

NB-IRDT DATA SERVICES LINES OF BUSINESS

DOCUMENT PURPOSE

To outline the data services NB-IRDT can provide as a research data centre defined in legislation.

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LINE OF BUSINESS #1

DATA PLATFORM DEVELOPMENT

– Transfer, Prepare, and Maintain Data Sets –

Overview

This business process includes the activities associated with receiving new data sets from Data Business Owner/Custodians, including Government of New Brunswick custodians (Part 1, 2, 3).¹ This process includes the signing of a Data Sharing Agreement (or similar contract) between Data Business Owners/Custodians and the University of New Brunswick (UNB) as NB-IRDT's signing authority and the secure transfer of administrative data to be stored on the NB-IRDT Secure Research Environments and made available to researchers through the Data Access Request process.

Information about these processes and activities are outlined in the following:

Data Transfer, Linking, and Management Services

There are three possible data sharing scenarios at NB-IRDT:

1. Data Sharing Agreement: Platform Data

These agreements allow data to be added to the NB-IRDT data platform, making the data available for researchers to apply to access for research by submitting a Data Access Request.

2. Data Sharing Agreement: Project Specific

These agreements allow data to be transferred for one data linkage project only. Project specific data are not added to the NB-IRDT data platform, cannot be accessed by any other project, and is removed after project conclusion.

3. Information Manager Agreement

These agreements allow individual data sets to be securely stored and accessed in our SRE for use by those designated in the agreement. Data linkage is not permitted with Information Manager Agreements.

Note: If data linkage becomes necessary, a new data sharing agreement under Scenario 1 or 2 above will be required. Each Information Manager scenario is unique; contact NB-IRDT to find out if an Information Manager Agreement is suitable for your needs.

¹ Part I includes the departments, which are often referred to as the civil service. Part II is comprised of the school system, including teachers, bus drivers, and school district employees. Part III encompasses all health sector employees.

NB-IRDT has the following data sharing agreement types:

Data Sharing Agreement Type	Description
Master Data Sharing Agreement	An agreement between a data partner and UNB for the sharing of multiple data sets with NB-IRDT as part of an ongoing partnership.
Data Sharing Agreement (Data Holder)	An agreement between a data partner and UNB for the sharing of one data set with NB-IRDT.
Individual Disclosure Schedule	This schedule gets attached to all data sharing agreements and describes the data set that is being shared with NB-IRDT in detail. Each data set has its own individual disclosure schedule.
Confirmatory Memorandum (for Individual UNB Researchers)	A data sharing agreement between NB-IRDT and a data partner that allows NB-IRDT to receive data that is owned by the University of New Brunswick.
Information Manager Agreement	An agreement between a data partner and UNB that allows NB-IRDT to receive and store an individual data set without linking to other data sources.
Indigenous Data Sharing Agreement	An agreement between an Indigenous data partner and UNB that outlines the sharing of data with NB-IRDT, as well as NB-IRDT's handling of the data according to the principles of OCAP (Ownership, Control, Access & Possession).

Data Transfer, Linking, and Management Standard Operating Procedures

Document(s)	Information Included
SOP Data Transfer	Outlines the processes to follow for the secure sharing of data to NB-IRDT, including the initiation of data transfer, execution of agreements, preparation of data files, and secure file transfer procedures.
SOP Data Transfer Agreement Amendment	Outlines the processes to follow for amending an active NB-IRDT Data Sharing Agreement.
SOP DH Crosswalk Process	Outlines the processes to follow for assisting applicants with navigating the crosswalk process with the NB Department of Health. This includes crosswalk agreement execution, crosswalk file preparation, and the Crosswalk data file transfer process.

SOP Data Receiving, Inspection & Acceptance	Outlines the processes to follow for loading, inspecting, and accepting data files inside NB-IRDT's Secure Research Environment (SRE).
SOP Data Intake & Quality Assessment	<p>Outlines the processes to follow for data intake and quality assessment at NB-IRDT. This includes:</p> <ul style="list-style-type: none"> - naming and labeling variable - comparing variables received to those listed in the data sharing agreement - performing initial data quality check - generating and outputting meta data to inform the creation of codebooks
SOP Crosswalk Linkage & Data Integration	<p>Outlines the processes to follow for crosswalk linkage and data integration. This includes:</p> <ul style="list-style-type: none"> - importing the crosswalk file - performing crosswalk file linkage and data matching - checking linkage quality (including linkage rates) - integrating data into the NB-IRDT data repository
SOP Codebook Development	The purpose of this standard operating procedure is to describe the process of codebook development at the New Brunswick Institute for Research, Data, and Training (NB-IRDT).
SOP Data Return and Destruction	This standard operating procedure outlines the processes to follow in the return/destruction of de-identified personal information and personal health information provided by the Data Business Owner / Custodian held at NB-IRDT, as directed in the Data Sharing Agreement.

LINE OF BUSINESS #2

SECURE DATA ACCESS AND USE

–Access & Use of Data Sets & Linked Data Sets–

Overview

This business process includes activities associated with NB-IRDT enabling access to NB-IRDT facilities and the use of platform data by Approved Users for research. This includes linking NB-IRDT Platform data sets to each other, as well as to project-specific external data sets that are not part of the NB-IRDT data platform. Project-specific external data sets provided by Data Business Owners/Custodians do not become part of the NB-IRDT data platform. UNB enters into a Data Access Agreement (DAA) with the project's Principal Investigator (if different from the Research Applicant) prior to disclosure of any data.

