

Diabetes Care Program of Nova Scotia

Data Access Policy and Procedures

Approved by the Board of Directors December 8, 2001

Due for review and possible revision in December 2003

Approved

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Diabetes Care Program of Nova Scotia

Data Access Policy and Procedures

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Introduction & Purpose

The Diabetes Care Program of Nova Scotia (DCPNS) is a provincial program of the Nova Scotia Department of Health. The mission of the DCPNS is to improve the health of Nova Scotians affected by or at risk of developing diabetes. The DCPNS recognizes the important role of evidence, evidence-based research and administrative planning in improving diabetes care, and demonstrates its support for these activities by considering requests for access to health data concerning diabetes under specific conditions.

The DCPNS has the following data sources available:

1. National Diabetes Surveillance System Data set (both aggregate and person-level data)
2. DCPNS Registry (inclusive of demographic, visit, and selective indicators of care data on persons referred to/attending Nova Scotia's diabetes centres since April 1994 (aggregate and person-identifiable data)
3. DCPNS Database of Newly Diagnosed Cases of Diabetes in Those < 19 Years (since 1992) (aggregate and person-identifiable data)

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

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 ensure that confidentiality is maintained.

Currently, the provincial legislation governing the collection, use and disclosure of data from the DCPNS data sources is the Freedom of Information and Protection of Privacy (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 DCPNS may disclose personal information for a research purpose, including statistical research, if:

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

Further, the DCPNS is required to approve conditions under which data is disclosed relating to:

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

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

3. Definitions of Data Types

The DCPNS data may be presented in three levels of anonymity, i.e. *aggregate*, *person-level*, and *person-identifiable*. The levels are defined as follows:

- *Aggregate data*: Data about groups of individuals. Data is grouped in a manner that does not permit residual disclosure (i.e. where there is less than 5 observations per cell, data is not released);
- *Person-level data*: Data about individuals from which identifying facts have been removed or encrypted; and
- *Person-identifiable data*: Data about individuals that includes individual identifiers such as name, date of birth, address, or personal health card number.

4. Principles for the Release of DCPNS Data

The DCPNS is authorized by the Nova Scotia Department of Health to decide whether and under what circumstances and conditions DCPNS data may be disclosed. The following principles are the foundation on which the DCPNS 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 DCPNS is accountable for DCPNS' adherence to these principles. The Data Access Subcommittee of the DCPNS Epidemiology Committee supports the Coordinator in this activity.
- 4.1.2. The DCPNS recognizes that it is responsible for all of the personal data in its possession, even when that data has been transferred to a third party for processing. DCPNS uses contractual agreements with third parties to ensure that data is provided with a comparable level of protection while being processed 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 public benefit. Priority will be given to research or administrative planning that benefits people living with diabetes in 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 supported by the Nova Scotia Department of Health and in the case of district-specific data, the District Health Authority representing the district from which the request originated;
- 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 is at the highest possible level of anonymity.

4.3 Limiting Retention

- 4.3.1. Researchers and health 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 is no longer required to fulfill the identified purpose, the data will be returned to DCPNS, which may maintain the data on behalf of the researcher or administrative planner for up to five years. The researcher will destroy all working files.

4.4. Accuracy

DCPNS will endeavor to ensure the quality, accuracy and reliability of records under its control, whether in written, electronic or other form.

4.5. Security

DCPNS shall establish and require from employees and contractors a high level of physical and electronic security for all DCPNS data.

4.6. Openness

- 4.6.1. Upon request, DCPNS will make available specific information about its policies and practices relating to the management of DCPNS data.

4.7. Individual Access

- 4.7.2. Upon request, an individual shall be informed of the existence, use and disclosure of his or her personal information. Requests of this nature will be processed in accordance with the provincial FOIPOP Act, and directed to the Nova Scotia Department of Health.

