Impact and Ethical Assessments of Study Proposal

Application Guidelines

Canadian Blood Services and its independent Research Ethics Board (REB) review all research involving human participants conducted by or on behalf of Canadian Blood Services, including all research involving personal information (e.g. registry data) or biologic materials (e.g. blood and cord blood) collected by Canadian Blood Services. Canadian Blood Services also conducts internal reviews of all quality improvement and training studies to ensure their feasibility and alignment with Canadian Blood Services' mandate. The application process is described below. For more information or at any time during this process, you may contact CBS REB Secretariat at CBSREB@blood.ca.

Principal Investigators are encouraged to read the application forms, which contain important information, prior to completing an application. The completed application should provide all relevant information to allow for review and authorization by Canadian Blood Services. A research study application should include the scientific, technical, procedural and ethics information necessary for the REB to evaluate both the ethics of the study and whether the subject information and consent material accurately represent the study to potential participants, including Canadian Blood Services participants.

What to include in your application?

- ✓ **Part A: General Information.** This section of the application provides **general information** about the study.
- ✓ **Part B:** This section of the application provides **specific information** about the study. It includes a list of additional documents required and a signature field. **Depending on the nature of your study, the following Part B must be completed.** Note that, depending on the study need(s), multiple Part Bs can be submitted with one application.
  - **Part B1**: Requesting Canadian Blood Services **Cord blood for research**.
  - **Part B2**: Requesting Canadian Blood Services **Blood for research.**
  - **Part B3**: Requesting Canadian Blood Services **Data for research**.
  - **Part B4**: **Other studies** pertaining to Canadian Blood Services.
- ✓ **Supporting documents** as per instructions in Parts A and B.

How to submit your application?

An application must be submitted according to instructions detailed in Part B. Submit Part A and Part B documents as separate word files (.docx) and all supporting documents as separate files.

How will your application be reviewed?

Step 1: Canadian Blood Services will review your application for completeness, to determine whether it can support your study from an operational perspective (e.g. staffing, scheduling, availability of products/data requested) and to assess whether it requires REB review. Canadian Blood Services may contact you to obtain further information about your application.

Anticipated completion time for Step 1: Canadian Blood Services is committed to reviewing your application within 30 days of receiving a **complete** application package. However, depending on the complexity of your study, more time may be necessary.

Step 2: Once your application is approved by Canadian Blood Services, it will be submitted to the Canadian Blood Service REB for review, if required. Canadian Blood Services REB may contact you to obtain further information about your application.

Anticipated completion time for Step 2: The REB is committed to reviewing your application within 30 days of Canadian Blood Services approval (Step 1). Note that the REB has three scheduled meetings per year (see https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program for details) and you are encouraged to submit applications consisting of Part B4 two months before these dates. Additional reviews can be organized throughout the year in addition to the scheduled meetings, as needed.

Step 3: If your study requires an agreement, Canadian Blood Services will contact you to initiate the process.

In general, an agreement will need to be executed between Canadian Blood Services and the Principal Investigator/Organization for distribution of blood, cord blood, and data if:

- The Principal Investigator is not a Canadian Blood Services employee; or
- The Principal Investigator is a Canadian Blood Services employee, but data and/or biologic materials will be shared with a third party outside Canadian Blood Services (as listed in Part A: Authorized Persons).

Anticipated completion time for Step 3: This step varies greatly depending on the nature of the material or data to be shared and the institutions involved in the execution of the agreement. Where possible, Canadian Blood Services has developed templates to facilitate this process.

Step 4: Once your study is approved by Canadian Blood Services **AND** the REB (if REB approval is required) **AND** an agreement has been finalized (if agreement is required) **then the study may begin**. Canadian Blood Services will notify you of the status of your application throughout this process.

How to manage your approved study?

For information about **annual study renewal**, **amendment**, **privacy breach disclosure** and **study closure**, please visit our website at https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program.

The Canadian Blood Services and REB's decisions to approve the operational feasibility and aspects related to the ethics of the study depends on the information submitted. Any new knowledge that changes the information on which the Canadian Blood Services and REB's approvals were based may invalidate that approval; therefore, Canadian Blood Services and REB must be informed about any changes/amendments to the study.