**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.*