

UNIVERSITY of NORTH TEXAS HEALTH SCIENCE CENTER
NORTH TEXAS REGIONAL INSTITUTIONAL REVIEW BOARD

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| SERIOUS ADVERSE EVENT (SAE) REPORT | NON- NORTH TEXAS REGIONAL IRB SITES (OFF-SITE) |
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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: _____

Department and Institution (UNTHSC or JPS): _____

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 **AND** 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:

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

Signature - Principal Investigator Date

Signature - IRB Chair / Vice Chair Date