

PLEASE COMPLETE ALL SECTIONS.

This form is to be used to report LOCAL Serious Adverse Events to the REB 4: HREB - Biomedical Panel.

Report **only** those local SAE's which are:

- SERIOUS and
- an unanticipated problem (UNEXPECTED, considered to be RELATED or POSSIBLY RELATED to participation in the research and places participant or others at a greater risk of harm than was previously known or recognized).

Local SAE's that are fatal or life threatening are to be reported to the HREB within 7 days of their discovery by the study site; all other local SAEs which are unanticipated problems must be reported within 15 days of their discovery by the study site.

STUDY INFORMATION

Study Investigator

Study Title

Pro #

Investigational Product

Study Sponsor

OR Investigator Initiated

Enrolled Locally to Date

Enrolled Study-wide to Date

PARTICIPANT INFORMATION

Participant ID

Age

Male

Female

EVENT INFORMATION

Initial Report

Follow-up Report

Type of Event (Check all that apply)

Death

Disability

Other

Life Threatening

Congenital Deformity

Hospitalization - initial or prolonged

Medically important event

In the opinion of the Local Principal Investigator is this reaction or event related to the study drug, device or procedure?

Yes - Definitely Related

Yes - Probably or Possibly Related

Uncertain or Unknown (may need to be reported)

No - Not Related (if does not otherwise meet definition of *unanticipated problem* does not need to be reported)

In the opinion of the Local Principal Investigator, does the reaction or event warrant any of these actions?

Closure of the study

Changes to study procedures

Revisions to information/consent documentation

Action Taken - mark all that apply

Hospitalization - initial or prolonged

Study treatment altered (e.g. drug stopped or device removed)

Study treatment stopped (e.g. drug stopped or device removed)

Study blind broken

Other (describe in synopsis)

Outcome - mark all that apply

Complete resolution

Ongoing

Partial Recovery

Disability or impairment (Permanent)

Disability or impairment (May improve with time)

Death

Other

Synopsis - Provide an event name, dates and a description of the symptoms and the diagnosis, if relevant.
(Use the space provided, if necessary you can attach an additional Word document to your submission in REMO).