

## Amendment Resource

### Criteria, Actions & Versioning

This resource is to help define the various amendment levels for projects. It also provides a high-level look at the approval process required for each level and how the project versioning works.

**Note:** If an Amendment is submitted with multiple criteria levels, it will be processed using the actions of the highest level.

### Criteria

#### Safe Project

#	Criteria	Level 1	Level 2	Level 3	Level 4
1	Minor update (correction) to the DAR or to the Qualitative project protocol. (e.g. spelling error, formatting, etc.)	Y	-	-	-
2	Extend the REB Application Approval.	-	Y	-	-
3	Extend the project term.	-	Y	-	-
4	An update/change to project funder.	-	Y	-	-
5	Modification to data collection criteria.	-	Y	-	-
6	Modification to the project scope or project protocol. (e.g. change to research questions, cohort, etc.)	-	-	-	Y
7	Substantial change in direction of the research and/or increase in risk.	-	-	-	Y
8	Change in DAR Type (retrospective, prospective, successive, multi-phase)	-	-	-	Y

#### Safe People

#	Criteria	Level 1	Level 2	Level 3	Level 4
9	Modification to Approved User Access. (i.e., expired administrative safeguards equate temporary loss of access to the TRE)	Y	-	-	-

#	Criteria	Level 1	Level 2	Level 3	Level 4
10	Add a research team member who <b>will not be</b> on the publication(s) relating to this project. (i.e., they will not be an author)	Y	-	-	-
11	Remove a research team member who <b>is not</b> on the approved REB Application.	Y			
12	Add a research team member who <b>will not be</b> accessing the TRE.	Y	-	-	-
13	Remove a research team member who <b>is not</b> currently accessing the TRE.	Y	-	-	-
14	Add a research team member who <b>will be</b> on the publication(s) relating to this project & on the REB Application. (i.e., they will need to sign the attestation form)	-	Y	-	-
15	Remove a research team member who <b>is on</b> the publication(s) relating to this project & on the REB Application. (i.e., they previously signed the attestation form)		Y		
16	Change the PI on the project. (i.e., the signing authority has changed)	-	Y	-	-

### Safe Data

#	Criteria	Level 1	Level 2	Level 3	Level 4
17	Extend date range(s) of previously approved data set(s).	Y			
18	Add open-source data set(s).	Y	-	-	-
19	Add researcher's own imported data set(s). (i.e., if they are the DBO/C)	Y	-	-	-
20	Add new data set(s): Non-Personal Information or Non-Personal Health Information. (e.g., CANUE air quality data)	Y	-	-	-
21	Add aggregate data.	Y	-	-	-
22	Add new/corrected variable(s).	-	-	Y	-
23	Add new/corrected data set(s).	-	-	Y	-

## 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 DataNB	Yes	Yes	Yes	Yes
DataNB reviews the amended DAR to verify amendment criteria listed, confirm the amendment level, & check administrative safeguards	Yes	Yes	Yes	Yes
DataNB 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
DataNB prepares REB recommendation letter	n/a	Yes	Yes	Yes
DataNB submits the PERC package on behalf of the PI. This includes the REB case modification/extension request (with, if applicable, the signed attestation form), the updated DAR, the DataNB REB recommendation letter, the PERC summary & final privacy review	n/a	Yes	Yes	Yes
Chair of the REB sends REB approval to the PI & cc's DataNB	n/a	Yes	Yes	Yes
DataNB approves the amendment	Yes	No	No	No
DataNB 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
DataNB notifies the Database Administrator of the amendment approval and requests updates to the project folder per the amended DAR	Yes	Yes	Yes	Yes
DataNB informs the PI that the project folder has been updated	Yes	Yes	Yes	Yes

## Versioning

The version of a project follows the project number (e.g., P0101\_0.0 or Q0065\_1.0). Only level 2, level 3, and level 4 amendments need approval through ORS. Level 1 Amendments are assessed internally by DataNB staff; they are not sent to ORS for approval.

Within the version number, the number preceding the decimal indicates a level 2, level 3, or level 4 Amendment has taken place; the number following the decimal indicates if a level 1 amendment has taken place (they are “counts”, they do not indicate the amendment level).

Example of project versioning	
Version #	Explanation
0.0	Indicates the initial project was submitted for approval.
0.1	A level 1 amendment was submitted for approval.
1.0	After the previous amendment occurred, a level 2, level 3, or level 4 amendment was submitted for approval. The <b>first</b> to require signature of a DAA Amendment.
1.1	After the previous amendment occurred, a level 1 amendment was submitted for approval.
1.2	After the previous amendment occurred, a second level 1 amendment was submitted for approval.
2.0	After the previous amendment occurred, another level 2, level 3, or level 4 amendment was submitted for approval. The <b>second</b> to require signature of a DAA Amendment.
3.0	After the previous amendment occurred, another level 2, level 3, or level 4 amendment was submitted for approval. The <b>third</b> to require signature of a DAA Amendment.
3.1	After the previous amendment occurred, a level 1 amendment was submitted for approval.
4.0	After the previous amendment occurred, another level 2, level 3, or level 4 amendment was submitted for approval. The <b>fourth</b> to require signature of a DAA Amendment.
4.1	After the previous amendment occurred, a level 1 amendment was submitted for approval.
4.2	After the previous amendment occurred, a second level 1 amendment was submitted for approval.
4.3	After the previous amendment occurred, a third level 1 amendment was submitted for approval.

In the example above, the project underwent 11 amendments, but only four (4) DAA Amendments were required.

## Acronyms & Key Defined Terms

<b>CANUE</b>	Canadian Urban Environmental Health Research Consortium
<b>DAA</b>	Data Access Agreement
<b>DAR</b>	Data Access Request
<b>DBO/C</b>	Data Business Owner/Custodian
<b>DRC</b>	Data Research Committee
<b>IR</b>	Institute Review
<b>IRCC</b>	Immigration, Refugees and Citizenship Canada
<b>ORS</b>	Office of Research Services
<b>PERC</b>	Preliminary Ethics Review Committee
<b>PI</b>	Principal Investigator
<b>REB</b>	Research Ethics Board
<b>RR</b>	Risk Review
<b>TRE</b>	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

<b>Version</b>	<b>Author</b>	<b>Nature of Change</b>	<b>Date</b>
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
3.2	A Lavigne	Changed NB-IRDT to DataNB	August 27, 2025
4.0	A Lavigne	DataNB update & accessibility refresh	October 7, 2025
5.0	A Lavigne	Reorganized Amendment Criteria in line with the 5 Safes model	November 17, 2025