

## DAR AMENDMENTS

### – Criteria and Actions –

Criteria	Level 1	Level 2	Level 3
Alternative/additional variables to correct approved research request	✓	-	-
Additional variables	-	-	✓
Additional variable years	✓	-	
Additional dataset(s): Personal Information (Example: IRCC) and Personal Health Information (Example: Discharge Abstract Data)	-	-	✓
Additional dataset(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	✓	-	-
New linkage of aggregate data	✓	-	-
New linkage between datasets – pseudonymous data (i.e., de-identified individual level data)	-	-	✓
New linkage including especially sensitive data (as defined in legislation e.g., vulnerable population)	-	-	✓
Add Research Assistant	✓	-	-
Add or remove anyone who could be listed as an author on intended output (Data Analyst, Co-Investigator, etc).	-	✓	-
Add or remove researcher accessing the SRE (aka lab)	-	✓	-

Criteria	Level 1	Level 2	Level 3
Add or remove researcher not accessing SRE	✓	-	-
Change in PI (aka Signing authority)	-	✓	
Change in Project scope	-	-	✓
Substantial change in direction of research	-	-	✓
Extend duration of access to data previously approved (not access to more years of data). Requires REB extension and / or amendment to ORS agreement if expired.	-	✓	-

**\*\* Amendment requests with multiple criteria are treated at the highest applicable Level \*\***

Actions	Level 1	Level 2	Level 3
Project PI (or a delegated member of the Research Team with the PI cc'd) 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:			
Institute Review	N/A	N/A	Yes
Data Research Committee	N/A	N/A	Yes
NB-IRDT Data Access Coordinator prepares REB Recommendation letter & advises PI to submit REB Case Modification Request	N/A	Yes	Yes
Chair of the REB sends REB approval	N/A	Yes	Yes
NB-IRDT Privacy Officer performs a final privacy review	Yes	Yes	Yes
NB-IRDT Privacy Officer approves amendment (if not available, the NB-IRDT Director)	Yes	No	No

Actions	Level 1	Level 2	Level 3
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 & to make edits (as per revised DAR) to the project folder	Yes	Yes	Yes
NB-IRDT Database Administrator informs PI that project folder has been updated.	Yes	Yes	Yes

Acronym Key					
CANUE	Canadian Urban Environmental Health Research Consortium	DRC	Data Research Committee	PI	Principal Investigator
DAA	Data Access Agreement	IRCC	Immigration, Refugees and Citizenship Canada	REB	Research Ethics Board
DAR	Data Access Request	ORS	Office of Research Services	SRE	Secure 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
			<b>June 2023</b>

Version	Author	Nature of Change	Date
1.3/2.0			