needed to address each research question or objective identified in b), and requested in Details of Data Requested, and how they will each be incorporated into the analyses (e.g. as outcome measures, predictors, controls, strata, etc.). The purpose of this description is to confirm an understanding of [Data Management Principles](http://rcp.nshealth.ca/sites/default/files/atlee-database/RCP%20Data%20Management%20Principles.pdf) necessary to undertake this project. <http://rcp.nshealth.ca/sites/default/files/atlee-database/RCP%20Data%20Management%20Principles.pdf> [insert hyperlink]

This description should also be included in the Project Proposal (Appendix 1) with the heading: “Plan for Data Analysis”. Maximum 2000 characters.

1. List all the variables to be used for linkage in Appendix 2, organized by database. See template below. It is strongly recommended that you consult with the Custodian/Agent/Manager of the database(s) to discuss availability and definitions of variables.
2. List all the requested variables in all the databases to be included in the “Data Analysis File” in Appendix 3. Be sure to identify each variable by code (for example NSAPD code, ICD-10 code) and by name with the definition as defined in the database. Organize the variables by database, and provide justification for use. If person-identifiable, health-provider-identifiable or institution-identifiable information are to be used in the analysis, provide additional details. See template below.

**PROJECT DETAILS (CONTINUED)**

1. Specify the level of identifiability for the "Data Analysis File" variables requested (See "Levels of Identifiability" in the Definitions section of the Instructions document). [Insert hyperlink]

Check all that apply:

□ Aggregate □ Person-Level

□ Person-Identifiable □ Health-Provider Identifiable □ Institution-Identifiable

**DETAILS OF DATA REQUESTED**

1. **LINKAGE - ATTACH AS APPENDIX 2**

***Only the minimum data set in the least identifiable form required to fulfill the project objectives will be considered for dataset creation or linkage. HDNS cannot link data sets containing unencrypted Health Card or provider numbers, or direct identifiers such as name or street address.***

Data linkage: If applicable, please provide a list of all sources from which data are being requested and linkage variables being requested for this project from each. If applicable, please also attach a detailed flow diagram of the data linkage process. The following template should be used to organize the information by the Database Custodian/Agent/Manager of the data (e.g. RCP, HDNS, DHW) and databases from which the variables are being requested (e.g. Atlee Perinatal Database, CIHI Discharge Abstract Database). An example of a detailed flow diagram may also be found below. Please visit the RCP website [insert hyperlink] and [the HDNS website](https://cdn.dal.ca/content/dam/dalhousie/pdf/faculty/medicine/departments/department-sites/community-health/research/hdns/HDNS%20Guidelines%20for%20Data%20Linkage.pdf) for guidelines on this process.

**Example of table of linkage variables:**

Table of linkage variables requested for this project with identification of Database Custodian/Agent/Manager (data sources) and databases for the project: e.g. Mode of delivery and postnatal hospitalization among school-aged Nova Scotia Residents born between 1999 and 2009 with follow-up to 2015.

|  |  |  |
| --- | --- | --- |
| **Database Custodian/Agent/Manager and Contact Information (Data Source)** | **Database** | **Linkage Variable** |
| *e.g. Reproductive Care Program of Nova Scotia -* (RCPDAC\_JDAC@iwk.nshealth.ca) | *e.g. Nova Scotia Atlee Perinatal Database (NSAPD)* | *e.g. HCN* |
| *e.g. Surname* |
| *e.g. Date of Birth* |
| *e.g. Health Data Nova Scotia -*  hdns@dal.ca | *e.g. Health Data Nova Scotia -*  hdns@dal.ca | *e.g. encrypted HCN* |
| *e.g. Admission date* |
| *e.g. Date of Birth* |

**Examples of a detailed flow diagram of the data linkage process**

Example of detailed flow diagram for a **JDAC** application:

Preparation of the Data Analysis file for the project: Mode of delivery and postnatal hospitalization among school-aged Nova Scotia Residents born between 1999 and 2009 with follow-up to 2015.

