

DATA ACCESS REQUEST TYPES

– Definitions and Processes –

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Purpose:

To define and explain the types of Data Access Requests (DARs) that may be submitted to the New Brunswick Institute of Research, Data, and Training (NB-IRDT).

Background:

There are two ways to request access to administrative data held in custody at NB-IRDT:

- Single site requests - sent directly to NB-IRDT.
 - Researchers must complete a Feasibility Request. If the project is found to be feasible, they will then be required to complete a DAR. Both forms can be found on the NB-IRDT website.
- Multi-regional requests - received through the Data Access Support Hub (DASH).
 - Researchers must complete the DASH Intake form, located on Health Data Research Network (HDRN) Canada website, and participate in an intake meeting. A feasibility review, performed by each local site, will also take place.

Regardless of how the project was received (single site or multi-regional), a multi-step approval process is required to protect the data in custody at NB-IRDT. These steps are also necessary for compliance with privacy legislation, and they uphold rigorous security practices.

The final step of DAR approval, regardless of the type, is to sign a Data Access Agreement (DAA), held between the PIs host institution, on behalf of the PI, and the University of New Brunswick (UNB) on behalf of NB-IRDT. In an instance that the PI is a UNB employee, the DAA will be signed by the PI and UNB. The DAA identifies the project terms and all conditions agreed upon pertaining to the research project. The DAA is a legally binding agreement.

The NB-IRDT Data Access Coordinator works with the PI and the research team members to facilitate the approval steps and ensures that the appropriate processes are followed.

Note: NB-IRDT reserves the right to determine the DAR type if PI assignment is deemed inaccurate.

Data Access Request Types

1. DATA ACCESS REQUEST – RETROSPECTIVE

A research project that will access data held on the NB-IRDT platform for research, or program evaluation, involving linked administrative data. Project specific data may also be transferred to NB-IRDT for use within such a project. This is the most common type of DAR received. It requires access to data looking backward into the past.

1.1 Requires:

A completed Feasibility Request form

- The PI, or a designated member of the Research Team, completes and submits the *NB-IRDT Feasibility Request* form.
 - 'Retrospective' will be indicated as the DAR Type.
 - Approximately two weeks after receipt, the Data Access Coordinator will inform the Research Team if the project is deemed feasible.

A completed Data Access Request form

- If found to be feasible, the PI, or a designated member of the Research Team, completes and submits the NB-IRDT Data Access Request (DAR) form.

A signed Data Access Agreement

- The NB-IRDT Data Access Coordinator facilitates the signing of the Data Access Agreement (DAA) once the data access approval process is complete.

1.2 Data Access Approval Process:

- a) Following the submission of the completed DAR, an Institute Review, a Data Research Committee Review, and a Preliminary Ethics Review takes place.
 - Note: Additional review requirements¹ may be needed.
 - Administrative Safeguard instructions are provided to all research team members listed on the DAR. Each research team member must complete these before they are granted access to the data.
 - A signed budget letter must be received before the Data Access agreement is sent to the Office of Research Services (ORS).
- b) At the conclusion of the review by the Preliminary Ethics Review Committee (PERC), the NB-IRDT Data Access Coordinator will submit the PERC package, including a copy of the REB application, to the UNB Fredericton REB office; the PI will be cc'd. REB approval must be obtained before the DAR may proceed through the remaining approval steps.
- c) Data Access Agreement (DAA) is prepared and signed by the Vice President (Research) on behalf of NB-IRDT.
- d) DAA counter signatures
 - UNB - Institutional - Data Access Coordinator forwards a draft of the DAA to the PI for signature at their host institution.
 - UNB – Individual Research (i.e., employee of UNB) – the ORS facilitates signature from the PI.
- e) The project folder is prepared, with approved data, for the research team members.
 - Note: The Database Administrator will inform the PI when the project folder and user accounts are ready.
 - Data analysis can now begin.

1.3 Data Access Considerations:

¹ At the request of certain Data Business Owners and as documented in certain data sharing agreements (e.g., IRCC, CANUE, CLSA, Atlantic Path, etc.).

