

## Data Access Amendments – Criteria –

#	Criteria	Level 1	Level 2	Level 3	Level 4
1	Extend date range(s) of previously approved data set(s)	✓	-	-	-
2	Add or remove a research team member (who is not on the REB)	✓	-	-	-
3	Add or remove researcher not accessing the TRE	✓	-	-	-
4	Add open-source data set(s)	✓	-	-	-
5	Add research's own imported data set(s)	✓	-	-	-
6	Add new data set(s): Non-Personal Information or Non-Personal Health Information (Example: CANUE air quality data) Amendment is level 1 if the following criteria is met: a) It is aggregate data, not person-level data b) No change in project scope (i.e., research questions have been reviewed and approved by the REB and the DRC) c) No change to participants' consent of data usage	✓	-	-	-
7	New linkage of aggregate data	✓	-	-	-
8	Modification to Approved User Access (e.g. expired administrative safeguards)	✓	-	-	-
9	Correction to the DAR (e.g. spelling error, formatting)	✓	-	-	-
10	Add or remove a research team member (who is on the REB)	-	✓	-	-
11	Add or remove a research team member accessing the TRE	-	✓	-	-
12	Change the PI on the project (the signing authority)	-	✓	-	-
13	Extend the REB	-	✓	-	-
14	Extend the project term	-	✓	-	-
15	Add new/corrected variable(s)	-	-	✓	-
16	Add new/corrected data set(s)	-	-	✓	-
17	New linkage between datasets – pseudonymous data (i.e., de-identified individual level data)	-	-	✓	-

18	New linkage including sensitive data (as defined in legislation e.g., vulnerable population)	-	-	-	✓
19	Modification to the Project scope	-	-	-	✓
20	Substantial change in direction of the research	-	-	-	✓

***\*\*Amendment submitted with multiple criteria levels will be processed using the actions of highest level\*\****

## – Actions –

Actions	Level 1	Level 2	Level 3	Level 4
PI (or a delegated member of the Research Team) will revise the DAR and send it to NB-IRDT	Yes	Yes	Yes	Yes
NB-IRDT reviews the amended DAR to verify amendment criteria listed, confirm the amendment level, & check administrative safeguards	Yes	Yes	Yes	Yes
NB-IRDT initiates reviews:				
IR .....	n/a	n/a	n/a	Yes
RR.....	n/a	n/a	Yes	n/a
DRC.....	n/a	n/a	n/a	Yes
PERC.....	n/a	Yes	Yes	Yes
NB-IRDT prepares REB recommendation letter	n/a	Yes	Yes	Yes
NB-IRDT submits the PERC package on behalf of the PI. This includes the REB case modification/extension request, the updated DAR, the NB-IRDT REB recommendation letter, the PERC summary & final privacy review	n/a	Yes	Yes	Yes
Chair of the REB sends REB approval	n/a	Yes	Yes	Yes
NB-IRDT approves the amendment	Yes	No	No	No
NB-IRDT drafts an amendment to the previously approved DAA and sends it for signatures	n/a	Yes	Yes	Yes
DAA Amendment signatures are obtained (first signed by the UNB Vice President (Research) and then by PI)	n/a	Yes	Yes	Yes
NB-IRDT notifies the Database Administrator of the amendment approval and requests updates to the project folder per the revised DAR	Yes	Yes	Yes	Yes
NB-IRDT informs the PI that the project folder has been updated	Yes	Yes	Yes	Yes

## – Versioning –

The version of a project follows the P# (e.g. P0001\_0.0). Only level 2 and level 3 amendments need approval through ORS. Level 1 Amendments are appraised internally by NB-IRDT staff; they are not sent to ORS for approval.

Within the version number, the number preceding the decimal indicates a level 2 or 3 Amendment; the number following the decimal indicates a level 1 amendment. They are counts and do not indicate level in and of themselves.

Example of project versioning	
Version #	Explanation
0.0	The initial Data Access Request
0.1	A level 1 amendment was submitted after the DAR was approved and the Data Access Agreement was signed.
1.0	A level 2 or level 3 Amendment was submitted
1.1	After the level 2 or 3 Amendment occurred a level 1 amendment was submitted
1.2	After the level 2 or 3 Amendment occurred a second level 1 amendment was submitted
2.0	Another level 2 or level 3 Amendment was submitted
3.0	Another level 2 or level 3 Amendment was submitted
3.1	After the level 2 or 3 Amendment occurred a level 1 amendment was submitted
4.0	Another level 2 or level 3 Amendment was submitted
4.1	After the level 2 or 3 Amendment occurred a level 1 amendment was submitted
4.2	After the level 2 or 3 Amendment occurred a second level 1 amendment was submitted
4.3	After the level 2 or 3 Amendment occurred a third level 1 amendment was submitted

Acronyms / Key Terms Defined	
CANUE	Canadian Urban Environmental Health Research Consortium
DAA	Data Access Agreement
DAR	Data Access Request
DRC	Data Research Committee
IR	Institute Review
IRCC	Immigration, Refugees and Citizenship Canada
NB-IRDT	New Brunswick Institute for Research, Data and Training
ORS	Office of Research Services
PERC	Preliminary Ethics Review Committee
PI	Principal Investigator
REB	Research Ethics Board
RR	Risk Review
TRE	Trusted Research Environment

## DOCUMENT VERSION, REVIEW, AND APPROVAL HISTORY

Version	Author	Nature of Change	Date
1.0	L Gilbert	Initial Draft	April 2021
1.1	A Lavigne	Header update; content review	May 16, 2022
1.2	A Lavigne	Edit to 'Actions' section. Adding Acronym key	June 1, 2022
1.3	C Hovey	Update Document Title	May 26, 2023
2.0	A Lavigne	Added Versioning information & numbered the Criteria. Updated criteria 9&10 for clarity, added 11 & 12.	November 2, 2023
2.1	A Lavigne	Updated SRE to TRE. Updated language of the criteria; now in line with new DAR Amendment Request form.	September 18, 2024
2.2	A Lavigne & C Hovey	Update criteria	February 4, 2025

3.0	A Lavigne & D Curtis Maillet	Added level 4 per DRC Core request to streamline process (minimize DRC review requirement)	February 24, 2025
3.1	A Lavigne	Updated font size for accessibility.	June 17, 2025