##### 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.

Section 1: Study Information

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| **1.a.** Principal Investigator (First and Last Name)  |  |
| **1.b.** Study title |  |
| **1.c.** CBS REB number |  |

Section 2: Closure Information

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| **2.a.** Study closure date (YYYY-MM-DD) |  |
| If premature, state reason for closure. |
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| **2.b.** 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: |
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| **2.c.** 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-2) 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-3) | [ ]  Yes [ ]  No |
| If **Yes**, provide the date the Adverse Event Report was submitted to Canadian Blood Services (YYYY-MM-DD).  |  |
| If you have not yet submitted an Adverse Event Report, do so immediately by completing a form available at <https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program>. |

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| **2.d.** Did any privacy breach occur during this study? | [ ]  Yes [ ]  No |
| If **Yes,** provide the date the Privacy Breach was reported to Canadian Blood Services (YYYY-MM-DD). |  |
| If you have not yet informed Canadian Blood Services, do so immediately. Contact information is available at <https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program>.  |

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| **2.e.** Were any complaints or concerns received by you or your institution from study participants or those contacted for study purposes? | [ ]  Yes [ ]  No |
| If **Yes**, describe the complaints or concerns and how the complaints or concerns were dealt with: |
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Section 3: Study Results to Date

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| **3.a.** Have any results from this study been published or presented? | [ ]  Yes [ ]  No |
| If **Yes**, provide citations details for abstracts, publications, reports, and presentations (you may attach documents, as applicable): |
|  |
| If **No**, provide justification as to why results of the study have not been published or presented. *Note: 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.*  |
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| **3.b.** Have the study participants been informed of results of this study? | [ ]  Yes [ ]  No |
| If **Yes**, describe how the results were provided to participants and include a copy of the results: |
|  |
| If **No**, provide justification as to why study participants have not been informed of the results of this study: |
|  |
| **3.c.** Provide a summary (500 words max.) **in lay terms**, detailing the key findings of your study and addressing the following questions: What issues did the study address? What were the methodologies used? Who were invited to be study 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?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 4: Supporting Documents

Please ensure that all questions have been answered appropriately and indicate all supporting documents submitted with this closure form below. Submission of a complete closure package will ensure timely processing of future study applications to Canadian Blood Services Research Ethics Program.

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| **4.a. Other supporting documents** |
| Publications (optional; see **3.a.**) | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Study results provided (see **3.b.**) | [ ]  Yes [ ]  No [ ]  Not Applicable |
| Other supporting documents | [ ]  Yes [ ]  No [ ]  Not Applicable |
| If **Yes** to other supporting documents, list the supporting document(s) |  |
| **4.b.** If **No** to any of **4.a.** provide details as to why documentation is not provided. |
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Section 5: Principal Investigator Signature

By typing my name and the date below, and submitting this closure package, I, the Principal Investigator on this study, declare that all of the information provided in the closure form and supporting documents is accurate and complete to the best of my knowledge.

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

**Instructions for submitting the completed closure package**

Submit the completed Closure Form as a word file (.docx) and all required supporting documents as separate files to CBSREB@blood.ca.

1. Guidance for Industry Good Clinical Practice: Consolidated Guideline ICH Topic E6. [↑](#endnote-ref-2)
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-3)