**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 datab) 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/AN/AN/A | N/AN/AYes | YesYesYes |
| 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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