- Once analysis is complete, the Research Team submits a request for vetting of (research) data results.
- Once vetting is complete, aggregate data is released to the PI.
- The Research Team prepares their research results, using the vetted aggregate data.
- Per the NB-IRDT Data Dissemination of Research Findings Policy, the research team must submit the research results to the Data Access Coordinator to initiate the Research Results Data Dissemination (R2D2) prior to publication/presentation/etc.
 - Note: A 25 business-day embargo period is in place during the R2D2 review.
- Project closure will be initiated by the Data Access Coordinator under the following circumstances: at the conclusion of the R2D2 process, at the expiry of the REB and/or project term. At that time, access to the project folder is removed for all research team members.
- UNB REB approvals are only valid for 3 years. Projects that wish to extend beyond the 3-year approved period, must follow the amendment process for REB renewal (see DAR Amendment Procedures).
- NB-IRDT reserves the right to re-evaluate resource needs for data access requests that extend beyond the initial approval period.

2. DATA ACCESS REQUEST - MULTI-PHASE

This type includes two phases. Phase 1- collection of primary data followed by Phase 2 - linking the collected primary data to data held on the NB-IRDT platform for research, or program evaluation, involving linked administrative data.

Before Phase 1 can begin, REB approval must be obtained and proof of consent for linking to administrative data must be provided (i.e., PI to provide NB-IRDT with a copy of the informed consent form explaining the intent to link collected primary data with administrative data held at NB-IRDT). A second REB approval is required prior to Phase 2.

The research team must submit the Feasibility Request **prior** to beginning the project (i.e., before primary data collection begins).

2.1 **Requires:**

A completed Feasibility Request form

- The PI, or a designated member of the Research Team, completes and submits the *NB-IRDT Feasibility Request* form.
 - 'Multi-phase' will be indicated as the DAR Type.
 - Approximately two weeks after receipt, the Data Access Coordinator will inform the PI if the project is deemed feasible.

A completed Data Access Request form

- If found to be feasible, the PI, or a designated member of the Research Team, completes and submits a NB-IRDT Data Access Request (DAR) form.
 - Note: the DAR will not be completed or submitted until the primary data collection work is complete. There is no interaction with NB-IRDT during primary data collection.

A Signed Data Access Agreement

- The NB-IRDT Data Access Coordinator facilitates the signing of the Data Access Agreement (DAA) once the data access process is complete.

2.2 **Data Access Approval Process:**

Phase 1 – Data Collection

- a) Following the feasibility review & acceptance, the NB-IRDT Data Access Coordinator sends a recommendation letter to UNB Fredericton REB for the data collection and informs the PI to submit their UNB Fredericton REB application for the data collection.
 - Once the data collection has been approved by the UNB Fredericton REB, the PI starts Phase 1 of their research project (e.g., primary data collection).
 - Processing of the DAR halts until phase 1 has concluded.
- b) Once primary data collection has concluded, the PI, or a designated member of the Research Team, submits a DAR.

Phase 2 – Data Linkage

- a) Following the submission of the completed DAR, an Institute Review, a Data Research Committee Review and Preliminary Ethics Review takes place.
 - Note: Additional review requirements² may be needed
 - Administrative Safeguard instructions are provided to all research team members listed on the DAR. Each research team member must complete these before they are granted access to the data.
 - A signed budget letter must be received before the Data Access agreement is sent to the Office of Research Services (ORS).
- b) At the conclusion of the review by the Preliminary Ethics Review Committee (PERC), the NB-IRDT Data Access Coordinator will submit the PERC package, including a copy of the REB application, to the UNB Fredericton REB office; the PI will be cc'd. REB approval must be obtained before the DAR may proceed through the remaining approval steps.
- c) Data Access Agreement (DAA) is prepared and signed by Vice President (Research) on behalf of NB-IRDT.
- d) DAA counter signature

² At the request of certain Data Business Owners and as documented in certain data sharing agreements (e.g., IRCC, CANUE, CLSA, Atlantic Path, etc.).