5. Access to Aggregate Data

Release of aggregate data is subject to the following conditions:

- 5.1 . Once published by the DCPNS, files and reports based on aggregate data may be accessed without review or approval.
- 5.2. Requests for unpublished aggregate data shall be made in writing to the Coordinator of the DCPNS, who has the authority to review the request in accordance with the Data Request Review Criteria established in section 7, and to deny or grant access to the data.
- 5.3. Requests for unpublished aggregate data will not be granted for commercial or income-generating purposes.

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. DCPNS 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 DCPNS 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 10. The DCPNS Data Access Sub-Committee, using review criteria outlined in section 7, will review the request.
- 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 or health planners requesting access to person-level or person-identifiable data must sign a written contract with DCPNS that outlines the conditions of access. The researchers or health planner will be required to demonstrate their compliance with required data security measures and their capacity to use the data in a manner that contributes meaningfully to improving the health of Nova Scotians.
- 6.6. Access to person-level or person-identifiable data for research purposes will not be granted unless the proposed research has received ethics approval from a recognized university or health care facility ethics approval board.
- 6.7. 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:
 - 6.7.1. a written complaint to the sponsoring organization,
 - 6.7.2. refusal of future access to data,
 - 6.7.3. seizure of any data released by DCPNS, and/or
 - 6.7.4. legal action.

7. DCPNS Data Request Review Criteria

The DCPNS Data Access Subcommittee uses the following criteria to guide the review of requests for access to person-level or person-identifiable data. The Subcommittee's decision to approve or deny requests for data access will be based on these criteria.

7.1. Ethical Review and Approval

All research projects requiring the use of person-level or person-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 organizations participating in the research.

7.2. Qualifications

The principal investigator and the research team must possess the requisite education and experience to successfully complete the proposed research. The research team should include a statistician or qualified data analyst who is involved in research design.

7.3. Data Appropriateness

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

7.4. Level of Anonymity

The proposed data analysis methodology must support the need for person-level or person-identifiable data.

7.5. Technical Merit

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

7.6. Resource Capacity

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

7.7. Administrative, Physical and Technical Safeguards

The researcher 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. Safeguards must protect against:

- 7.7.1. Any reasonably anticipated threats or hazards to the security or integrity of the data,
- 7.7.2. Loss of the data, and
- 7.7.3. Unauthorized access, use, modification or disclosure of the data.

7.8. Significance

The 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.

8. Cost Recovery

Data extraction and production services are provided to researchers and health planners on a cost recovery basis. Direct and indirect costs are recovered, i.e. time for administration, data extraction, production, and if applicable, storage. Estimates will be provided by DCPNS as part of initial discussions about proposed projects.

9. Publication of Information Using DCPNS Data

9.1. Pre-publication Review

Any reports, manuscripts or any other type of electronic or paper publications that include DCPNS data must be provided to the DCPNS at least four weeks **prior** to submission for publication.

Copies of publications will be submitted to the DCPNS for information purposes only. Information obtained from publications shall not be used or disclosed without the written consent of the authors.

The authors shall notify the Data Access Subcommittee of the date of publication of any publication that includes DCPNS data.

9.2. Acknowledgement of DCPNS

All publications that include DCPNS data must contain the following acknowledgement:

“The data used in this research was made available by the Diabetes Care Program of Nova Scotia. Any opinions expressed by the authors do not necessarily reflect the opinion of DCPNS.”

10. Procedures for Accessing DCPNS Data for Research Purposes

The following section describes the procedures for accessing DCPNS data for research purposes. To access DCPNS data for administrative planning purposes see Section 11. It is recommended that researchers contact the DCPNS as early as possible in the research design process.

