**UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER**

**NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD**

**SERIOUS ADVERSE EVENT (SAE) REPORT**

**NON- NORTH TEXAS REGIONAL IRB SITES (*OFF-SITE*)**

**Federal guidelines require timely reporting (<u>within 10 working days</u>) of serious adverse events. 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:

Protocol # _____

Date of Report from Sponsor: _____ Date Report Received from Sponsor: _____

**Check one:** Initial Report ☐ Follow-Up Report ☐ Follow-Up, however, Initial to this IRB ☐

If Follow-Up, Indicate Date of Initial Report _____

**ATTACH A COPY OF THE REPORT SENT BY THE SPONSOR**

Provide a brief, concise, description of the serious adverse event. If follow-up report, provide **initial** report information **<u>AND</u>** summarize the **new** information.

Was the event associated with or the cause of any of the following? (**check all that apply**)

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

**Study sponsor's** assessment of the event(s) to the study drug/device: (if **not** applicable, leave blank)

- ☐ Related
- ☐ Probably Related
- ☐ Possibly Related
- ☐ Unlikely Related
- ☐ Not Related

Reporting **investigator's** assessment of the event(s) to the study drug/device:

- ☐ Related
- ☐ Probably Related
- ☐ Possibly Related
- ☐ Unlikely Related
- ☐ Not Related
- ☐ Not Provided

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