

**INTERNAL SERIOUS ADVERSE EVENT (SAE)**

**REPORTING FORM**

**INSTRUCTIONS**

* ALL internal SAEs (Events involving RVH patients), must be reported to the RVH REB for review and approval that the research remains scientifically and ethically sound.
* Please use a separate form for each event, and attach the sponsor SAE reporting form where applicable.
* Please submit **three (3) paper copies** and **one (1) scanned or electronic copy** of your completed forms and attachments 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: EVENT DETAILS**

1. Name or Medical Term for SAE:
2. Internal Participant/ Subject ID #:
3. Select the type of report: [ ]  Initial [ ]  Follow-up #
4. Date of SAE Report:       Onset Date of SAE:
5. SAE resolution Date:       or [ ] N/A- ongoing
6. Provide a narrative description of the event:
7. Name of Drug, device or intervention:
8. Is there a Data Safety Monitoring Board (DSMB)? [ ]  Yes [ ]  No
9. Patient Outcome:

 [ ]  Hospitalization [ ]  Medical Intervention [ ]  Recovered [ ]  Death

 [ ]  Other (specify):

1. Action taken with Investigational Product:

 [ ]  None [ ]  Dose Adjusted [ ]  Discontinued from Study [ ]  Other (specify):

1. Relationship to Study Intervention:[ ]  \*Related [ ]  Unrelated

**\*Note that any events found to be possibly or probably related will be considered related**

1. Does PI recommend changes to the:

Protocol: [ ]  Yes [ ]  No

Consent form: [ ]  Yes [ ]  No

Other:

**SECTION C: INVESTIGATOR ATTESTATION AND SIGNATURES**

* I attest that I have reviewed the SAE and its safety implications, and have assessed the relationship to the study intervention of the SAE.

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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*