**HREBA – Community Health Committee**

**Serious Adverse Event (SAE) Report Form**

(Serious, Unexpected, Related, Affecting Conduct of Study, Adverse Events Only)

\*Complete this form and send it as an attachment to: [communityhealth@hreba.ca](mailto:communityhealth@hreba.ca)\*

**Principal Investigator:** Click here to enter text.

**HREBA – CHC Ethics ID #:** Click here to enter text.

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

**Current Status of Study:** Click here to enter text.

**If approved, CHC approval date:** Click here to enter text.

**SAE Description:**

**Provide a brief narrative description of the SAE (symptoms, diagnosis if relevant):**

Click here to enter text.

**Date of SAE:** Click here to enter text.

**Date PI notified of SAE:** Click here to enter text.

**SAE was:** Expected:  Unexpected:

**At the time of the SAE, participant was:** Active in study  In Follow-up  Off Study

**Outcome of SAE (check all that apply):**

Death

Life Threatening

Hospitalization – Initial or Prolonged

Disability

Congenital Anomaly

Other (specify)  Click here to enter text.

**In the opinion of the Principal Investigator, is this SAE related to the study drug, device or procedure?**

Definitely Related

Probably Related

Possibly Related

Not Related

Unknown

**Action(s) taken as a result of the SAE (check all that apply):**

Hospitalization

Study Treatment Altered

Study Treatment Temporarily Suspended

Study Treatment Stopped

Other (specify)  Click here to enter text.

**If study treatment was stopped, is the subject still being followed according to the study protocol?** Click here to enter text.

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

**In the opinion of the Principal Investigator, does the SAE warrant the following? (check all that apply:**

Closure of the study

Changes to the Study Procedure

Revisions to the Informed Consent Form (attach revised ICF)

Advising the subject verbally (attach suggested script)

**\*I have reviewed the clinical details pertaining to the SAE reported above:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Principal Investigator Date**

**Thank you for the SAE Report which will be added to your file. You will receive an acknowledgment of receipt and review from** [communityhealth@hreba.ca](mailto:communityhealth@hreba.ca). **You will be contacted if** **further information or acknowledgement is required.**