UNIVERSITY OF ALBERTA

RESEARCH ETHICS OFFICE

Local Serious Adverse Event Report

CLEAR FORM

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
☐ Life Threatening
☐ Hospitalization - initial or prolonged
☐ Disability
☐ Congenital Deformity
☐ Medically important event
☐ Other

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)

If Yes, Uncertain or Unknown, have you discussed this with the study participant?
Yes ◯ No ◯

- ☐ 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
- ☐ N/A

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 ARISE).