Application Form Part B1: Requesting Canadian Blood Services Cord Blood for Research

Instructions for completing Part B1

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 B1 for studies requesting cord blood for research.

The Cord Blood for Research Program distributes **whole cord blood (fresh)** and **processed cord blood units (frozen)** for research for non-human use. For details about the available research products, review the “Cord Blood Product Specifications for Biomedical Research” document prior to completing your application. Research products may be distributed to approved studies for a fee in order to recover some of the costs incurred by the Program. These fees may change at the discretion of Canadian Blood Services. Download the “Cord Blood Product Specifications for Biomedical Research” document at <https://www.blood.ca/en/research/products-and-services-researchers/products-research/obtain-cord-blood-research>.

For details on the process Canadian Blood Services follows to involve donors in the Cord Blood for Research Program, read the documents known as **“Permission to collect form”** and **“Information for Cord Blood Donation for Biomedical Research”** prior to completing your application. Download the documents at <https://www.blood.ca/en/research/products-and-services-researchers/products-research/obtain-cord-blood-research>.

For additional information about the Cord Blood for Research Program, visit <https://www.blood.ca/en/research/products-and-services-researchers/products-research#cordbloodproducts>. For any questions about the Cord Blood for Research Program, contact researchcordblood@blood.ca.

Instructions for submitting an application including Part B1

Submit the completed Application Form Part A and Part B1 as separate word files (.docx) and all required supporting documents as separate files to researchcordblood@blood.ca. If your application package includes more than one Part B, submit the completed application package 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 Cord Blood 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 cell transplantation medicine including hematopoietic progenitor cell transplantation practices and cord blood banking practices (e.g., improvements in clinical outcomes of cellular transplantation, development of new cord blood cellular therapies, improvements to stem cell collection, manufacturing and storage).

[ ]  Study outcomes may benefit transfusion medicine practices.

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

1. Cord Blood Products Requested for the Study

Identify the products requested from the Cord Blood for Research Program.

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| Number and type of cord blood products requested for the duration of the study |
| Fresh (unprocessed) whole cord blood units | [ ]  Yes [ ]  No |
| If yes, number of unit(s) |  |
| Frozen (processed) whole cord blood units | [ ]  Yes [ ]  No |
| If yes, number of unit(s) |  |
| Anticipated delivery schedule (i.e., number of unit(s) per month) |  |
| Intended start date of product delivery |  |
| Requesting sex assigned at birth of the baby on provided cord blood units | [ ]  Yes [ ]  No |
| Provide a rationale of the number of products required to complete the study. |
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| Indicate if there are any requirements for the cord blood products. *Note: For details about the available research products, review the “Cord Blood Product Specifications for Biomedical Research” document. Additional specifications may impact the ability of the Cord Blood for Research Program to approve the application.* |
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1. Stem Cell Oversight Committee (SCOC)

**4.a.** Does the proposed study involve the derivation of human pluripotent stem cells?

 [ ]  Yes [ ]  No

**4.b.** Does the study involve grafting or transferring human pluripotent or human totipotent stem cells into humans or non-human animals?

 [ ]  Yes [ ]  No

**4.c.** Is the proposed study conducted under the auspices of a Tri-Council Agency funded institution?

 [ ]  Yes [ ]  No

**4.c.** If **yes to 4.a., 4.b. and 4.c.**, your study likely requires review by the SCOC. Please refer to [Article 12.10](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter12-chapitre12.html) of the Tri-Council Policy Statement (TCPS 2). For SCOC application requirements, please visit <https://cihr-irsc.gc.ca/e/15351.html> . For any questions about the SCOC, please reach out directly to the SCOC at stemcell@cihr-irsc.gc.ca .

Where SCOC is required, provide the following information **and** attach a copy of the SCOC approval letter with your application.

If SCOC is not required, leave the table blank.

|  |  |
| --- | --- |
| SCOC submission date (YYYY-MM-DD) |  |
| SCOC approval obtained | [ ]  Yes [ ]  No |
| SCOC approval date (YYYY-MM-DD) |  |
| Has the research project changed in design since the original approval/submission to SCOC? | [ ]  Yes [ ]  No |
| If the research project has changed in design since the original approval/submission to SCOC, please provide a description of changes. |
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1. Genetic Testing and Genetic Analysis

**5.a.** Will genetic testing and/or genetic analysis be conducted on the cord blood sample(s) or any of the cells isolated from the cord blood sample(s)?

[ ]  **No**, we will not be performing genetic testing and/or genetic analysis on the cord blood sample(s) or any cells isolated from the cord blood sample(s) provided by Canadian Blood Services.

[ ]  **Yes**, we will be performing genetic testing and/or genetic analysis on the cord blood sample(s) or on cells isolated from the cord blood sample(s) provided by Canadian Blood Services.

**5.b.** If **yes to 5.a.**, please describe the planned genetic testing and/or genetic analysis in as much detail as possible.*Note: The Cord Blood for Research Program cannot support all types of projects involving genetic testing and/or genetic analysis; therefore, depending on the nature of the proposed study, your application may not be approved.*

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1. Incidental Findings

**6.a.** Is there potential for reasonably foreseeable incidental findings?

*(Note: ‘Reasonably foreseeable’ means that the researcher anticipates that incidental findings may be found)*

 [ ]  **No,** proceed to 7.

