##### Renewal Form

You are required to obtain approval for continuation of your study annually by submitting this Renewal Form to CBSREB@blood.ca. Submission of this Form will ensure timely renewal of your study and prevent its unwanted termination.

A lay summary detailing the key findings of your study, as well as a list of publications and presentations, are required. Canadian Blood Services may share this information with its stakeholders, including donors whose voluntary contributions of blood and health information enables Canadian Blood Services supported studies.

Note: An Amendment Form must be submitted to request changes to the protocol, consent forms, recruitment materials, blood products or data fields being requested, or changes in the principal investigator or other authorized persons (e.g. co-investigator, contact). A Renewal Form and an Amendment Form can be submitted and reviewed in parallel.

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| Section 1: Study Information |
| 1. Principal Investigator Name (First, Last):
2. Project title:
3. CBS REB protocol number:
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| 1. Report date (yyyy-mm-dd):
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| 1. Did your study application to Canadian Blood Services include an institutional REB approval?
 | [ ]  Yes [ ]  No |
| If yes, please provide evidence of renewal of the Institutional REB approval. Please provide the Institutional REB approval letter when available: |
| 1. Has Canadian Blood Services approval lapsed?
 | [ ]  Yes [ ]  No |
| If yes, provide reasons for the lapse and identify steps taken or corrective actions: |
| If yes, confirm that you have suspended all study activities or provide justifications should there be a need to continue for the safety and well being of the research participants and describe study activities from time of lapse to current date: |
| 1. Has the study principal investigator or other authorized persons (e.g. co-investigator, contact) changed?
 | [ ]  Yes [ ]  No  |
| If yes, please provide the submission date of your Amendment Form submitted to Canadian Blood Services (yyyy-mm-dd): |
| If you have not yet submitted an Amendment Form, please do so immediately by completing a form available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-board>.  |
| 1. Did the study deviate from the application approved by Canadian Blood Services, including amendments approved during the course of the study?
 | [ ]  Yes [ ]  No  |
| If yes, submit an Amendment Form available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-board>.  |
| 1. During the course of the study, did any significant new information arise from any source that changed the basis on which Canadian Blood Services provided its original approval?
 | [ ]  Yes [ ]  No  |
| If yes, please provide the submission date of your Amendment Form submitted to Canadian Blood Services (yyyy-mm-dd): |
| If the new information did not necessitate an amendment to your study, please provide an explanation: |
| 1. Did the study participants suffer any serious or unexpected harm? An adverse event is “any unfavorable and unintended occurrence in a participant including abnormal laboratory finding, symptom or disease.”[[1]](#endnote-1) Further, it is a requirement to report to the REB “any unanticipated issue or event that may increase the level of risk to participants or has other ethical implications that may affect participants’ welfare.”[[2]](#endnote-2)
 | [ ]  Yes [ ]  No  |
| If yes, please provide the submission date of your Adverse Event Report to Canadian Blood Services(yyyy-mm-dd): |
| If you have not yet submitted an Adverse Event Report, please do so immediately by completing a form available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-board>.  |
| 1. Did any privacy breach occur during this study?
 | [ ]  Yes [ ]  No  |
| If yes, please provide the date you informed Canadian Blood Services of the privacy breach (yyyy-mm-dd): |
| If you have not yet informed Canadian Blood Services, please do so immediately. Contact information is available at <https://blood.ca/en/research/products-and-services-researchers/research-ethics-board>. |
| 1. Were any complaints or concerns received by you or your research institution from research participants or those contacted for study purposes?
 | [ ]  Yes [ ]  No  |
| If yes, please describe: |
| Section 2: Study Results |
| 1. Have any results from this study been published or presented?
 | [ ]  Yes [ ]  No  |
| If yes, please provide citations details for abstracts, publications and presentations (you may attach the publications to your report, as applicable): |
| If no, please justify. Note that dissemination of study results, whether positive or negative, to the scientific community is an ethical expectation required for justifying the inclusion of participants in research: |
| 1. Have the study participants been informed of the results?
 | [ ]  Yes [ ]  No  |
| If yes, describe how the results were provided to participants and include a copy of the results: |
| If no, please justify not informing study participants of results: |
| 1. Please provide a summary (500 words max.), in **lay terms**, of your study. Please address the following questions: What issues are being addressed in the study? What are the methodologies being used? Who have been invited to be research participants? What products or data have been used in the study (if applicable)? What was been learned so far from the study? What will likely result from the study’s discoveries? What is the potential impact of the study?

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| Principal Investigator Name: | Signature: | Date: (yyyy-mm-dd) |

1. Guidance for Industry Good Clinical Practice: Consolidated Guideline ICH Topic E6. [↑](#endnote-ref-1)
2. Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, December 2018. [↑](#endnote-ref-2)