

DATA ACCESS AMENDMENTS

- Criteria -

#	Criteria	Level 1	Level 2	Level 3
1	Add corrected data set(s) or variables	✓	-	-
2	Add open-source data set(s)	✓		
3	Add research's own imported data set(s)	✓		
4	Add new variable(s)	-	-	✓
5	Extend date range(s) of previously approved data set(s)	✓	-	-
6	Add new data set(s)	-	-	✓
7	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	✓	-	-
8	New linkage of aggregate data	✓	-	-
9	New linkage between datasets – pseudonymous data (i.e., de-identified individual level data)	-	-	✓
10	New linkage including sensitive data (as defined in legislation e.g., vulnerable population)	-	-	✓
11	Add or remove a research team member (who is not on the REB)	✓	-	-
12	Add or remove a research team member (who is on the REB)	-	✓	-
13	Add or remove a research team member accessing the TRE	-	✓	-
14	Add or remove researcher not accessing the TRE	✓	-	-
15	Change the PI on the project (the signing authority)	-	✓	-
16	Modification to the Project scope	-	-	✓
17	Substantial change in direction of the research	-	-	✓
18	Extend the REB	-	✓	-
19	Extend the project term		✓	
20	Correction to the DAR (e.g. spelling error, formatting)	✓		

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

– Actions –

Actions	Level 1	Level 2	Level 3
Project PI (or a delegated member of the Research Team) revise the DAR and send it to the NB-IRDT Data Access Coordinator	Yes	Yes	Yes
NB-IRDT Data Access Coordinator reviews the amended DAR to verify amendment criteria listed, confirm the amendment level, & check administrative safeguards	Yes	Yes	Yes
NB-IRDT Data Access Coordinator initiates reviews:			
IR.....	N/A	N/A	Yes
DRC.....	N/A	N/A	Yes
PERC.....	N/A	Yes	Yes
NB-IRDT Data Access Coordinator prepares REB Recommendation letter	N/A	Yes	Yes
NB-IRDT Data Access Coordinator submits PERC package, including REB case modification/extension request, updated DAR, REB Recommendation letter, PERC Summary & Final Privacy Review, to UNB REB	N/A	Yes	Yes
Chair of the REB sends REB approval	N/A	Yes	Yes
NB-IRDT Data Access Coordinator approves amendment (if not available, the NB-IRDT Privacy Officer or NB-IRDT Director approves)	Yes	No	No
NB-IRDT Data Access Coordinator prepares an Amendment to the previously signed DAA	N/A	Yes	Yes
Amendment to DAA signed by Vice President (Research) and then by PI	N/A	Yes	Yes
NB-IRDT Data Access Coordinator informs NB-IRDT Database Administrator that the amendment has been approved and requests the appropriate changes be made to the project folder (as per revised DAR)	Yes	Yes	Yes
NB-IRDT Database Administrator informs the PI and the NB-IRDT Data Access Coordinator that the project folder has been updated.	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 with explanation	
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
TRE	Trusted Research Environment

DOCUMENT VERSION, REVIEW, AND APPROVAL HISTORY

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