

**EXTERNAL SERIOUS ADVERSE EVENT (SAE)**

**REPORTING FORM**

**INSTRUCTIONS**

* This form is to be used for submission of external SAE reports (events that did not involve a RVH research participant), that meet the following criteria:
	+ Serious **AND**
	+ Unexpected **AND**
	+ Related (unlikely, possibly, probably, definitely)
* External Serious Adverse Events definition:
* An event is also reportable if an increase in frequency or severity makes it ‘unexpected’, placing the research participants or others at a greater risk of harm than was previously known or recognized
* Please submit **three (3) paper copies** and **one (1) scanned or electronic copy** of this form, along with accompanying sponsor line listing (if available), 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**

|  |  |  |
| --- | --- | --- |
| Full Study Title: |   | RVH REB #  |
| Short Title of Study: |   | Study Sponsor:  | Protocol #  |
| Principal Investigator name: |   | [ ]  Clinical Trial [ ]  Observational Trial[ ]  Chart Review [ ]  Other\_\_\_\_\_\_\_\_\_\_ |
| Name of Primary Contact: |   | Primary contact email/phone: |   |

**SECTION B: SAFETY REPORT SUMMARY**

1. Please attach a copy of each of the reportable external safety reports listed below:

Note: Please request a safety report analysis if the sponsor provides a line listing only.

|  |  |  |  |
| --- | --- | --- | --- |
| Manufacturer report # | Initial/ Follow Up | Type/ Name of Event | Recommended Action*(Protocol amendment, notify participants verbally, re-consent)* |
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1. Name of Person completing this form:

|  |  |  |
| --- | --- | --- |
| Title:       | First Name:       | Last Name:       |
| Dept/Div:       | Institution:       |
| Full Address:       | Room Number:       |
| Telephone:       | Extension:       | E-mail:       |

**SECTION C: INVESTIGATOR ATTESTATION AND SIGNATURES**

* I have read and reviewed all of the above listed external safety reports
* I understand that it is my responsibility to retain copies of these reports in the Investigator Study File as per Health Canada Regulations

Name of Principal Investigator Signature Date (DD-MMM-YYYY)

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