

Research Ethics Board (REB)

**PROTOCOL DEVIATION REPORTING FORM**

**INSTRUCTIONS**

* This form is required for the submission of a protocol deviation. A protocol deviation is defined as an unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current approved research protocol, consent document, or study addenda
* Protocol deviations may or may not have a significant effect on research participants’ rights, safety, or welfare, or on the integrity of the study data. Deviations are different from amendments in that they generally apply to a single occurrence or participant and are not intended at the time to modify the entire protocol. Please note, the term ‘*protocol deviation’* and ‘*protocol violation*’ may be used interchangeably

**SUBMISSION PROCEDURE**

* Please submit three (3) paper copies and one (1) scanned or electronic copy of your completed application to the address below. Do not staple any sections of your submission; use paperclips to keep copies together.

RVH Research Ethics Board

Centre for Education & Research, Room 3357

Royal Victoria Regional Health Centre

201 Georgian Drive

Barrie, ON, L4M 6M2

Email: ethics@rvh.on.ca

Phone: 705-728-9090 Ext. 43318

**SECTION A: STUDY INFORMATION**

**RVH STUDY NUMBER: (Internal Use Only) only)**

|  |
| --- |
| Full Study Title: Click here.  |
| Abbreviated Study Title (max. 10 words): Click here. | Study Sponsor:Click here.  | Protocol # Click here. |
| Principal Investigator Name: Click here. | [ ]  Clinical Trial [ ]  Observational Trial[ ]  Chart Review [ ]  Other: Click here. |
| RVH REB Study #: Click here.  | Start Date: Click to enter a date. |
| Anticipated Local Enrollment: Click here.  | Anticipated End Date: Click to enter a date. |
| Name of Primary Contact: Click here.  | Primary Contact Email: Click here.  |

**SECTION B: TYPE OF REPORT**

1. Type of Protocol Deviation (select all that apply):

|  |  |
| --- | --- |
| [ ]  | Change in study procedure(s) initiated to eliminate immediate hazard(s) to research participants |
| [ ]  | Enrolment of a research participant who did not meet all protocol inclusion / exclusion criteria, whether agreed to or not by the study sponsor |
| [ ]  | Over-enrollment (i.e., exceeding the target number of participants approved by the RVH REB) |
| [ ]  | Deviation in the consent process (e.g., failure to obtain informed consent, use of an invalid consent form, missing date of consent, missing signature) |
| [ ]  | Performance of a study procedure not approved by the RVH REB |
| [ ]  | Failure to perform a required study procedure that, in the opinion of the Principal Investigator, may affect participant safety and/or data integrity  |
| [ ]  | Study procedure(s) performed outside the required timeframe that, in the opinion of the Principal Investigator, may affect participant safety and/or data integrity |
| [ ]  | Study drug/intervention error(s) (e.g., incorrect study drug/intervention, incorrect dosage of the study drug) |
| [ ]  | Breach of confidentiality, whereby a research participant’s personal health information (PHI) is revealed to a person without a need to know, or by data exposure (e.g., digital device security breach, documents containing PHI are left unsecured) |
| ☐ | Other (describe): Click here to enter text. |

**SECTION C: PARTICIPANT INFORMATION**

1. Study ID: Click here to enter text.
2. Age (years) at time of event: Click here to enter text.
3. Sex/Gender: Click here to enter text.
* If protocol deviation involves more than one participant, please complete a Protocol Deviation Reporting Form for each impacted participant

**SECTION C: EVENT INFORMATION**

1. Please provide a brief description of protocol deviation (max. 10 words): Click here to enter text.
2. Date of protocol deviation: Click or tap to enter a date.
3. Date study team became aware of protocol deviation: Click or tap to enter a date.
4. Date sponsor notified of protocol deviation: Click or tap to enter a date.
5. Date RVH REB notified of protocol deviation: Click or tap to enter a date.
6. Type of Report: [ ]  Initial\* [ ]  Follow-up\*† [ ]  Final†

\*If this is an initial or follow-up report, please ensure that the follow-up or final report is submitted in a timely manner

†If this is a follow-up or final report, please indicate the REB submission date(s) of any previous report(s):

1. Click or tap to enter a date.
2. Click or tap to enter a date.
3. Click or tap to enter a date.
4. Provide a detailed description of the specific protocol deviation, including an explanation for the reason of its occurrence:

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| --- |
| Click here to enter text.  |

1. Please provide a detailed description of how the event was handled including any corrective actions for this event:

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| --- |
| Click here to enter text.  |

1. Please provide a detailed plan to prevent future reoccurrences:

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| --- |
| Click here to enter text.  |

1. Was the research participant informed of the event? [ ]  Yes [ ]  No

If “No”, please explain why:

|  |
| --- |
| Click here to enter text.  |

1. Please describe the outcome of the event, if known:

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| --- |
| Click here to enter text.  |

1. Has the sponsor been notified of this protocol deviation? [ ]  Yes [ ]  No

If the Sponsor was not notified of the protocol deviation, please explain why

* Please note that all protocol deviations must also be reported to the study Sponsor.

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| Click here to enter text.  |

**SECTION D: IMPACT ASSESSMENT**

1. Does the protocol deviation impact the research participants’ rights, safety, or well-being? [ ]  Yes [ ]  No
2. Does the protocol deviation compromise the scientific integrity of the entire study? [ ]  Yes [ ]  No
3. Is the protocol deviation repetitive in nature? [ ]  Yes [ ]  No

If “Yes”, what actions can be taken to prevent future occurrences?

1. Does the protocol deviation require change(s) to the study protocol? [ ]  Yes [ ]  No

If “Yes”, please changes using the “Amendments, Notifications, Ongoing Communication Form” to the REB

1. Does the protocol deviation require change(s) to the informed consent form(s) [ ]  Yes [ ]  No

If “Yes”, please submit changes using the “Amendments, Notifications, Ongoing Communication Form” to the REB

1. Did the protocol deviation result in a Serious Adverse Event (SAE)/Unanticipated Problem? [ ]  Yes [ ]  No

If “Yes”, please submit a “Serious Adverse Event Reporting Form” to the REB

1. Additional Comments (to be completed by the Principal Investigator or Study Coordinator):

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| --- |
| Click here to enter text.  |

**SECTION E: PRINCIPAL INVESTIGATOR STATEMENT & SIGNATURE**

* I have reviewed the protocol deviation and confirm the accuracy of this report
* I warrant that this study will continue to be conducted in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2018), the Ontario Personal Health Information Protection Act, 2004, S.O. 2004, c. 3, Sched. A, and any other relevant laws, regulations, or guidelines.

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| Principal Investigator | Signature | Date |

*An RVH Sub-/Co-Investigator may sign in absence of PI if delegated by PI on the Task Delegation Log*