Application Form Part B4: Other studies pertaining to Canadian Blood Services

Instructions for completing Part B4

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. Note that Part A must be completed in addition to Part B4 for all studies which are not captured under the Cord Blood for Research Program (Part B1), the Blood4Research Program (Part B2), and Canadian Blood Services data sets (Part B3).

For any questions or for clarity as to which Part B to complete for your study, contact CBSREB@blood.ca.

Instructions for submitting an application including Part B4

Submit the completed Application Form Part A and Part B4 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 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 practices or hematopoietic progenitor cell transplantation practices.

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

1. Study Design

**3.a. Study participant population**

**3.a.i.** Identify the study participant population(s) linked to Canadian Blood Services. Check all that apply.

[ ]  General population of Canadian Blood Services blood donors\*

[ ]  Specific population of Canadian Blood Services blood donors\* (e.g., blood group, aberrant test results, deferred donors)

[ ]  General population of Canadian Blood Services non-blood donors (e.g., stem cell donors)

[ ]  Specific population of Canadian Blood Services non-blood donors (e.g., adult stem cell donors)

[ ]  Other population linked to Canadian Blood Services (e.g., Canadian Blood Services staff, Canadian Blood Services volunteers)

*\* Blood donors includes whole blood, plasma, and platelet donors at Canadian Blood Services.*

**3.a.ii.** Will your study involve other participant population(s) not linked to Canadian Blood Services (e.g., hospital patient population)?

[ ]  Yes. Provide institutional REB application and approval letter.

[ ]  No, the study will not involve participant populations not linked to Canadian Blood Services.

**3.b. Study design and methodology**

Describe in detail the study design and methodology. Explain how study participants – Canadian Blood Services participants (e.g., blood donors, Canadian Blood Services staff) and others – will be involved. Provide details about the nature of the participant populations, how participants will be identified and approached, how participants will be involved, and how samples and/or data will be used. Alternatively, attach a detailed study protocol addressing these requirements.
*Note: Provide as much detail as possible. For example, provide details about whether participants are approached during a normal blood clinic or outside of a blood clinic (e.g., by email or telephone), whether samples will be collected as part of a normal donation or will require a special collection, whether participant data will be retrieved from Canadian Blood Services records or collected using non-routine questionnaires or surveys.*

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**3.c. Study participant population details and involvement**

Provide details about the Canadian Blood Services study participant population(s) including why the population(s) identified is required for the study, the inclusion and exclusion criteria, and the number of participants required.

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**3.d. Study participant recruitment**

Describe how potential Canadian Blood Services participants will be identified and invited to participate and by whom. Indicate if any reimbursements or payments will be provided to the participants. **Attach copies of written material(s) to your application** (e.g. recruitment letters).

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**3.e. Study participant consent**

**3.e.i.** Will consent be sought from Canadian Blood Services participants to participate in the research?

 [ ]  **Yes**, consent is to be sought from participants.

 [ ]  **No**, consent will not be sought from participants.

**3.e.ii.** If **Yes to 3.e.i.**, (a) describe the consent process and **attach a copy of the consent form** to your application; (b) indicate who will seek consent and how consent will be sought; and (c) indicate how much time will be given to participants to review the information prior to being asked to provide consent.

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**3.e.iii.** If **No to 3.e.i.**, justify why consent will not be sought.

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**3.f. Risk/benefit estimates**

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| List potential benefits for Canadian Blood Services participants. |
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| List potential risks/harms for Canadian Blood Services participants. |
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**3.g. Incidental findings**

Provide details if there is potential for data to be generated from this study that would be meaningful to the health of the individual donor, and/or the study results in data that would be required to be reported to the public health system.

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1. Study Data
2. Data Collected from Canadian Blood Services Participants

**4.1.a.** Identify all data to be collected directly from Canadian Blood Services participants during the course of the study. Provide a rationale as to why the data will be collected. 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.*

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| **Data element** | **Rationale** |
| [ ]  The data elements to be collected directly from participants are attached as a separate document. |
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*Insert rows as needed.*

**4.1.b.** Does the research require the ability to identify participants?

 [ ]  **Yes**, the research requires the ability to identify participants.

 [ ]  **No**, the research does not require the ability to identify participants.

**4.1.c.** If **Yes to 4.1.b.**, (a) explain why the research cannot reasonably be accomplished without identifiable data; and (b) indicate how long the personal information will remain identifiable and explain why.

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**4.1.d.** If **No to 4.1.b.**, provide details on how the data/samples will be de-identified and the protections in place to prevent their re-identification.

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1. Data Requested from Canadian Blood Services’ Existing Data Sets

**4.2.a.** Will any data be requested from Canadian Blood Services database(s) for the study?

[ ]  **Yes**, data will be requested from Canadian Blood Services database(s) for the study.

 [ ]  **No**, data will not be requested from Canadian Blood Services database(s) for the study. **Go to Section 4.3.**

**4.2.b.** 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). |

**4.2.c.** 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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**4.2.d**. 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.*

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

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

**4.2.f.** Indicate the requested frequency of data transfer.

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

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

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**4.2.h.** 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. Additional Information about Study Data

**4.3.a.** 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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**4.3.b.** Will the study result in reporting of any individual physicians, hospitals or institutions?

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**4.3.c.** Will the data collected from participants or obtained 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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**4.3.d.** 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

Identify all locations where data will be stored and confirm that the following minimum data security requirements for devices storing or accessing the 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 and indicate the safeguards used to protect the confidentiality and security of the personal information throughout the research (during recruitment, data collection, analysis and publication). |
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1. Data storage after project completion

**6.a.** How long will data be stored after completion of the project?

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**6.b.** Where will data be stored after completion of the project?

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**6.c.** How will data be destroyed after completion of the project?

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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. Participant recruitment documents (see Part B4: Study design)**  |
| Recruitment documents | [ ]  Yes [ ]  Not Applicable |
| **7.d. Participant consent documents (see Part B4: Study design)** |
| Consent documents | [ ]  Yes [ ]  Not Applicable |
| **7.e. Data elements to be collected (see Part B4: Study data)** |
| Table of data elements to be collected | [ ]  Table included in Part B4: Study data[ ]  Table appended to application |
| **7.f. Data elements requested (see Part B4: Study data)** |
| Table of data elements requested | [ ]  Table included in Part B4: Study data[ ]  Table appended to application[ ]  Not Applicable |
| **7.g. Other supporting documents** |
| Other supporting documents | [ ]  Yes [ ]  No [ ]  Not Applicable |
| If Yes, list the supporting document(s) |  |
| **7.h.** If **No** to **7.a., 7.b., 7.c., 7.d., 7.e., 7.f.,** and/or **7.g.,** provide details as to why documentation is not provided. |
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1. Principal Investigator Signature

*Note: The Principal Investigator signing Part B4 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 B4 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) |   |

Instructions for submitting an application including Part B4

Submit the completed Application Form Part A and Part B4 as separate word files (.docx) and all required supporting documents as separate files to CBSREB@blood.ca.