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

**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.

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

**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 CFREB from the date the PI was notified of the event.**

(Local SAEs should be reported within 7 calendar days of the PI becoming aware of the SAE)

1. **Synopsis of SAE:**

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

Click here to enter text.

1. **What, if any, actions have been taken as a result of the SAE :**

Click here to enter text.

1. **Due to the SAE, does the PI believe changes should be made to the study** Yes  No

**If YES, please explain, including outlining any proposed modifications to the study:**

Click here to enter text.