UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER

NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD

SERIOUS ADVERSE EVENT (SAE) REPORT

ON-SITE

The FDA defines a serious adverse event as any experience that suggests a significant hazard, contraindication, side effect or precaution. With respect to human clinical experience, a serious adverse drug or device event includes any experience that is fatal or life-threatening, is permanently disabling, requires or prolongs impatient hospitalization, results in a congenital anomaly/birth defect, pregnancy*, or may be classified as an important medical event (requiring medical or surgical intervention). This form must be completed and forwarded, along with supporting documentation, within 10 working days of the incident. Please use lay terminology when possible and avoid the use of abbreviations.

IRB Project #_____ Contact Person and Phone # (if different from P.I.)_____

Principal Investigator: _____

Department and Institution : _____

Project Title:

Sponsor Protocol #_____ Subject's Initials: _____ Sex M ☐ F ☐ Age: _____

Date and Time of Adverse Event _____ Date Study Staff Informed of Event_____

Nature of Problem: (If follow-up report, provide initial report information AND summarize the new information)

ATTACH A DETAILED DESCRIPTION OF THE ADVERSE EVENT, TREATMENT AND LONG-TERM PROGNOSIS.

Initial ☐ Follow-Up ☐ Will the subject remain in study? Yes ☐ No☐

Was the event associated with or the cause of any of the following?

☐ Death
☐ Life-Threatening Situation
☐ Hospitalization or Prolonged Hospitalization
☐ Severe or Permanent Disability
☐ Congenital Anomaly/Birth Defect
☐ Pregnancy *
☐ Other (Important Medical Event)

In the **Principal Investigator's** opinion, was the adverse event related to the protocol?

☐ Definitely Yes
☐ Probably Yes
☐ Possibly
☐ Probably No
☐ Definitely No
☐ Unknown

Pregnancy does NOT have to be reported if the subject is receiving follow-up only, and conception occurred outside of the time period that the study protocol requires contraception (e.g. contraception is required for 6 months after the last dose of the study drug)

In the case of an investigational drug or device, have you reported the event to the sponsor? ☐ **Yes** ☐ **No**

*If yes, **please attach a copy** of the information sent to the study sponsor.*

Has this type of adverse event been reported before? ☐ **Yes** ☐ **No**

Is this type of event likely to occur again? ☐ **Yes** ☐ **No** ☐ **Possibly** ☐ **Unknown**

Action to be taken as a result of this report: (**check all that apply**)

☐ None (*causality assessed as NOT related or follow-up report with NO change in causality or event terms*)
☐ Information on this type of event already contained in consent form
☐ First report of event assessed as related
☐ Will monitor for trends
☐ Consent Form to be revised (***Attach the revised consent form with changes highlighted and a "clean" copy***)
☐ Other (please specify): _____

The undersigned agrees that the submitted information is accurate and, to the best of their knowledge, complete:

_____ _____

Signature - Principal Investigator Date

Receipt and review of this serious adverse event report is acknowledged:

_____ _____

Signature - IRB Chair / Vice Chair / Designee Date