Application Form Part B3: Requesting Canadian Blood Services Data for Research

Instructions for completing Part B3

Please review the Application Guidelines available at https://blood.ca/en/research/products-and-services-researchers/research-ethics-program prior to completing an application form. Part A must be completed in addition to Part B3 for studies requesting Canadian Blood Services data sets.

Data sets held by Canadian Blood Services are distributed electronically to approved studies. For any questions about available Canadian Blood Services data sets or how to submit an application, contact CBSREB@blood.ca.

Instructions for submitting an application including a Part B3

Submit the completed Application Form Part A and Part B3 as separate word files (.docx) and all required supporting documents as separate files to CBSREB@blood.ca.

1. Study Lay Title

*Study lay title must match study lay title provided in Part A*

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1. Study Alignment to the Goals of the Data for Research Program

Of the following three possible study outcomes, please indicate which best reflects the expected outcome for your study:

[ ]  Study outcomes may benefit transfusion medicine practices.

[ ]  Study outcomes may benefit organs and tissues transplantation medicine or hematopoietic progenitor cell transplantation practices.

[ ]  There is no direct benefit to either transplantation or transfusion practices.

1. Data Requested

**3.a.** Indicate the type of data requested for the study.

[ ]  Aggregate data\*

[ ]  De-identified record-level data#

[ ]  Identifiable record-level data#

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| \*Aggregate data | Summed and/or categorized data that can answer research questions about populations or groups of organizations. The data has been compiled from record-level data to a level that ensures the identities of individuals cannot be determined and that individual records cannot be reconstructed. |
| #Record-level data | Data in which each record is related to a single individual. Record-level data can be ***identifiable*** (identifies individuals, alone or in combination with other available information) or ***de-identified*** (information that identifies an individual has been removed and information has been modified so that there is no reasonable expectation of re-identification if combined with other available information). |

**3.b.** If **requesting** **identifiable record-level data**, explain (a) why the study cannot reasonably be accomplished without identifiable record-level data and (b) Indicate how long the information will remain identifiable and explain why.

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**3.c.** In terms of contextual sensitivities or foreseeable harms, is there any potential for data to be generated that would identify, stigmatize, or harm any person, group, or institution?

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**3.d.** Will the study result in reporting of any individual physicians, hospitals or institutions?

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**3.e.** Provide a brief description of the scope of the required data, including, but not limited to, the target study population, inclusion and exclusion criteria, and geographical location.

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**3.f**. Identify the data elements requested from Canadian Blood Services and provide rationale as to their inclusion in the requested data set. Use the table below or append a separate and clearly labelled document. If both a table and separate document are provided, only the table below will be reviewed.
*Note: Ensure that the data elements list is final. Any changes to the data elements list following approval of the study will need to be resubmitted as an amendment, prior to the release of data.*

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| **Data Element** | **Rationale** | **Special instructions** | **Indicate Canadian Blood Services data sources, if known** |
| *Example: Donor age* | *Example: For calculating age adjusted incidence rates* | *Example: Include donors 20 – 30 years old inclusive* | *Example: eProgesa* |
| [ ]  The requested data elements are attached as a separate document. |
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*Insert rows as needed.*

**3.g.** Indicate the timeframe for which data is requested.
*Note that this may be different than the study start and end dates.*

|  |  |
| --- | --- |
| From (YYYY-MM-DD)  |  |
| To (YYYY-MM-DD) |  |

**3.h.** Indicate the requested frequency of data transfer.

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| Single data transfer | [ ]  |
| Multiple data transfers | [ ]  |
| Requested frequency (e.g. weekly, monthly) |  |

**3.i.** Indicate the preferred format in which data should be provided (e.g., SAS data cut, tab delimited text file).

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**3.j.** Will the data from Canadian Blood Services be linked to any other data, database, or registry?

[ ]  Yes [ ]  No

If **Yes**, describe the data elements that will be linked, how linkages will be performed, and why the linkages are required.

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**3.k.** Will any data be stored outside of Canada?

[ ]  Yes [ ]  No

If **Yes**, describe where the data will be stored.

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1. Data Storage and Security

**4.a.** If **requesting aggregate data,** go to **Section 5**.

**4.b.** If **requesting record-level data**, identify all locations where data will be stored and confirm that the following minimum data security requirements for devices storing or accessing the provided record-level data will be met.

