UNIVERSITY *of* NORTH TEXAS HEALTH SCIENCE CENTER """"""OFFICE *of* TGUGCTEJ 'EQORNKCPEG INSTITUTIONAL REVIEW BOARD	SERIOUS ADVERSE EVENT (SAE) REPORT	NON-UNTHSC 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: _____

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)

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

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

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

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

IRB Form 3b (revised 02/14)