**LOCAL SERIOUS ADVERSE EVENT (SAE) REPORT - CHREB**

**Date of this report:** Click here to enter a date.

**Is this a(n):** [ ]  Initial report, OR

[ ]  Follow-Up report

**Ethics ID#** Click here to enter text.

**Complete Study Title:** Click here to enter text.

**Participant ID**: Click here to enter text.

**Participant initials**:

**Age**: Click here to enter text.

**Sex:** M [ ]  F [ ]

**Manufacturer's SAE # (if applicable)**:

**Date of SAE:** Click here to enter a date.

**Date PI was notified of SAE:** Click here to enter a date.

1. **Explain any time lapse in reporting to the CHREB from the date the PI was notified of the event.**

(>7 days for fatal or life-threatening SAEs; >15 days for all other local SAEs)

1. **Synopsis of SAE:**

*Provide a brief description of the SAE (reason for/cause of the event, symptoms, diagnosis, and concerning trend, if relevant).*

Click here to enter text.

*If you feel a longer narrative would assist, write in letter format (on appropriate letterhead) and upload with this form. Please DO NOT upload additional documents unless requested by the CHREB or Sponsor.*

1. **In the opinion of the PI, is the SAE related to the study drug, device or procedure?**

[ ]  Definitely related

[ ]  Probably related

[ ]  Possibly related

[ ]  Not related

[ ]  Unknown

If ‘not related’, please clarify why this SAE is being reported to the CHREB:

[ ]  Sponsor requirement

[ ]  Other, please explain:

1. **Was the SAE a natural progression of disease?** Yes [ ]  No [ ]

If yes, please clarify why this SAE is being reported to the CHREB:

[ ]  Sponsor requirement

[ ]  Other, please explain:

1. **Was the SAE an expected outcome from the study treatment?** Yes [ ]  No [ ]

If yes, please clarify why this SAE is being reported to the CHREB:

[ ]  Sponsor requirement

[ ]  Other, please explain:

1. **At the time of the SAE, the participant was:**

[ ]  Actively on Study

[ ]  On Follow-Up

[ ]  Off Study

1. **Outcome of SAE** (indicated all that apply)**:**

[ ]  Death [ ]  Disability

[ ]  Life Threatening [ ]  Congenital anomaly

[ ]  Hospitalization – initial or prolonged [ ]  Medically significant event

[ ]  Other, Please specify: Click here to enter text.

1. **Action taken as a result of the SAE** (indicate all that apply)**:**

[ ]  Hospitalization

[ ]  Study treatment altered (e.g. dose changed)

[ ]  Study treatment temporarily stopped

[ ]  Study treatment stopped (e.g. drug stopped)

[ ]  Other, Please explain: Click here to enter text.

**Additional Comments**: Click here to enter text.

1. **If noted above in “Action taken” that the study treatment was stopped, is the participant still being followed-up according to the study protocol?** Yes [ ]  No [ ]

**If no, please comment**: Click here to enter text.

1. **Due to the SAE, does the PI believe:**
	1. **That the study should be closed?** Yes [ ]  No [ ]
	2. **That the study procedures should be changed to mitigate risks?** Yes [ ]  No [ ]
	3. **That the risk information in the consent should be revised?** Yes [ ]  No [ ]
	4. **That the study participants should be advised about the SAE?** Yes [ ]  No [ ]

*\*NOTE: If ICF changes are required, please submit any changes as a modification. In the modification summary, please indicate that a corresponding local SAE report was submitted.*