Information about these processes and activities are outlined in the following:

Data Access Services

There are two main data access scenarios in the Secure Research Environment (SRE):

Note: Access to the SRE requires NB-IRDT privacy training, data security training, secure facility orientation, and custom project folder creation. These services are provided to all users before access is granted.

1. Access NB-IRDT platform data to answer a research question

This is the most common method of data access; upon approval of a [Data Access Request](#), data are linked by NB-IRDT and the research team are able to access a custom project folder in the SRE.

Type of Request	Description
Retrospective Data Access Request	A request to commence a longitudinal retrospective research project that will access data sets and variables, held on the NB-IRDT platform, for research or program evaluation work involving linking of administrative data.
Successive Data Access Request	A request to commence a research project that will access data sets and variables, held on the NB-IRDT platform for research or program evaluation work conduct, in a sequence. The series of subprojects will follow the same scope, research question, and methodology as the original request but, each successive subproject will change one element. (e.g., The whole series would examine a <i>different</i>

	disease with the same cohort asking the same questions).
Multi-Phase Data Access Request	<p>A request to commence a research project that will include a phase 1 of primary data collection for linking to data sets and variables (i.e., phase 2), held on the NB-IRDT platform for research or program evaluation work conduct. REB project approval and consent for linking to administrative data held at NB-IRDT must be obtained by human participants prior to any data collection.</p> <p>The research team must submit a multi-phased data access request to NB-IRDT prior to beginning the project and primary data collection.</p>
Prospective Longitudinal Data Access Request	A request to commence a research project that will access data sets and variables, held on the NB-IRDT platform for research or program evaluation work that will require ongoing data analysis and the periodic addition of a defined data set for a specific cohort of study. This type of Data Access Request extends multiple years into the future.

2. Access data transferred to NB-IRDT through an Information Manager Agreement

This scenario is suitable for allowing individuals to access data in a secure environment only if there is no linking to additional data sets required. Information about preparing for the transfer of data via an information manager agreement is available in LOB 1.

Data Access Standard Operating Procedures

Document	Procedures Outlined
SOP Data Access	Processing a Data Access Request at NB-IRDT.
SOP Data Access Amendment	To outline the processes to follow when amending an active NB-IRDT data access project.
SOP Administrative Safeguards	<p>To outline the procedures and actions taken to ensure the integrity and protection of the data within the custody of NB-IRDT.</p> <p>To strengthen employee knowledge surrounding data privacy and security.</p> <p>To cultivate trust with NB-IRDT stakeholders by demonstrating accountability for the data held in NB-IRDTs secure custody.</p>
SOP <i>Research Results Data Disclosure</i>	To provide Data Business Owners/Custodians with the opportunity to review, in advance of dissemination, the work product developed using data shared with NB-IRDT. To verify that adequate acknowledgments have been included in the work product as agreed in the Data Access Agreement



SOP Data Vetting	To outline the process to be followed by NB-IRDT Approved Users and Employees, to request vetting of (research) data results. Data results must be vetted prior to disclosing them with anyone not on the Research Team. If this process is not followed, no data results can be removed from the secure research environment. Following this process is mandatory.
SOP Project Closure	To outline the procedures followed to close an active data access request project, ensure approved user data and or access to the secure research environment are removed as appropriate, and that proper retention of project data sets in secure storage following a project end date.
SOP Data Access Project Status Change	Includes procedures to follow for re-opening a closed data access project.

LINE OF BUSINESS #3

INFORMATION MANAGER SERVICES

– Provision of Information Manager Services –

Overview

NB-IRDT can provide the physical infrastructure and secure research environment for Data Business Owners/Custodians' data sets as an *Information Manager*, as defined under the Personal Health Information Protection and Privacy Act (PHIPAA). An **information manager agreement** allows individual data sets to be securely stored and accessed in our SRE for use by those designated in the agreement.

Information Manager services do not provide any type of access to, or use of data contained in one or more data holdings in the NB-IRDT data platform (with or without linking). Accessing PHI or PI stored in the NB-IRDT secure facility is available only as directed by the Data Business Owner/Custodian (i.e., Information Manager data are not available on the NB-IRDT data platform for a Data Access Request).

Data transfers under the terms and conditions of an Information Manager Agreements follow the same steps as outlined in Line of Business 1 Data Platform Development (see Standard Operating Procedure: Data Transfer) with appropriate concessions as outlined in the SOP Information Manager Services and Agreements.

NOTE: An **Information Manager Agreement and Contract** must be in place between UNB (on NB-IRDTs behalf) and the Data Business Owner/Custodian prior to any of these options taking place. A Statement of Work or equivalent 'contract' will accompany all agreements in this NB-IRDT Line of Business.

Information Manager Services

The following three (3) Information Manager service options are offered by NB-IRDT:

1. **Processing, storing, retrieving, archiving, or disposing of PI or PHI for a Data Business Owner/Custodian**
2. **Providing third-party secure data access for users who have entered into a data sharing agreement with the data business owner**
3. **Value-added services (e.g., data quality assurance, answering a question using client's data sets, special one-off assistance, analysis, etc.)**

Information Manager Standard Operating Procedures

Document(s)	Procedures Outlined
SOP Information Manager Services & Agreements	Outlines the processes to follow for the selection of the appropriate Information Manager Service and subsequent Agreement. Includes the initiation of the service request and data sharing.

Document History

Version	Author	Nature of Change	Date
1.0	L. Gilbert, D. Curtis Maillet, and C. Hovey	Document Creation	2023/05/05