Example of detailed flow diagram for a **HDNS** application:





1. **DATA ANALYSIS FILE – ATTACH AS APPENDIX 3**

Please identify all databases from which data are being requested and provide a list of the individual variables being requested from each database. The following template should be used to organize the information by the Database Custodian/Agent/Manager of the data (e.g. RCP, HDNS, DHW) and databases from which the variables are being requested (e.g. Atlee Perinatal Database, CIHI Discharge Abstract Database). Variable codes (for example, NSAPD codes, ICD-10 codes) for all requested data are required and can be clarified by consultation with the Reproductive Care Program or Health Data Nova Scotia.

An example of a table of analysis file variables: Table of analysis file variables requested for this project with identification of Database Custodian/Agent/Manager (data sources) and databases for the project: e.g. Mode of delivery and postnatal hospitalization among school-aged Nova Scotia Residents born between 1999 and 2009, with follow-up until 2015. Include in the table grouped variables derived from individual variables.

|  |
| --- |
| **Reproductive Care Program of Nova Scotia – Nova Scotia Atlee Database, 1999-2015.** |
| Variable description | Level of variable detail/variable description | Variable Code | Why is this specific element required in the requested detail? |
| *e.g. Date of Birth* | *Categorical variable, Year of Birth* | *BrthYear* | *To restrict analyses to individuals born during the study period to measure trends over time and as a co-variate* |
| *e.g. Mode of Delivery* | *Categorize as C-section or vaginal* | *delmod* | *To distinguish C-sections from other types of births and to compare outcomes by mode of delivery* |
| **Health Data Nova Scotia – CIHI Discharge Abstract Database – 1999-2015.** |
| Variable description | Level of variable detail/variable description | Variable Code | Why is this specific element required in the requested detail? |
| *e.g. admission date* | *Month/year* | *addate* | *To select hospital admissions that occurred during the study period and to restrict analyses to hospitalizations occurring while individuals were NS residents.*  |

**CONSENT**

1. Will participants in this project be providing consent to having their personal health information accessed for the objectives identified in the PROJECT DETAILS section?

□ Yes (please attach Participant Introduction Letter as Appendix 9 and Participant Consent Form as Appendix 10 and skip to the INFORMATION SECURITY PRACTICES section)

□ No

□ Not Applicable (for example, consent not required for quality improvement review, PHIA 35(1), 38(1)(f)

1. If your response to the previous question was “No”, please indicate why it is impracticable to obtain consent and attach the relevant documentation explaining request for waiver of consent from the Research Ethics Board (REB) for review by the Data Access Committee (attach as Appendix 5 with the completed REB application).

*The Nova Scotia Personal Health Information Act (PHIA) stipulates that the Database Custodian/Agent/Manager of any personal health information may disclose that information to an applicant without the consent of the individuals to whom it pertains under specific circumstances, including but not limited to a determination by a REB that consent is not required. Please see section 57 of PHIA for all requirements.*

The following links are provided as resources:

1. The IWK Health Centre Impracticability Guideline: <http://www.iwk.nshealth.ca/research/reb-application-process> - please look under the Privacy Section and click on “Impracticability Guideline”.
2. Nova Scotia Personal Health Information Act, Section 57: <https://novascotia.ca/dhw/phia/custodians.asp>

**INFORMATION SECURITY PRACTICES**

Note that only authorized users/study personnel may have access to the data. Data are retrieved and linked for approved project purposes only. Ongoing access to data for research projects will not be available upon project closure through a Research Ethics Board. HDNS data can be accessed via remote access through its secure data platform. Further, **all individuals requesting access to person-level data through HDNS/RCP are required to undergo annual HDNS/RCP privacy training.**

1. Will analyses take place solely on the HDNS secure data platform, Citadel, using remote access?

□ Yes □ No

Comments:

1. Will the computer(s) used to access the data be…
	1. …laptops or other portable computers?

□ Yes □ No

Comments:

* 1. …located in a room with access restricted to the project personnel identified in the PROJECT TEAM section? Please provide the asset tag(s) and physical location(s) of the computers on which the data will be accessed (complete address, including office number if applicable) in the ‘Comments’ section.

□ Yes □ No

Comments:

* 1. …password-protected, with a different password for each user?

□ Yes □ No

Comments:

* 1. …equipped with an automatic password-protected time-out feature set for 5 minutes or less?

□ Yes □ No

Comments:

* 1. …equipped with laptop hard disk encryption?

□ Yes □ No

Comments:

1. Will any of the requested data be…..
	1. Downloaded to a mobile storage device (e.g. USB memory key or external hard drive acceptable to the Data Access Committee)?