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| **Storage on fixed workstations/storage devices** |
| Data will be stored on fixed workstations/storage devices (e.g., desktop computers, servers, and database systems). | [ ]  Yes[ ]  No |
| If **data will be stored on fixed workstations/storage devices**, the following data security requirements will be met.* Only computing devices connected to a secure, trusted network will be used to store or access data.
* The network will employ up-to-date firewalls and antivirus software, and the antivirus software will automatically check for updates on a weekly basis, at minimum.
* Devices will employ logical access controls (strong passwords) at the file, device, and network level, with an automatic screen lock-out after no more than 15 minutes of inactivity.
* Users will have individual accounts (no shared accounts), and data access by users will be tracked and logged.
* Fixed devices will be located in a physically secure location with restricted access to authorized personnel.
 | [ ]  Yes[ ]  No |
| **Storage on mobile workstations/storage devices** |
| Data will be stored on mobile workstations (e.g., laptops, mobile phones, tablets) and/or storage devices (e.g., USB keys, CDs, DVDs). | [ ]  Yes[ ]  No |
| If **data will be stored on mobile workstations/storage devices**, the following data security requirements will be met.* Data will be encrypted at the file or device level.
 | [ ]  Yes[ ]  No |
| **Storage on cloud storage services** |
| Data will be stored on cloud storage services. | [ ]  Yes[ ]  No |
| If **data will be stored on cloud storage services**, the following data security requirements will be met.* Cloud storage services will be corporate governed or assigned.
* Cloud storage services will be hosted in Canada.
* Cloud storage services will be compliant with applicable privacy legislation.
 | [ ]  Yes[ ]  No |
| If **data will be stored on cloud storage services**, specify the service. |
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| **Data in transit** |
| Data in transit via a mobile device or a network transmission will be encrypted. | [ ]  Yes[ ]  No [ ]  N/A |
| **Storage as paper copies** |
| Paper copies of data will be stored. | [ ]  Yes[ ]  No |
| If **paper copies of data will be stored**, the following data security requirements will be met.* Paper files will be located in a physically secure location with restricted access to authorized personnel.
* Paper files will be transported by bonded courier services.
 | [ ]  Yes[ ]  No |
| **Other approaches to storage** |
| Other approaches will be used to store data | [ ]  Yes[ ]  No |
| If **other approaches will be used to store data**, provide details. |
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1. Data storage after study completion

**5.a.** How long will data be stored after completion of the study?

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**5.b.** Where will data be stored after completion of the study?

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**5.c.** How will data be destroyed after completion of the study?

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1. Data recipient information

Provide contact details for the individual to whom Canadian Blood Services will send data.

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| First Name  |  |
| Last Name  |  |
| Title/Position  |  |
| Organization  |  |
| Department |  |
| Address  |  |
| City, Province, Postal Code |  |
| Phone (**not** a personal phone number) |  |
| Email (**not** a personal email) |  |

1. Supporting Documents Checklist

Please indicate all supporting documents submitted with this application.

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| **7.a. Academic or commercial REB documentation (see Part A)** |
| Application | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Approval letter | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Study protocol (Canadian Blood Services staff only) | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **7.b. CCAC accredited Animal Care Committee documentation (see Part A)** |
| Approval letter | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **7.c. Data elements requested (see Part B3: Data requested)** |
| Table of requested data elements | [ ]  Table included in Part B3: Data Requested[ ]  Table appended to application |
| **7.d. Other supporting documents** |
| Other supporting documents | [ ]  Yes [ ]  No [ ]  Not Applicable |
| If Yes, list the supporting document(s) |  |
| **7.e.** If **No** to **7.a., 7.b., 7.c.,** and/or **7.d.,** provide details as to why documentation is not provided. |
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1. Principal Investigator Signature

*Note: The Principal Investigator signing Part B3 must be the Principal Investigator identified in Part A.*

[ ]  By ticking this box, I declare that the facility and equipment used to handle, manipulate, and store the study data comply with security standards as described in this application.

By typing my name and the date below, and submitting this application, I, the Principal Investigator on this study, declare that all of the information provided in Part A and Part B3 of this application is accurate and complete to the best of my knowledge and I agree to accept responsibility for the scientific conduct of the proposed study.

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| First, Last Name  |  |
| Date (YYYY-MM-DD) |  |

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