10.1 Preliminary Discussion with DCPNS about Research Design

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

- 10.1.1. The researcher initiates contact with the DCPNS Coordinator via telephone or e-mail to hold a preliminary discussion about the feasibility of the proposed project, to obtain a complete description of the appropriate data sets, and to obtain an electronic copy of the *Diabetes Care Program of Nova Scotia Application for Access to Data for Research Purposes* (Appendix A).
- 10.1.2. The researcher submits to the DCPNS the following preliminary information using the designated portions of the *Diabetes Care Program of Nova Scotia Application for Access to Data for Research Purposes*:
 - 10.1.2.1.1. Name of the researcher (principal investigator) who is submitting the request,
 - 10.1.2.1.2. Principal investigator's organizational affiliation, position, address, telephone and fax numbers, and e-mail address,
 - 10.1.2.1.3. Title of research project,
 - 10.1.2.1.4. Purpose and objectives of the project,
 - 10.1.2.1.5. Proposed methodology
 - 10.1.2.1.6. Data required, including level of anonymity, data elements, months/years for which the data is required
 - 10.1.2.1.7. Target date for the receipt of the data
- 10.1.3. The DCPNS reviews the preliminary data request regarding data availability and the required level of anonymity to fulfill the purpose of the research. The purpose of the review is to determine any additional items or issues concerning use of DCPNS data that should be reflected in the *Application for Access to Data for Research Purposes*.
- 10.1.4. The DCPNS prepares a preliminary cost estimate.
- 10.1.5. The DCPNS discusses the review and preliminary cost estimate with the researcher via meeting or conference call, to provide the researcher with guidance in the completion of the *Application for Access to Data for Research Purposes*.
- 10.1.6. The DCPNS and the researcher agree upon the data requirements and the preliminary research design.
- 10.1.7. Once agreement on the data requirements and preliminary research design is reached, the DCPNS will prepare a more definitive cost estimate for the researcher.

10.2 Completion of Application for Access to Data for Research Purposes

The researcher completes the *Application for Access to Data for Research Purposes*, incorporating the data requirements confirmed in step 10.1.6. Upon completion, the researcher submits the final *Application for Data Access for Research Purposes* to the DCPNS for consideration.

10.3 Review of the Request by DCPNS

The following steps outline the DCPNS request review process:

- 10.3.1. The DCPNS acknowledges receipt of the *Application for Access to Data for Research Purposes*, and identifies any omissions. The researcher forwards materials that address the omissions to the DCPNS before the review proceeds.
- 10.3.2. The DCPNS Coordinator reviews requests for aggregate data. The Data Access Subcommittee reviews requests for person-level or person-identifiable data. Reviews of all data access applications use the review criteria described in section 7. Reviews of requests for aggregate data will normally be completed within one month; reviews of requests for person-level or person-identifiable data will normally be completed within three months of submission to the DCPNS. However, unforeseen circumstances may delay processing.
- 10.3.3. The DCPNS notifies the researcher in writing about the approval or denial of the request. Any conditions on approvals are communicated in writing as well, such as the requirement for approval from an appropriate ethics review board.

10.4 Contractual Agreement

For requests that have been approved, DCPNS forwards the contractual agreement (sample contract in Appendix C) to the researcher. The researcher reviews, signs, and returns the contractual agreement to DCPNS.

10.5 Data Preparation

- 10.5.1. The DCPNS prepares the data for the researcher in the format specified in the contractual agreement.
- 10.5.2. The DCPNS sends the data to the researcher via courier or other mutually agreed upon mechanism.
- 10.5.3. Within two weeks of receipt of the data, the researcher confirms with the DCPNS that the data meets the agreed upon specifications for the request.
- 10.5.4. The DCPNS sends an invoice to the researcher for the amount specified in the contractual agreement.

10.6 Publication Submission

The researcher provides all publications that include DCPNS data to the DCPNS for publication review four weeks prior to the submission for publication.

10.7 Return of Data and Destruction of Working Files

The researcher returns the data to DCPNS at the end of the research project (a mutually agreed upon date stipulated in the contract between DCPNS and the researcher) in accordance with the contractual agreement. The researcher destroys working files and sends a written notice to DCPNS 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 DCPNS 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 DCPNS 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 by DCPNS is transferred to DCPNS via secure means, prior to the destruction of the researcher's working files.

11. Procedures for Accessing DCPNS Data for Administrative Planning Purposes

The following section describes the procedures for accessing DCPNS data for administrative planning purposes. As per section 4.2.4, the proposed use of DCPNS data for administrative planning purposes must be supported by the Nova Scotia Department of Health and in the case of district-specific data, the District Health Authority representing the district from which the request originated. To access DCPNS data for research purposes see Section 10. In the case of administrative planning, the proposed use of the data is supported.

