**DATA ACCESS AMENDMENTS**

**– Criteria –**

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

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

**– Actions –**

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| **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……………………………………………………………………………….……………...…  DRC………………………………………………………………………….…...……………..  PERC……………………………………………………………………………………………. | N/A  N/A  N/A | N/A  N/A  Yes | Yes  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.

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| 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 |

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| **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

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| --- | --- | --- | --- |
| **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 |
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