**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\*

**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. **You will be contacted if** **further information or acknowledgement is required.**