 [ ]  **Yes**, proceed to 6.b.

**6.b.** Would the incidental findings be considered ‘material’?

*(Note: Incidental findings are considered ‘material’ if they are reasonably determined to have significant welfare implications for the participant. For more information on incidental findings and how to determine if they are ‘material’, refer to* [*Article 3.4*](https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html) *of the Tri-Council Policy Statement (TCPS2) and the* [*How to Address Material Incidental Findings*](https://ethics.gc.ca/eng/incidental_findings.html) *Guidance document)*

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| --- | --- |
| [ ]  **No**, provide rationale below.

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| [ ]  **Yes**, provide a description of the analytical validity, potential significance to the participant, and the actionability of the findings below. A management plan will be required as a support document.*(Note: Where there is potential for a reasonably foreseeable ‘material’ incidental finding, you will be required to provide a management plan as a support document. The plan should include a detailed description of the determination of the materiality of the findings including expertise/resources involved in making the assessment and relevant support documents as applicable, i.e. participant notification letter. See the ‘*[*How to Address Material Incidental Findings’*](https://ethics.gc.ca/eng/incidental_findings.html) *Guidance document for additional details on a management plan. External researchers should consult with their institutional REB for guidance on developing a management plan.)*

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***Note: If during the course of the study, a foreseeable or unexpected material incidental finding is discovered, the principal investigator is required to report the finding to the CBS REB within 7 days*** *using the ‘*Adverse Event Report*’ form found on the* [*REP website*](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*](https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program)*) and sending to* *CBSREB@blood.ca* *. External researchers must also notify their institutional REB following their policies and processes. A management plan for an unexpected material incidental finding must be developed promptly.*

1. Shipping Information

Identify the person to be contacted about shipment and receipt of cord blood product(s).

 If the same as Principal Investigator identified in Part A of the application, leave the section below blank.

If different, please provide contact and shipping details for the person who would be contacted about shipment and receipt of cord blood product(s).

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

1. Billing Information

Identify the person to be contacted for invoicing purposes.

**Note: Canadian Blood Services cannot accept payment by credit card.**

If the ssame as Principal Investigator identified in Part A: Section 1 of the application, leave the section below blank.

If different, please provide customer information for invoicing purposes below*.*

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

1. Supporting Documents Checklist

Please indicate all supporting documents submitted with this application.

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| **8.a. Academic institutional or commercial REB documentation (see Part A)***Please provide academic institutional REB or a commercial REB as applicable.* |
| Institutional REB Application included | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Institutional REB Approval letter included | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.b. CCAC accredited Animal Care Committee documentation (see Part A)** |
| Approval letter | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.c. SCOC documentation (see Part B1: Stem Cell Oversight Committee)** |
| Approval letter | [ ]  Yes [ ]  No [ ]  Not Applicable |
| **8.d. Other supporting documentation** |
| Study Protocol | [ ]  Yes [ ]  No [ ]  Not Applicable |
| List any other supporting document(s). If not applicable, enter “N/A”. |  |
| **8.e.** If **No** to **8.a., 8.b., 8.c., and/or 8.d.,** provide details as to why documentation is not provided. |
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1. Principal Investigator Signature

*Note: The individual signing Part B1 must be the Principal Investigator identified in Part A.*

[ ]  By ticking this box, I declare that to my knowledge, no researchers involved in this study are affiliated with, or in receipt of funding or in-kind support, from an organization included on the Government of Canada’s ‘[Named Research Organizations](https://science.gc.ca/site/science/en/safeguarding-your-research/guidelines-and-tools-implement-research-security/sensitive-technology-research-and-affiliations-concern/named-research-organizations)’ list.

Canadian Blood Services obtains consent from cord blood donors to distribute unbankable cord blood units and by-products under the Cord Blood for Research Program. Please confirm that you have read and understand the Canadian Blood Services documents known as “Permission to collect” and “Information for Cord Blood Donation for Biomedical Research” available at <https://www.blood.ca/en/research/products-and-services-researchers/products-research/obtain-cord-blood-research>.

I have read and understood the most recent versions of the following documents available on www.blood.ca:

 [ ]  “Permission to collect” form.

 [ ]  “Information for Cord Blood Donation for Biomedical Research” form.

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 B1 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.

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

Instructions for submitting the completed application package

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Cord Blood for Research Program Internal Application Review

*To be completed by Canadian Blood Services Cord Blood for Research Program*

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| Final approval requirements |
| Pre-approval score |  |
| CBS REB approval obtained | [ ]  Yes [ ]  No [ ]  Not Applicable |
| MTA executed | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Application status | [ ]  Approved [ ]  Not Approved |
| Comments |
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| --- | --- |
| Director – Stem Cells, Canadian Blood ServicesFirst, Last Name  |  |
| Date (YYYY-MM-DD) |  |

By typing my name and the date above, and submitting this internal application review, I, on behalf of the Canadian Blood Services Cord Blood for Research Program, declare that I have reviewed the application and all accompanying documents and am providing a decision on the status of this application as noted above.