

**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](mailto: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*