□ Yes □ No

Comments:

* 1. Transmitted or transferred electronically using secure file transfer protocol (SFTP), e.g. SEND?

□ Yes □ No

Comments:

* 1. Printed out?

□ Yes □ No

Comments:

1. Do you have a formal procedure for maintaining confidentiality of data, output files, and printouts?

□ Yes □ No

Comments:

1. Will electronic data be reviewed in a restricted access viewing room?

□ Yes □ No

Comments:

1. Will printouts be reviewed in a restricted access viewing room?

□ Yes □ No □ N/A

Comments:

1. Do you have a secure storage area for electronic data?

□ Yes □ No □ N/A

Comments:

1. Do you have a secure storage area for printouts?

□ Yes □ No □ N/A

Comments:

1. Please explain how the various datasets created for this project will be destroyed or returned to their respective Database Custodian/Agent/Manager upon completion, in keeping with the policies specified by the Database Custodian/Agent/Manager: [Include links to data destruction policies, RCP/HDNS]

**CONFLICT OF INTEREST**

1. Will the interest of the applicants in the disclosure of the personal health information or the conduct of the project potentially result in an actual or perceived conflict of interest on the part of the applicant(s)?

□ No

□ Yes - Please explain how the applicant(s) intend(s) to address the potential conflict.

**OTHER INFORMATION**

1. Please provide any information about this project relevant to data access that has not been included elsewhere in this form. Maximum 1000 characters.

**DECLARATIONS AND SIGNATURE** [This will be a separate form]

*Please note that the requested data will not be released until a signed form, signed by all team members, is received by the Data Access Committees. This Declaration is required with submission of the JDAC application for data access approval (original or scanned copy), and for HDNS Data Access Committee once the data is ready to be accessed.*

As Principal Applicant/Co-Applicant for this project, I declare that:

* 1. The personal health information received will only be used for the objectives of the

 project specified in the PROJECT DETAILS section. \_\_\_\_\_\_

* 1. The project cannot reasonably be accomplished without the use of personal health

 information. \_\_\_\_\_\_

* 1. The requested personal health information will be used in the most de-identified form

 possible for the conduct of the project. \_\_\_\_\_\_

* 1. The project plan ensures the security of the personal health information and its

 destruction when finished. \_\_\_\_\_\_

* 1. Our interest in the disclosure of the personal health information or the conduct

 of the project will not potentially result in an actual or perceived conflict of interest

 on the part of the applicant(s) except as outlined in the CONFLICT OF INTEREST

 section of this document. \_\_\_\_\_\_

* 1. Any report, abstract, presentation, manuscript, or other communication, including

 results of analyses of the data requested in this document will be provided to the

 Data Access Committee(s) responsible for these data (i.e. HDNS, RCP, or the JDAC)

 **for review at least four weeks** prior to being submitted to any publication source,

 and no such results may be published without prior review and approval by these

 Committees to ensure that Data Access conditions have been maintained. \_\_\_\_\_\_

* 1. A copy of all published reports will be provided to their respective Database

Custodian/Agent/Manager via their respective DAC(s). \_\_\_\_\_\_

* 1. Any report, presentation, manuscript, or other communication including results of

analyses of the data requested in this document will include the requisite disclaimers

and acknowledgements required by their respective Database

Custodian/Agent/Manager, as specified in their respective policy documents.

[provide links] \_\_\_\_\_\_

* 1. In no communication pertaining to this project will we release data from cells

containing 1-4 individuals, or present data derived from cells containing 1-4

individuals, without specific prior written approval from the Database

Custodian/Agent/Manager or their designates (e.g. the relevant Data Access

Committee). \_\_\_\_\_\_

* 1. We agree to abide by all other data access and management principles and practices

 stipulated by the DAC(s) in their respective policy documents along with any

 conditions imposed by the REB(s) approving this project. \_\_\_\_\_\_

1. We agree to report any privacy breach or incident, perceived or real, immediately to

The relevant DAC(s) and REB(s). \_\_\_\_\_\_

Principal Applicant Name:

Principal Applicant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Academic Supervisor Signature (if Lead is a student): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

Names, signatures, and dates for all project team members requesting access to person-level data:

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_