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 |  |
| 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 pluripotent stem cells?

 [ ]  Yes [ ]  No

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

 [ ]  Yes [ ]  No

**4.c.** If **yes to both 4.a. and 4.b**., please provide the following information **and** attach a copy of the SCOC approval letter with your application.

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| 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

**5.a.** Will genetic testing 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 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 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 in as much detail as possible.*Note: The Cord Blood for Research Program cannot support all types of projects; therefore, depending on the nature of the proposed study, your application may not be approved.*

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1. Shipping Information

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

[ ]  Same as Principal Investigator identified in Part A of the application. If different, please provide contact and shipping details for the person who would be contacted about shipment and receipt of cord blood product(s).

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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) |  |
| Fax |  |

1. Billing Information

Identify the person to be contacted for invoicing purposes.

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

[ ]  Same as Principal Investigator identified in Part A: Section 1 of the application. If different, please provide customer information for invoicing purposes*.*

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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) |  |
| Fax |  |

1. Supporting Documents Checklist

Please indicate all supporting documents submitted with this application.

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| **8.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 |
| **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** |
| Other supporting document(s) | [ ]  Yes [ ]  No [ ]  Not Applicable |
| If Yes, list the supporting document(s) |  |
| **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 Principal Investigator signing Part B1 must be the Principal Investigator identified in Part A.*

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.

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

Instructions for submitting the completed application package

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.

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.