

 DALHOUSIE UNIVERSITY Health Data Nova Scotia Data Access Request Policy	Author: S.Kennedy	Review Date: 01.01.2018
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1. BACKGROUND & PURPOSE

- 1.1 The data housed at Health Data Nova Scotia (HDNS) are Personal Health Information (PHI) and therefore HDNS must comply with Personal Health Information Act (*PHIA*) and with the terms and conditions defined in Data Sharing Agreement with the Nova Scotia Department of Health and Wellness (DHW).
- 1.2 The purpose of this policy is to demonstrate compliance with *PHIA* and the DHW Data Sharing Agreements and outline the HDNS Data Access process.

2. APPLICATION

- 2.1 This policy applies to all researchers and health service assessment analysts requesting access to HDNS data, referred to as requestor(s).

3. DEFINITIONS

- 3.1 *Aggregate-Level Data:* Data about groups of individuals. The data are aggregated in such a manner as to prevent the identification of individuals.
- 3.2 *Contractual Agreement for Data Access and Management (CADAM):* The agreement which specifies the conditions under which HDNS grants data access to a requestor(s).
- 3.3 *Data Access Committee (DAC):* The Committee tasked with reviewing requests to conduct secondary data analysis for research or health service assessment purposes using the administrative databases held by Health Data Nova Scotia of Dalhousie University for privacy, security, and confidentiality concerns.
- 3.4 *Data Access Request (DAR) Form:* The request form completed by the requestor(s) to request access to data for projects. It is reviewed for privacy, confidentiality, and security concerns by the HDNS Data Access Committee.

- 3.5 *Health Service Assessment*: activity to assess, investigate or evaluate the provision of healthcare services.
- 3.6 *Personal Health Information*: 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.
- 3.7 *Privacy Review Officer*: The Review Officer under the Nova Scotia Privacy Review Officer Act and referred to in the Personal Health Information Act (PHIA).
- 3.8 *Project Charter*: The document which identifies the details around the analysis, packaging, and deliverables of the data and services provided by HDNS which must be signed by both the Principle Investigator (PI) and the HDNS Manager prior to the former being granted access to HDNS data.
- 3.9 *Research*: A systematic investigation designed to develop or establish principles, facts or generalizable knowledge, or any combination of them, and includes the development, testing and evaluation of research.
- 3.10 *Research Ethics Board (REB)*: An REB established and operating in conformity with the Tri-Council Policy Statement. A body of researchers, community members, and others with specific expertise (e.g. research ethics, or relevant research disciplines) established by an institution to review the ethical acceptability of all research involving humans conducted within the institution's jurisdiction or under its auspices.

4. POLICY STATEMENT

- 4.1 Under *PHIA*, personal health information (PHI) about an individual may be disclosed for research without the consent of the individual if a Research Ethics Board (REB) has determined that consent is not required and:

- The custodian is satisfied that:
 - o The research cannot be conducted without using the PHI
 - o The PHI is limited to that necessary to accomplish the purpose of the research
 - o The PHI is in the most de-identified form possible
 - o The PHI will be used in a manner that ensures its confidentiality
 - o It is impracticable to obtain consent
 - The custodian informs the Review Officer.
- 4.2 There is no requirement for approval from an REB for the disclosure of PHI for health service assessment projects. However, the rest of the requirements regarding privacy, confidentiality and security found in *PHIA* still apply.
- 4.3 To ensure due diligence in its review process for approval to access data, HDNS has established a Data Access Committee (DAC) to review data access requests. Prior to granting approval for access to HDNS data, the DAC members must be satisfied that the requirements in *PHIA* and the Data Sharing Agreements with DHW are met. (**Data Access Committee Terms of Reference** is attached).

5. PROCEDURES

5.1 *Data Access Requests*

- 5.1.1 Requestor(s) who wish to apply for access to HDNS data for a project should first consult with HDNS to understand whether and how HDNS data and services can assist in meeting their objectives.
- 5.1.2 After initial consultation with HDNS, requestor(s) must submit a Feasibility and Cost Estimate Request Form to obtain a feasibility letter and cost estimate to complete the project. (See **HDNS Guide to Using Our Services**)
- 5.1.3 Requestor(s) seeking access to HDNS data are required to complete **HDNS Data Access Request (DAR) Form** and submit a copy via email to hdns@dal.ca, along with the following documents:
- REB application and supporting documents (not applicable to QA projects)
 - REB Letter of Approval (if available)
 - REB Waiver of Consent (if applicable)
 - Principal Investigator's current CV
 - Academic Supervisor's current CV (if PI a Student)
 - CVs of any project team members requiring access to individual-level data
 - Study Participant Consent form (if applicable)

- Research or Health Service Assessment Plan
- Any other relevant supporting documents

The requirements for Research or Health Service Assessment Plans are set out in the **Research Plan Policy** and **Health Service Assessment Plan Policy**.

5.1.4 Upon receipt of the completed DAR Form, HDNS reviews the form to ensure that all sections are complete. If incomplete, the form is sent back to the PI with instructions of what additional information is required.

5.1.5 Once the form is complete, the DAC Co-Chairs determine whether the request requires minimal risk review or full DAC review.

5.1.5.1 Studies which qualify for minimal risk reviews are determined by the HDNS Co-chairs based on the following criteria:

- Only HDNS analyst(s) will have access to line-level data.
- Only aggregate data will be accessible to the external requestor(s)
- Requestor(s) have successfully completed three (3) projects using HDNS data without incident.

5.1.5.2 For minimal risk reviews, a Data Access Committee Co-Chair and one other Committee member review and discuss the request form and supporting documentation. If both agree that the requestor(s) has satisfactorily addressed privacy, security, and confidentiality issues, the Co-Chairs email a letter of approval to the requestor(s). The approval letter contains a statement indicating that actual disclosure of the data to the requestor(s) is dependent upon the receipt of a letter of approval from the Research Ethics Boards (if applicable); signature of the contractual and confidentiality agreements, CV and an analyst accreditation certification (if applicable).

5.1.5.3 If the request requires full DAC review, the documents must be emailed to HDNS at least two weeks prior to the meeting date to allow review by the Co-Chairs and clarification of any outstanding questions. Documents are emailed to members of the DAC at least one week prior to the meeting and the review is placed on the next available committee meeting agenda.

5.1.6 If the DAC is satisfied that the requestor(s) has satisfactorily addressed privacy, security, and confidentiality issues, the Co-Chairs email a letter of approval to the requestor(s). In the case of research, the approval letter

contains a statement indicating that actual disclosure of the data is dependent upon the receipt of a letter of approval from all applicable REB(s) (if applicable), and signed contractual and confidentiality agreements (see 5.1.10), CV, as well as the completion of HDNS privacy training as needed by any team members requiring access to line-level data.

5.1.7 If the Co-Chairs or the DAC are not satisfied that the requestor(s) has satisfactorily addressed privacy and confidentiality issues, the Co-Chairs send an email to the requestor(s) outlining the concerns and seeking additional information.

5.1.7.1 In the case of research projects, this email is copied to the REB of record for their information.

5.1.7.2 Once the additional information is received, the review may be approved by the Co-Chairs, may be circulated for immediate review by the DAC, or placed on the next DAC meeting agenda.

5.1.7.3 If DAC is still not satisfied that the requestor(s) has satisfactorily addressed privacy, security and confidentiality issues, the Co-Chairs email a letter requesting further clarifications. This process is repeated until the DAC or Co-Chairs are satisfied that all the issues raised have been addressed.

5.1.8 Once the approval letter from REB (if applicable) is received at HDNS, requestor(s) are required to sign and submit a Confidentiality Agreement (CA) and a Contractual Agreement for Data Access and Management (CADAM).

5.1.9 Once all letters and signed agreements are received, the approved project is placed in the queue for data access / analysis. The HDNS Manager, in consultation with the senior analyst, will provide the requestor(s) with an estimated start date.

5.1.10 While waiting for the start date, the HDNS analyst works with the requestor(s) to create a Project Charter. The completed document is then signed by the requestor(s) and the HDNS Manager.

5.2 Requests for Access to Additional Data

5.2.1 If, during the project, requestor(s) discovers that they require access to data that were not included in their initial request, they must submit a written amendment request using the **HDNS Data Access Amendment Form** to HDNS. The Co-Chairs of DAC will review the request and

determine whether to assign a minimal risk or full committee review to this request:

- Amendments to previously approved requests deemed to be of minimal risk in terms of privacy, security, and confidentiality concerns may undergo expedited review by co-chair and one committee member.
- Amendments to previously approved requests deemed to be of moderate to high risk in terms of privacy, security, and confidentiality concerns will undergo full committee review in if applicable notice of the project amendment will be sent to collaborating Data Access Committees and/or the relevant REB.

6. ADMINISTRATIVE STRUCTURE

6.1 *Accountability*

6.1.1 Requestor(s) are responsible to arrange a meeting with HDNS prior to requesting HDNS services / data access and to ensure all forms are completed appropriately.

6.1.2 The Data Access Committee Co-Chairs are responsible to review all documents prior to forwarding the application to the Data Access Committee.

6.1.3 The Data Access Committee is responsible to follow the relevant policies and procedures and terms of reference when reviewing and making decisions about data access requests and any subsequent requested amendments.

6.2 *Monitoring, Auditing and Reporting*

6.2.1 The Data Access Committee Co-Chairs and Finance and Administrative Officer monitor the status of the files and reports back to the Data Access Committee as required.

7. RELATED POLICIES AND OTHER DOCUMENTS

7.1 *HDNS Policies and Procedures*

- Passwords Policy
- Privacy Training Policy
- Research Plan Policy
- User Account Access and Permissions Policy

7.2 *HDNS Forms*

- Contractual Agreement for Data Access and Management (CADAM)
- Confidentiality Agreement (CA)
- HDNS Data Access Request Form
- HDNS Feasibility and Cost Estimate Form
- HDNS Project Charter
- HDNS Data Access Amendment Form
- HDNS Annual Approval/Study Closure Form

7.3 Other Documents

- HDNS Data Access Committee Terms of Reference
- HDNS and DHW Data Sharing Agreement
- HDNS Guide to Using Our Services