

**UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER  
OFFICE for the PROTECTION of HUMAN SUBJECTS  
INSTITUTIONAL REVIEW BOARD**

**SERIOUS  
ADVERSE EVENT  
(SAE) REPORT**

**NON-UNTHSC  
SITES  
(OFF-SITE)**

Federal guidelines require timely reporting (within 10 working days) 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: \_\_\_\_\_

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 UNTHSC

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 known, indicate study drug dosage (unblinded or open-label). If follow-up report, provide **initial** report **AND** summarize the **new** information given.

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:

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

\_\_\_\_\_  
Signature - Principal Investigator      Date

\_\_\_\_\_  
Signature - IRB Chairman      Date