11.1 Preliminary Discussion with DCPNS about the Project

The following steps are required as part of this phase in the process:

- 11.1.1. The person requesting the data (the "requestor") initiates contact with the DCPNS Coordinator via telephone or e-mail to hold a preliminary discussion about the feasibility of the proposed project, to obtain a complete description of the appropriate data sets, and to obtain an electronic copy of the *Diabetes Care Program of Nova Scotia Application for Access to Data for Administrative Planning Purposes* (Appendix B).
- 11.1.2. The requestor submits to the DCPNS the following information using the *Diabetes Care Program of Nova Scotia Application for Access to Data for Administrative Planning Purposes*:
 - 11.1.2.1.1. Name of the person who is submitting the request,
 - 11.1.2.1.2. The requestor's organizational affiliation, position, address, telephone and fax numbers, and e-mail address,

- 11.1.2.1.3. Description of how the data will be used,
 - 11.1.2.1.4. Description of the expected audience for the results of the project,
 - 11.1.2.1.5. Description of the required data and data format,
 - 11.1.2.1.6. Contact name for the supporting organization (i.e. Nova Scotia Department of Health or a District Health Authority).
- 11.1.3. The DCPNS reviews the data request regarding data availability and the required level of anonymity to fulfill the purpose of the project.
- 11.1.4. The DCPNS prepares a preliminary cost estimate.
- 11.1.5. The DCPNS discusses the review and preliminary cost estimate with the requestor via meeting or conference call to agree upon the data requirements and the project methodology.
- 11.1.6. Once agreement on the data requirements and project methodology is reached, the DCPNS will prepare a more definitive cost estimate for the requestor.
- 11.1.7. The DCPNS and the requestor agree upon the cost estimate.

11.2 Review of the Request by DCPNS

- 11.2.1 The DCPNS Coordinator reviews and approves or denies requests for access to data for administrative purposes. Reviews of all data access applications use the review criteria described in section 7. Reviews of *Applications for Access to Data for Administrative Planning Purposes* will normally be completed within one month, however unforeseen circumstances may delay processing.
- 11.2.2 The DCPNS Coordinator reserves the right to refer the data access application to the Data Access Subcommittee for the Subcommittee's review. In this case, the review will normally be completed within three months, however unforeseen circumstances may delay processing.

11.3 Contractual Agreement

For requests that have been approved, DCPNS forwards the contractual agreement (sample contract in Appendix C) to the requestor. The requestor reviews, signs, and returns the contractual agreement to DCPNS.

11.4 Data Preparation

- 11.4.1. The DCPNS prepares the data for the requestor in the format specified in the contractual agreement.
- 11.4.2. The DCPNS sends the data to the requestor via courier or other mutually agreed upon mechanism.
- 11.4.3. Within two weeks of receipt of the data, the requestor confirms with the DCPNS that the data meets the agreed upon specifications for the request.
- 11.4.4. The DCPNS sends an invoice to the requestor for the amount specified in the contractual agreement.

11.5. Return of Data and Destruction of Working Files

The requestor returns the data to DCPNS at the end of the project (a mutually agreed upon date stipulated in the contract between DCPNS and the requestor) in accordance with the contractual agreement. The requestor destroys working files and sends a written notice to DCPNS 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 Administrative Planning Purposes* is prohibited.

12. Evaluation of Policy and Procedures

Once per year, the DCPNS Epidemiology Committee will review the DCPNS Data Access Policy and Procedures, and make necessary amendments. The review will include discussion with the Department of Health about the development of provincial data access policies that may have an impact on the content of the DCPNS Data Access Policy and Procedures.

Appendix A

Diabetes Care Program of Nova Scotia

Application for Access to Data for Research Purposes

Diabetes Care Program of Nova Scotia

Application for Access to Data for Research Purposes

The information on this form will be used to evaluate the request for access to DCPNS data. Any questions about the form should be directed to:

Insert appropriate contact name

Address

Contact info.

