##### Study/Protocol Deviation/Violation Report

You are required to report any Study/Protocol Deviations or Violations occurring during the course of your study to Canadian Blood Services and the Canadian Blood Services Research Ethics Board (REB) by submitting this Protocol Deviation/Violation Report to CBSREB@blood.ca.

Protocol Deviations and Violations are an unplanned or unforeseen change to an REB approved process, protocol, or document. Any substantive change to the study should not be implemented without documented approval by the REB, except when necessary to eliminate an immediate risk(s) to the participant(s)[[1]](#endnote-1). Deviations and Violations are different than Amendments in that they generally only occur once and/or involve only a subset of participants and are not intended at the time to permanently modify a process, protocol, or document.

Deviations are a less serious minor divergence that may not have significant consequences to the study or participants.

Violations are a serious non-compliance with significant consequences that can:

* materially reduce the quality or completeness of data;
* make the consent form inaccurate; and/or
* impact a participant’s safety, rights, or welfare.

Depending on the seriousness of a Protocol Violation, a temporary suspension may be issued.

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| Section 1: Study Information |

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| Principal Investigator Name | Click or tap here to enter text. |
| CBS REB # | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| Date of this Protocol Deviation Report | Click or tap to enter a date. |
| Date Protocol Deviation occurred | Click or tap to enter a date. |
| Date Study Team became aware of Protocol Deviation | Click or tap to enter a date. |

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| Section 2: Type of Deviation/ViolationCheck all that apply. |

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|[ ]  Change in study process to eliminate immediate hazard to research participant. |
|[ ]  Over-enrollment (exceeding the target number of participants approved by the REB). |
|[ ]  Deviation in the consent process (e.g., failure to obtain consent, use of an outdated consent form, missing information on consent form – name, signature, date). |
|[ ]  Deviation in the study procedure (e.g., participant did not meet eligibility criteria, randomized to wrong group). |
|[ ]  Use of a study document not approved by the REB (e.g., changes made to survey instrument) |
|[ ]  Non-compliance or non-adherence to study procedure by research participant (e.g., participant unable to complete portion of study, scheduled visit window missed) |
|[ ]  Other, please specify:  |

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| Section 3: Event Information |

Support documents may be attached but ensure they contain no identifiable information of participants.

**3.a.** Describe the Protocol Deviation/Violation and Reason

Provide a detailed description of the protocol deviation/violation, including an explanation for its occurrence.

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| Click or tap here to enter text. |

**3.b.** Corrective Actions

Provide a detailed description of how the event was handled, including any corrective actions that were taken by your team or others for this event.

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| Click or tap here to enter text. |

**3.c.** Future Actions to Prevent Reoccurrence

Provide a detailed plan to prevent reoccurrence.

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| Click or tap here to enter text. |

**3.d.** Participant’s outcome of the event

Explain the outcome for the participant(s).

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| Click or tap here to enter text. |

**3.d.** Was/were the research participant(s) informed of the event?

 [ ]  Yes [ ]  No

**3.e.** Have you or should you inform any other divisions or staff at Canadian Blood Services about this event?

 [ ]  Yes [ ]  No

If yes, list the other CBS divisions/staff that were informed about this event.

Please be aware that notifying other divisions/staff of this event is the responsibility of the PI.

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| Click or tap here to enter text. |

**3.f.** Have you informed any other stakeholder(s) about this event (e.g., institutional REB, sponsors, etc.)?

 [ ]  Yes [ ]  No

If yes, list the stakeholder(s) that were informed about this event.

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| Click or tap here to enter text. |

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| Section 4: Impact Assessment

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| Does the Protocol Deviation impact or affect the research participants’ rights, safety, or well-being? | [ ] Yes | [ ] No |
| Does the Protocol Deviation compromise the integrity of the study or study data? | [ ] Yes | [ ] No |
| Does the Protocol Deviation require a change(s) to the processes, study documents (e.g., consent form) and/or protocol? | [ ] Yes | [ ] No |
| If yes, I have also submitted the changes using the ‘Amendment Form’ including supporting documents as required. | [ ] Yes | [ ] No |
| Did this Protocol Deviation result in an Adverse Event (AE) or Incidental Finding? | [ ] Yes | [ ] No |
| If yes, I have also submitted the ‘Adverse Event Report’. | [ ] Yes | [ ] No |
| Other, please describe: | [ ] Yes | [ ] No |

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Section 5: Principal Investigator Declaration

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

[ ]  The appropriate support documents are included, if applicable.

[ ]  The appropriate additional forms have been submitted (e.g., Amendment Form), if applicable.

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

1. 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 2022. [↑](#endnote-ref-1)