

# DATA ACCESS APPROVAL

## – Policy –

### 1. PURPOSE

- 1.1 This Policy outlines the security practices, requirements, and obligations of the New Brunswick Institute for Research, Data, and Training (NB-IRDT) with respect to enabling access to data held in custody by NB-IRDT as a Research Data Centre (RDC) as defined under the [New Brunswick Personal Health Information Privacy and Access Act, SNB 2009, c P-7.05 \(PHIPAA\)](#) and [New Brunswick Right to Information and Protection of Privacy Act, SNB 2009, c R-10.6 \(RTIPPA\)](#).

### 2. SCOPE

- 2.1 This Policy applies to all NB-IRDT Employees and Approved Data Users seeking to access data held in custody by NB-IRDT.

### 3. DEFINITIONS

- 3.1 *Approved Data User(s)*: Individuals, such as NB-IRDT Employees, researchers, students, and government employees, who have been issued an electronic identification access card, personal identification number, and project access account following the approval of access according to all relevant NB-IRDT procedures, including a Criminal Record Check (CRC).
- 3.2 *Custodian*: As defined in PHIPAA, an individual or organization that collects, maintains, or uses personal health information for the purpose of providing or assisting in the provision of health care, and treatment, the planning, and management of the health care system, or delivering a government program or service, and management of the health care system, or delivering a government program or service.
- 3.3 *Data Access Agreement (DAA)*: A written agreement that stipulates the terms imposed on the researcher by the NB-IRDT with regards to the access of data.
- 3.4 *Data Access Request*: A form filled out by a researcher that describes their research project, lists members of their research team, and identifies the Data Sets and variables needed to perform the research.

- 3.5 *Data and Research Committee (DRC):* Serves four main functions for the NB-IRDT:
1. Assembles working groups (Data Research Committee working groups (DRC-WGs)) to review and provide feedback on Data Access Requests received from researchers seeking access to Administrative Data Sets held at NB-IRDT, as well as draft reports from these projects.
  2. Provides a forum to discuss issues relevant to Database Transfers and Data Linkage procedures.
  3. Serves as a forum for consultation on procedural changes.
  4. Organizes a forum at least once per year to present results of projects to the Government of New Brunswick (GNB) and other Stakeholders.
- 3.6 *Data Business Owner:* The entity holding legal rights and control over a Data Set(s) and its variables. In the context of a Data Sharing Agreement, this is the entity (e.g., Custodian, Public Body) who has signed the Data Sharing Agreement and who has shared/disclosed a Master Data Set with/to NB-IRDT.
- 3.7 *Data Sharing Agreement (DSA):* A formal contract used for the transfer of data that has been developed by a non-profit, government, private industry, or an academic body where the data are non-public or otherwise restricted in use. A DSA clearly documents the parameters of the data to be transferred, data usage and access, defined Data Retention times, and final disposition. This agreement serves two purposes: to protect the owner of the data, ensuring that the data will not be misused; and, to prevent any miscommunication between the provider of the data and the NB-IRDT by making certain that any questions about Data Transfer, use, access, retention, and disposition are discussed before the data is shared.
- 3.8 *Principal Investigator (PI):* The individual who holds principal responsibility for a research project such as a project grant recipient or the head of a laboratory, most often the lead researcher on the Data Access Request.
- 3.9 *Research Data Centre (RDC):* A public body that compiles and links personal information or personal health information for the purposes of research, analysis, or evidence-based decision- making (Source: PHIPAA).
- 3.10 *Security Personnel:* The infrastructure housing NB-IRDT data resources and equipment for accessing resources. The facilities are located on the University of New Brunswick (Fredericton) campus (Keirstead Hall, 38 Dineen Drive; Units 316, 317, and 317-A); on the Saint John campus (Hazen Hall, 93-97 Tucker Park Road; Unit 339); and, on the Université de Moncton campus (Bibliothèque Champlain, 415 avenue de l'Université; salle 031). The

buildings housing these facilities are under respective campus security surveillance.

#### 4. POLICY STATEMENTS

- 4.1 Data in the custody of NB-IRDT is held on the secure NB-IRDT platform servers.
- 4.2 Data Business Owners/Custodians wishing to share data with NB-IRDT must enter into a Data Sharing Agreement (DSA) with UNB. The DSA includes provisions for the review of the Data Access Request by the Data Business Owner/Custodian before access to the data is permitted.
- 4.3 All requests to access data are obligated, under PHIPAA and RTIPPA, to have been approved by a research review board prior to accessing data at NB-IRDT.
- 4.4 Approved Data Users are obligated, under the PHIPAA and the RTIPPA, to enter into a written Data Access Agreement with NB-IRDT prior to accessing data at NB-IRDT. This Agreement includes obligations as stated in this Policy.

#### 5. PROCEDURES

##### 5.1 Access to Platform and Project-Specific External Data

- 5.1.1 Refer to Standard Operating Procedure: **Data Access** for detailed procedure steps.

Process Step	Actor
1. A Data Access Request Feasibility is submitted.	<ul style="list-style-type: none"> <li>• Principal Investigator</li> </ul>
2. Feasibility review.	<ul style="list-style-type: none"> <li>• NB-IRDT Director</li> <li>• NB-IRDT Research and Evaluation Manager</li> <li>• NB-IRDT Privacy Officer</li> <li>• NB-IRDT Data Transfer Coordinator</li> <li>• NB-IRDT Data Access Coordinator</li> <li>• Assigned Data Analysts</li> </ul>
3. Submission of full Data Access Request.	<ul style="list-style-type: none"> <li>• Principal Investigator</li> <li>• NB-IRDT Data Access Coordinator</li> </ul>
4. NB-IRDT Institute Review of the Data Access Request.	<ul style="list-style-type: none"> <li>• NB-IRDT Data Access Coordinator</li> <li>• NB-IRDT Research and Evaluation Manager</li> <li>• NB-IRDT Privacy Officer</li> <li>• NB-IRDT Database Administrator</li> </ul>

Process Step	Actor
	<ul style="list-style-type: none"> <li>Assigned NB-IRDT Data Analyst</li> <li>Principal Investigator</li> <li>Research Team Members if requested by Principal Investigator</li> </ul>
5. NB-IRDT Data and Research Committee review of the Data Access Request.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> <li>NB-IRDT Data and Research Committee</li> <li>Data Business Owners/Custodian Representatives</li> <li>Principal Investigator</li> <li>Research Team Members if requested by Principal Investigator</li> </ul>
6. Completion of Data Business Owner/Custodian requirements.	<ul style="list-style-type: none"> <li>Principal Investigator</li> <li>NB-IRDT Data Access Coordinator</li> </ul>
7. Completion of Administrative Safeguards requirements.	<ul style="list-style-type: none"> <li>NB-IRDT Data Services Coordinator</li> <li>Individuals listed on section 2 of Data Access Request</li> </ul>
8. UNB Fredericton Research Ethics Board project review.	<ul style="list-style-type: none"> <li>UNB Fredericton Research Ethics Board</li> <li>NB-IRDT Data Access Coordinator</li> <li>NB-IRDT Director</li> <li>Principal Investigator</li> </ul>
9. Privacy and legislation review.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> <li>NB-IRDT Privacy Officer</li> </ul>
10. Final submission, review, and approval of project.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> <li>UNB Office of Research Services signing authority (VP Research)</li> </ul>
11. Data Access Agreement signed.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> <li>Principal Investigator</li> </ul>

## 5.2 Approved Data Users Criteria

5.2.1 Refer to Standard Operating Procedure: **Administrative Safeguards** for detailed procedure steps.

Process Step	Actor
1. Identification of Approved Data Users.	<ul style="list-style-type: none"> <li>Individuals listed on section 2 of Data Access Request</li> </ul>
2a. Criminal Record Check.	<ul style="list-style-type: none"> <li>Research Applicant</li> <li>Provincial Police Department or RCMP</li> </ul>
2b. Administrative Data Privacy Training.	<ul style="list-style-type: none"> <li>Research Applicant</li> <li>NB-IRDT Privacy Officer</li> <li>NB-IRDT Data Services Coordinator</li> </ul>
2c. NB-IRDT SRE Data User Acknowledgement Form or UNB Employee/Student Policy	<ul style="list-style-type: none"> <li>Research Applicant</li> </ul>

Acknowledgement Form and NB-IRD Confidentiality Agreement.	
2d. Data Vetting and Security Training.	<ul style="list-style-type: none"> <li>• Research Applicant</li> <li>• NB-IRDT Database Administrator</li> </ul>
3. Pass card and PIN received.	<ul style="list-style-type: none"> <li>• NB-IRDT System Administrator</li> </ul>
4. Approved Data Users Status received.	<ul style="list-style-type: none"> <li>• NB-IRDT Data Access Coordinator</li> </ul>

**NOTE:** The process steps 2a Criminal Record Check, 2b Administrative Data Privacy Training, and 2c Data Vetting and Security Training, can be completed in any order and parallel to the Data Access Request approval process.

### 5.3 Data Access Amendment Request

5.3.1 Refer to Standard Operating Procedure: **Data Access Amendment** for detailed procedure steps.

Process Step	Actor
1. An amended Data Access Request is submitted.	<ul style="list-style-type: none"> <li>• Principal Investigator</li> <li>• NB-IRDT Data Access Coordinator</li> </ul>
2. Determination of Amendment level.	<ul style="list-style-type: none"> <li>• NB-IRDT Data Access Coordinator</li> <li>• NB-IRDT Privacy Officer (if required)</li> <li>• NB-IRDT Director (if required)</li> </ul>
3. Amendment review.	<ul style="list-style-type: none"> <li>• NB-IRDT Privacy Officer (or NB-IRDT Director)</li> <li>• UNB Office of Research Services</li> <li>• UNB Fredericton Research Ethics Board</li> <li>• NB-IRDT Data and Research Committee</li> <li>• Principal Investigator</li> </ul>
4. Amendment Approval	<ul style="list-style-type: none"> <li>• NB-IRDT Data Access Coordinator</li> </ul>

### 5.4 Dissemination of Work Product

5.4.1 Refer to Standard Operating Procedure: **Data Results Disclosure Request Review** for detailed procedure steps.

Process Step	Actor
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1. Notice of intent to disseminate work product.	<ul style="list-style-type: none"> <li>Principal Investigator</li> </ul>
2. Data Results Disclosure Request sent to NB-IRDT Data and Research Committee.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> </ul>
3. Data Results Disclosure Results given to Principal Investigator.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> </ul>

## 5.5 Project Closure

- 5.5.1 Refer to Standard Operating Procedure: **Closing NB-IRDT Data Access Project** for detailed procedure steps.

Process Step	Actor
1. Notice of intent to close a project.	<ul style="list-style-type: none"> <li>Principal Investigator or NB-IRDT Data Access Coordinator</li> <li>NB-IRDT Database Administrator</li> <li>NB-IRDT Systems Administrator</li> </ul>
2. Notice to NB-IRDT Employees of intent to close project.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> <li>Principal Investigator</li> </ul>
3. Notice to Principal Investigator of Project Closure.	<ul style="list-style-type: none"> <li>NB-IRDT Data Access Coordinator</li> </ul>

## 6. ADMINISTRATION

### 6.1 Accountability

- 6.1.1 The NB-IRDT Data Access Coordinator is responsible for facilitating the DAR process (including Amendments) with the PI, informing the NB-IRDT of the DAR status and facilitating the Project Closure process.
- 6.1.2 The DRC and convened Working Group members are accountable for review of the DAR, level 3 Amendments, and Data Results Disclosure requests, as outlined within the DRC Terms of Reference.
- 6.1.3 The NB-IRDT Privacy Officer is responsible for ensuring privacy training has been provided and privacy advice relating to any given research project and/or DAR.
- 6.1.4 The NB-IRDT Database Administrator is responsible for providing data security and Vetting training as well as preparations of project files upon approval and project folder closure.
- 6.1.5 The NB-IRDT Research, and Evaluation Manager is accountable for addressing needs for quotes and service costs prior to or during the institute review.

6.1.6 The NB-IRDT Systems Administrator is responsible for Approved Data User access to the NB-IRDT Secure Research Environment.

6.1.7 The NB-IRDT Director is responsible to ensure that this policy is followed.

## 6.2 **Monitoring, Auditing, and Reporting**

6.2.1 The NB-IRDT Data Access Coordinator will initiate the DAR review process and notify appropriate NB-IRDT Employees on receipt of the request. The Data Access Coordinator will track the progress and outcomes as requests are processed.

6.2.1 All NB-IRDT Employees participating in the DAR process will respond to requests for review and feedback respecting the requested timelines.

6.2.3 The NB-IRDT Data Access Coordinator will monitor and ensure that Project Data records are maintained. The Data Access Coordinator will conduct a monthly progress report on data access by approved projects.

6.2.4 The NB-IRDT Systems Administrator generates monthly reports and shares with the NB-IRDT Data Access Coordinator and Privacy Officer for data security and access Audits. The NB-IRDT Privacy Officer will prepare and submit annual reports on privacy and related activities to the VP (Research) Office of Research Services at UNB Fredericton and copy the University Secretariat on the reports.

## 7. **RELATED DOCUMENTS**

- *NB-IRDT Confidentiality Agreement*
- *NB-IRDT Data and Research Committee Terms of Reference*
- *NB-IRDT Data Access Agreement*
- *NB-IRDT Data Access Amendment Criteria and Actions*
- *NB-IRDT Data Access Request*
- *NB-IRDT Glossary of Data Privacy and Security Terms*
- *NB-IRDT Standard Operating Procedure: Administrative Safeguards*
- *NB-IRDT Standard Operating Procedure: Data Access Request*
- *NB-IRDT Standard Operating Procedure: Data Access Amendment*
- *NB-IRDT Standard Operating Procedure: Data Results Disclosure Request*
- *NB-IRDT Standard Operating Procedure: Project Closure*
- *NB-IRDT SRE Data User Acknowledgement Form*
- *NB-IRDT UNB Employee/Student Policy Acknowledgement Form*

## 8. REFERENCES

- [Right to Information and Protection of Privacy Act, SNB 2009, c R-10.6](#)
- [Personal Health Information Privacy and Access Act, SNB 2009, c P-7.05](#)

## 9. DOCUMENT VERSION, REVIEW, AND APPROVAL HISTORY

Version	Author	Nature of Change		Date
1.0	NB-IRDT Staff	Document development		August 2021
1.1	NB-IRDT Staff	Edits		February 2022
1.2	NB-IRDT Staff	Edits		May 26, 2023
Approved by VP Research UNB		Approval Date	Effective Date	Review Date
David MaGee		July 2023	July 2023	July 2024