Items that are marked with an asterisk (*) are to be completed for preliminary requests (outlined in section 10.1 of the DCPNS Data Access Policy and Procedures for Research Purposes).

Please ensure that your application is complete and that attachments are numbered accordingly. An electronic version of this application is available.

If this request is approved, prior to obtaining access to DCPNS data, you may be asked to sign a contractual agreement that ensures that individual privacy will be protected when the data is in your custody.

SECTION A: RESEARCHERS

1) *Please provide the following information for the Principal Investigator.**

Name:
Position:
Organization:
Address:
Telephone:
Fax:
E-mail:

2) *If the Principal Investigator is a student, please provide the following information for the Academic Advisor.**

Name:
Position:
Organization:
Address:
Telephone:
Fax:
E-mail:

3) *Please provide the following information for Co-Investigator(s)*

Name:
Position:
Organization:
Address:
Telephone:
Fax:
E-mail:

Name:
Position:
Organization:
Address:
Telephone:
Fax:
E-mail:

4) *Please attach the following:*

- a) The curriculum vitae for the Principal Investigator which includes education, knowledge of the subject and proposed methodology, a list of relevant successfully completed research studies, presentations and publications.
- b) The curriculum vitae for the academic advisor if the Principal Investigator is a student.
- c) The curriculum vitae of the person responsible for designing the study methodology (if not the PI).

SECTION B: DESCRIPTION OF THE RESEARCH PROJECT

1) Please describe the following:

a) Project Title:*
b) Purpose and Objectives of the Project:*
c) Significance/benefits to be derived from the research project:*
d) Methodology:*
e) Data analysis resource capacity for this project, including hardware, software and data analysis personnel:
f) Budget and time schedule (include funds allocated for data retrieval from DCPNS, and project end date):

1) Please attach the following information:

- a) A copy of the ethics approval received from a recognized ethics review committee for each participating organization. Ethics approval is required for all projects requesting person-level or person-identifiable data. If not yet available, indicate when you expect to receive approval (DCPNS may approve requests conditional on ethics approval).
- b) A document confirming approved funding for this project from the funder.
- c) Literature review.

SECTION C: DESCRIPTION OF THE DATA REQUIREMENTS

1) Please specify the level of anonymity for the requested data:*

a) Aggregate	()
b) Person-level	()
c) Person-identifiable	()

2) Please provide the following information:

a) Detailed methodology for the use of DCPNS data.
b) Anticipated data sources, data elements and how each will be used.*
c) Define the study population, including selection, inclusion and exclusion criteria and size.
d) Describe the data elements for each output record (include formulas, algorithms and aggregation schemes to create the release data from the source data)
e) Describe proposed linkages to be made between DCPNS data and any other personal information. Include a detailed description of the non-DCPNS data source including all data elements to which the DCPNS data will be linked.
f) Target date(s) for receipt of data from DCPNS.*
g) Expected period of time during which access to the requested data is required.

SECTION D: SECURITY

1) Please provide the following information:

Describe how the data that is released into your custody will be protected to ensure that unauthorized disclosure does not occur. Include a description about where the data will be stored and accessed, as well as the administrative, physical and technical safeguards that will be implemented to protect the data requested for this project.

Signature of Applicant

Date

Appendix B

Diabetes Care Program of Nova Scotia

Application for Access to Data for Administrative Planning Purposes

Diabetes Care Program of Nova Scotia

Application for Access to Data for Administrative Planning Purposes

Name:
Position:
Organization:
Address:
Telephone:
Fax:
E-mail:

Please complete the following:

- 1. Describe how the data will be used:**
- 2. Describe the expected audience for the results of the project:**
- 3. Describe the format in which the data is required (paper, electronic), with details about the fileformat or table format:**
- 4. The use of DCPNS data for the above stated purpose is supported by (check one):**
 - Nova Scotia Department of Health
 - District Health Authority # ___ (specify number)

Specify contact name and phone number for Nova Scotia Department of Health or District Health Authority: