Application Form Part A: General Information

**Instructions for completing Part A**

Please review the Application Guidelines available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-program> prior to completing an application. At least one Part B must be completed in addition to Part A for all applications for studies involving human participants conducted by Canadian Blood Services or using Canadian Blood Services resources (e.g. biological materials, data, staff, donors, etc.).

For any questions, contact CBSREB@blood.ca.

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| Canadian Blood Services Use Only |
| Canadian Blood Services REB # | Click or tap here to enter text. |
| Part B submitted | Click or tap here to enter text. |
| Type of study | Choose an item. |
| Notes about request | Click or tap here to enter text. |

1. Study Information

**1.a.** **Study Period**

Provide the approximate study period where Canadian Blood Services is involved, or Canadian Blood Services resources are being used.

*Review and approval time will vary based on the quality of the application and complexity of the study. Please be aware that a study may not begin until all required approvals are in place. Ensuring all approvals are in place is the responsibility of the Principal Investigator (PI). Additional approvals may include an institutional REB approval, biohazard permit, etc. Once approved, all studies are approved for a maximum of 5 years, with a yearly renewal requirement. If the study would like to collect new data/biological materials after five years, a new application must be submitted. Studies in the data analysis phase past the 5-year limit, will be permitted to renew their CBS REB approval with the submission of a renewal form only.*

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| Anticipated study start date (YYYY-MM-DD)*Anticipated date of Canadian Blood Services involvement* | Click or tap to enter a date. |
| Anticipated study end date (YYYY-MM-DD) | Click or tap to enter a date. |

**1.b. Study Lay Title**

Provide a title that is fewer than 10 words, written in language that would be clear to the public (e.g., to research participants).

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| Click or tap here to enter text. |

**1.c Principal Investigator (PI)**

Provide details about the study PI.

*The PI is responsible for managing the study and for reporting to Canadian Blood Services. For PIs with multiple affiliations, please clearly identify the primary affiliation for this study. An undergraduate, master’s or PhD student/candidate cannot serve as the PI.*

|  |  |
| --- | --- |
| First Name  | Click or tap here to enter text. |
| Last Name  | Click or tap here to enter text. |
| Title/Position  | Click or tap here to enter text. |
| Organization/Institution  | Click or tap here to enter text. |
| Department | Click or tap here to enter text. |
| Address  | Click or tap here to enter text. |
| City, Province, Postal Code | Click or tap here to enter text. |
| Phone (**not** a personal phone number) | Click or tap here to enter text. |
| Email (**not** a personal email) | Click or tap here to enter text. |
| The PI must have completed the TCPS 2 Course on Research Ethics (CORE) training and attached proof of completion for research studies. | Choose an item. |
| Is the PI a Canadian Blood Services employee? | Choose an item. |

**1.d. Type of Organization**

Identify the type of organization/institution with which the PI is associated and/or where the study will occur (select all that apply):

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| Choose an item. |

*Add rows to table as needed to identify additional types of organizations/research institutions. Click on the plus sign (+) at bottom right of table to add another row.*

If type is “Other”, please specify

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| Click or tap here to enter text. |

**1.e. Contact Person**

In addition to the PI, who should receive correspondence related to this study?

*If an additional individual should receive communications about this study (e.g., renewal reminders), provide additional contact information below. If only the PI should receive communications, leave this section blank.*

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| --- | --- |
| First Name  | Click or tap here to enter text. |
| Last Name  | Click or tap here to enter text. |
| Title/Position  | Click or tap here to enter text. |
| Organization/Institution  | Click or tap here to enter text. |
| Department | Click or tap here to enter text. |
| Address  | Click or tap here to enter text. |
| City, Province, Postal Code | Click or tap here to enter text. |
| Phone (**not** a personal phone number) | Click or tap here to enter text. |
| Email (**not** a personal email) | Click or tap here to enter text. |

1. Authorized Person(s)

Identify all study team members who are actively involved in the study and/or involved with the processing of Canadian Blood Services data or biological materials (including third party testing), including applicant’s trainees.

*For study team members with multiple affiliations, please clearly identify under which affiliation they are performing the study. As of* ***January 1, 2024****, all study team members* ***must provide proof of ethics training*** *(TCPS 2 Course on Research Ethics “CORE” certificate) for research studies.*

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| First Name: | Click or tap here to enter text. |
| Last Name: | Click or tap here to enter text. |
| Organization/Institution Name: | Click or tap here to enter text. |
| Organization City, Province, Postal Code: | Click or tap here to enter text. |
| Professional Position (e.g. Professor, Director, student): | Click or tap here to enter text. |
| Role in study team (e.g., Co-Investigator, Laboratory Manager, Research Assistant): | Click or tap here to enter text. |
| Has this individual completed the TCPS 2 Course on Research Ethics (CORE) training and attached proof of successful completion? | Choose an item. |
| Provide details as to this individual’s role in the study (e.g., interviewing participants, data or biological materials will be distributed/accessed by this individual for experiment or analysis; clearly indicate when it is CBS biologicals or CBS data).If they will not have direct contact with participants or access data/biologicals, indicate their involvement in this study (e.g., manuscript preparation). | Click or tap here to enter text. |

*Add table(s) as needed to identify additional authorized persons. Click on the plus sign (+) at bottom right of table to add another table.*

1. Agreements

To help identify whether an agreement with Canadian Blood Services is required to support this study, please answer the following questions.

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| Do Canadian Blood Services and the PI and/or institution/organization have a signed agreement in place in support of this study? | Choose an item. |
| If yes, please provide the contract number. | Click or tap here to enter text. |
| For the purpose of the study, are you requesting from Canadian Blood Services: |
| * Biological materials?
 | Choose an item. |
| * Data?
 | Choose an item. |
| If “Yes” to biological materials OR data, please provide the name of the institution/organization who will be party to the agreement and the contact information of their legal office for agreement purposes. Please add multiple contacts if Canadian Blood Services will provide biological materials/data directly to multiple institutions/organizations.If for internal use at Canadian Blood Services, indicate “Internal use”. | Click or tap here to enter text. |
| Are any data or biological materials being transferred to Canadian Blood Services from an institution/organization for the purpose of this study? | Choose an item. |
| If “Yes”, please provide the name of the institution/organization that will be providing the data/biological materials (party to the agreement), and the contact information for their legal office for agreement purposes. | Click or tap here to enter text. |

1. Project Funding Support

**4.a. Source(s) of Funding**

Identify all sources of funding for this study.

*If not funded through a specific grant or award, indicate the study team member and organization primarily providing the resources to support the study.*

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| Name of funding recipient(First name, Last name) | Click or tap here to enter text. |
| Name of funding organization | Click or tap here to enter text. |
| Funding start date (YYYY-MM-DD) | Click or tap to enter a date. |
| Funding end date (YYYY-MM-DD) | Click or tap to enter a date. |
| Type of funding | Choose an item. |

*Add table(s) as needed to identify additional sources of funding. Click on the plus sign (+) at bottom right of table to add another table.*

**4.b. Direct Personal Payments**

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| Will any team members receive direct personal payments from the funding? | Choose an item. |
| If yes, describe payments to be made. |
| Click or tap here to enter text. |

1. Potential Conflict(s) of Interest

Disclose any conflicts of interest (COI) (actual, apparent, perceived or potential) relating to this study and the plan to mitigate the COI. If no COI, indicate ‘No COI to disclose’.

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| Click or tap here to enter text. |

1. Study Lay Summary

**Summarize the study in language that would be clear to the public (e.g., to a donor or research participant) (max. 200 words)**. Indicate the rationale for this study, the hypothesis or research question, and the significance of the study (e.g. overall anticipated public and/or scientific benefit). Describe the primary goals and outcomes of the study, and explain the relevance of this study to Canadian Blood Services.

*Note: if the study is approved, this lay summary may be published on Canadian Blood Services website to inform donors/participants and the public about studies that are supported by Canadian Blood Services.*

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| Click or tap here to enter text. |

1. Application Type

Indicate the type of application(s) you are submitting (select all that apply).

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| Choose an item. |

*Insert rows as needed to identify additional Part B applications needed. Click on the plus sign (+) at bottom right of table to add another row.)*

1. Study Design

Describe the study design and methodology. Please make sure to provide information specific to how and where Canadian Blood Services resources are involved (e.g., staff, data, biological materials or participants). If this is longer than 1 page, please attach a Word document with the detailed study design and methodology (indicate in this form, “Please see attachment”).

*You may attach a protocol as a support document but the details on the involvement of Canadian Blood Services must still be clearly defined.*

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| Click or tap here to enter text. |

1. Team Expertise

Briefly describe the experience of the PI and the study team in this field of study.

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| Click or tap here to enter text. |

1. Dissemination of Findings

Indicate how the results will be communicated to a) participants and b) other stakeholders e.g. advocacy groups, scientific community, Canadian Blood Services (CBS).

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| Click or tap here to enter text. |

1. Research Ethics Board requirements

**11.a.** What type of study would you consider your application to represent ?

*For guidelines to aid in assessing whether a study is a research study or a quality improvement/assurance study/training/program evaluation, visit* [*https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program)*.*

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| Choose an item. |

If the application is for **a research study** involving an external PI, they **must** secure approval from their institutional REB or a commercial REB. If the PI is conducting this study primarily under their Canadian Blood Services affiliation, the Canadian Blood Services REB will have primary oversight. Additional institutional REB review may be required for other study team members depending on their role in the study and their primary affiliated institutional REB policies.

*Contact* *CBSREB@blood.ca* *for questions or more information on research versus quality improvement/assurance/training/program evaluation and on institutional/commercial REB requirements.*

**11.b.** Has this or will this study be submitted somewhere other than Canadian Blood Services for REB review?

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| Choose an item. |

**11.c.** If **yes to 11.b**., please provide information about the institutional/commercial REB below.

 *If already submitted or approved****,*** *attach a copy of the application(s), including all supplemental documents,* ***and*** *any current approval letter(s).*

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| Name of institutional REB (or equivalent) | Click or tap here to enter text. |
| REB (or equivalent) approval obtained | Choose an item. |
| If submitted, original institutional REB submission date (YYYY-MM-DD) | Click or tap to enter a date. |
| Original institutional REB (or equivalent) approval date (YYYY-MM-DD) | Click or tap to enter a date. |
| Has the study changed in design since the original approval/submission to the institutional REB? | Choose an item. |
| If yes, indicate changes made since approval. | Click or tap here to enter text. |
| Institutional REB Amendment Submission date(s) (YYYY-MM-DD) | Click or tap to enter a date. |

*Add tables as needed to identify additional REBs. Click on the plus sign (+) at the bottom right of the table to add another table.*

1. Canadian Council on Animal Care (CCAC)

**12.a.** Does the proposed study involve animals?

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| Choose an item. |

**12.b.** If **yes to 12.a**., please provide the following information **and** attach a copy of the Animal Care Committee approval letter.

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| Name of the CCAC accredited Animal Care Committee that will oversee this use of animals | Click or tap here to enter text. |
| CCAC approval number | Click or tap here to enter text. |
| CCAC approval date (yyyy-mm-dd) | Click or tap to enter a date. |

**Instructions for submitting an application**

This is the end of “Part A: General Information”. To complete your application package, complete the appropriate Part B form(s). To identify which Part B needs to be completed, consult Part A: Application Type or the Application Guidelines.