##### Closure Form

You are required to report the termination of your study to Canadian Blood Services by submitting this Closure Form to CBSREB@blood.ca. Submission of this Form will ensure timely processing of future study applications to Canadian Blood Services.

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.

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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. Study closure date (yyyy-mm-dd):
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| If premature, state reason for closure:  |
| 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, please state deviations from the approved study and reasons for them: |
| 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, 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 institution from study participants or those contacted for study purposes?
 | [ ]  Yes [ ] No  |
| If yes, please describe the concerns and how you dealt with them:  |
| 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 did the study address? What were the methodologies used? Who were invited to be research participants? How were the products or data used (if applicable)? What was learned from the study? What will 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)