##### Annual Renewal Form for Research Ethics Program Approval

You are required to obtain approval for continuation of your study annually by submitting this Renewal Form to [CBSREB@blood.ca](mailto:CBSREB@blood.ca). Submission of this Form will ensure timely renewal of your study and prevent its termination by Canadian Blood Services.

Note: A Renewal Form must not be used for requesting an amendment. An Amendment Form must be submitted to request changes to the study. A Renewal Form and an Amendment Form can be submitted and reviewed in parallel.

Section 1: Study Information

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

Section 2: Renewal Information

|  |  |
| --- | --- |
| **2.a.** Renewal submission date (YYYY-MM-DD) |  |

|  |  |
| --- | --- |
| **2.b.** Does the study have REB approval from an institution that is not Canadian Blood Services? | Yes  No |
| If **Yes**, attach the renewal approval letter(s) from the institutional REB(s). | |
| If **No**, please explain why evidence of the renewal approval is not available and provide a timeline as to when you anticipate obtaining this approval. | |
|  | |

|  |  |
| --- | --- |
| **2.c.** Has Canadian Blood Services approval of the study lapsed? | Yes  No |
| If **Yes**, provide reasons for the lapse and identify steps taken or corrective actions. Confirm that you have suspended all study activities or provide justification should there be a need to continue for the safety and wellbeing of the research participants. Describe study activities from time of lapse to current date. | |
|  | |

|  |  |
| --- | --- |
| **2.d.** Has the study investigator or authorized persons (e.g. co-investigator, contact person) changed during this reporting period? | Yes  No |
| **2.e.** Did the study deviate from the application approved by Canadian Blood Services, including amendments approved during this reporting period? | Yes  No |
| **2.f.** 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 the new information did not necessitate an amendment to your study, provide an explanation. | |
|  | |
| **2.g.** If **Yes** to **2.d.**, **2.e.** and/or **2.f.**, provide the date the Amendment Form was submitted to Canadian Blood Services (YYYY-MM-DD). |  |
| If you have not yet submitted an Amendment Form, do so immediately by completing a form available at <https://www.blood.ca/en/research/products-and-services-researchers/research-ethics-program>. | |

|  |  |
| --- | --- |
| **2.h.** Have the study participants suffered any serious injuries 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>. | |

|  |  |
| --- | --- |
| **2.i.** 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>. | |

|  |  |
| --- | --- |
| **2.j.** 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: | |
|  | |

Section 3: Study Results to Date

|  |  |
| --- | --- |
| **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.* | |
|  | |

|  |  |
| --- | --- |
| **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 are being addressed in the study? What are the methodologies being used? Who have been invited to be study participants? What products or data have been used in the study (if applicable)? What has been learned so far from the study? What will likely 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. |
|  |

Section 4: Supporting Documents

Please ensure that all questions have been answered appropriately and indicate all supporting documents submitted with this renewal form below. Submission of an incomplete renewal package will lead to delays in Canadian Blood Services’ ability to review and renew your study.

|  |  |
| --- | --- |
| **4.a. Institutional REB documentation (see 2.b.)** | |
| Institutional REB Renewal Approval letter | Yes  No  Not Applicable |
| **4.b. 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) | Yes  No  Not Applicable |
| **4.f.** If **No** to **4.a.** and/or **4.b.,** provide details as to why documentation is not provided. | |
|  | |

Section 5: Principal Investigator Signature

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

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

**Instructions for submitting the completed renewal package**

Submit the completed Renewal 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)