- UNB – Institutional - Data Access Coordinator forwards a draft of the DAA to the PI for signature at their host institution.
- UNB – Individual Research (i.e., employee of UNB) - the ORS facilities signature from the PI.
- e) The project folder, with approved data and variables, and the user accounts are prepared for the research team members.
 - Note: The Database Administrator will inform the PI when the project folder and user accounts are ready.
 - Data analysis can now begin.

2.3 **Data Access Considerations:**

- If 1 year (or more) has passed, between phase 1 and phase 2, the DAR will undergo another feasibility review to ensure adequate resources are still available.
- A second UNB Fredericton REB approval is required during the processing of Phase 2.
- All data considerations, listed under DAR Retrospective, apply to Multi-Phase Retrospective projects (see 1.3 above).

3. DATA ACCESS REQUEST – PROSPECTIVE LONGITUDINAL

A research project that will access data held on the NB-IRDT platform for research, or program evaluation involving linked administrative data, that will require ongoing data analysis and the periodic addition of one or more defined data set(s) for a specific cohort of study. This type of Data Access Request extends multiple years into the future; meaning amendments will be required as new data is added to the platform.

3.1 **Requires:**

A completed Feasibility Request form

- The PI, or a designated member of the Research Team, completes and submits the *NB-IRDT Feasibility Request* form.
 - 'Prospective Longitudinal' will be indicated as the DAR Type.
 - Approximately two weeks after receipt, the Data Access Coordinator will inform the Research Team if the project is deemed feasible.

A completed Data Access Request form

- If found to be feasible, the PI, or a designated member of the Research Team, completes and submits a *NB-IRDT Data Access Request (DAR) form*.

A Signed Data Access Agreement

- The NB-IRDT Data Access Coordinator facilitates the signing of the

Data Access Agreement (DAA) once the data access process is complete.

3.2 **Data Access Approval Process:**

- The approval process mirrors those found with the DAR Retrospective (see 1.2 above).

3.3 **Data Access Considerations:**

- NB-IRDT can only approve access to data currently held in custody; therefore, as new years of data become available amendments will be required to add the new years of data to a project folder.
- The inclusion of additional variables, not previously approved, requires a DAR amendment.
- All data considerations, listed under DAR Retrospective, apply to Prospective Longitudinal projects (see 1.3 above)

4. DATA ACCESS REQUEST - SUCCESSIVE

A research project that will access data held on the NB-IRDT platform for research, or program evaluation, to conduct multiple research projects 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 predetermined element (i.e., cohort, or key variable of interest, or period of study) across each successive project.

Only the predetermined element as can change (; (i.e., cohort, or key variable of interest, or period of study) all other aspects of the DAR will remain the same. (e.g., A succession of projects examining a *different* disease using the same cohort, period of study and research questions.)

4.1 **Requires:**

A completed Data Access Request form

- The PI, or a designated member of the Research Team, completes and submits an *NB-IRDT Data Access Request (DAR)* form.
- DAR Type 'Successive' is selected.
 - Must specify the element to change and how many successive runs of the project will be required. (e.g.: six diseases)

A signed Data Access Agreement

- The NB-IRDT Data Access Coordinator facilitates the signing of the Data Access Agreement (DAA) once the data access process is complete.

4.2 **Data Access Approval Process:**

- The approval process mirrors those found with the DAR Retrospective (see 1.2 above).

4.3 **Data Access Considerations:**

- Once the next successive project is ready to begin an Amendment must be submitted (to modify the one key element that will change from the initial DAR that was approved).
- All data considerations, listed under DAR Retrospective, apply to Successive projects (see 1.3 above).

DOCUMENT VERSION, REVIEW, AND APPROVAL HISTORY

Version	Author	Nature of Change	Date
1.0	A Lavigne and L Gilbert	Document refresh	July 5, 2023
2.0	A Lavigne	Reordered & finalized DAR Types	August 30, 2023
2.1	A Lavigne	Final look at Successive project	May 6, 2024
2.2	A Lavigne, C Hovey and L Gilbert	Updates	June 17, 2024