##### Adverse Event Report

You are required to report adverse events occurring during the course of your study to Canadian Blood Services by submitting this Adverse Event Form to CBSREB@blood.ca.

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)

|  |
| --- |
| Section 1: Study Information |
| 1. Principal Investigator Name (First, Last):
2. Project title:
3. CBS REB protocol number:
 |
| Section 2: Description of adverse event |
| 1. Date:
2. Location:
 |
| 1. Describe adverse event, including who was involved:
 |
| 1. Describe action taken, including reports made to a Canadian Blood Services Medical Director, any treatment administered and dates of the reports:
 |
| 1. Describe actions recommended as a result of adverse events to date, for consideration by Canadian Blood Services, including recommended changes to the protocol, informed consent form or investigator’s brochure. (**Please submit an Amendment form**).
 |

|  |  |  |
| --- | --- | --- |
| 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)