**Serious Adverse Event Assessment Form**

***Only* for Non Investigator-Initiated Trials**

**IRB#** Click or tap here to enter text. **PI:** Click or tap here to enter text.

**TITLE:** Click or tap here to enter text.

***Only* for UNMC Investigator-Initiated Trials**

***For all IIT Trials: All Serious Adverse Events (SAEs), regardless of severity or relationship, require reporting to the DSMC via the PRMS Office with seven (7) days of the Study Staff’s knowledge.***

**IRB#** Choose an item. **PI:** Choose an item.

**TITLE:** Choose an item.

**Site:** Click or tap here to enter text.

**Site PI:** Click or tap here to enter text.

**Report date:** Click or tap to enter a date. **Reported by:** Click or tap here to enter text.

**All Serious Adverse Events (SAEs), regardless of severity or relationship, require reporting to the PRMS Office with seven (7) days of the Study Staff’s knowledge.**

Subject ID (DO NOT use MRN): Click or tap here to enter text. Site: Click or tap here to enter text.

Date of Event: Click or tap to enter a date.

Event Narrative:

Click or tap here to enter text.

**Adverse Event Details**

Course Start Date: Click or tap to enter a date.

Category: Click or tap here to enter text.

AE Detail: Click or tap here to enter text.

Grade/Severity: Choose an item.

Unexpected: Choose an item.

Action: Choose an item.

Therapy: Choose an item.

Additional Comments: Click or tap here to enter text.

**Source Attribution Last Dose/Treatment Date**

Investigational Tx Choose an item.

Study Drug Choose an item. Click or tap to enter a date.

Non-Investigational Tx Choose an item.

Disease Choose an item.

Other Choose an item.

Site PI or Consenting MD is required to assess, grade an attribute each SAE on this form.

Submit the completed form and all supporting documentation related to the event to the UNMC PRMS Office. If a separate SAE form is required for the FDA and/or Sponsor, please include it in the submission.

Click or tap here to enter text.

Site PI/Consenting Sub-I Printed Name

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap to enter a date.

Signature of Site PI/Consenting Sub-I Date

-------------------------------------------------------*UNMC Only*----------------------------------------------------------------------------

Click or tap here to enter text.

Name of UNMC Principal Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Click or tap to enter a date.

Signature of UNMC Principal Investigator Date

UNMC Clinical Research Support Administrative Reporting Review:

FDA: [ ] Yes [ ] No [ ] N/A UNMC IRB: [ ] Yes [ ] No [ ] N/A DSMC: [ ] Yes [ ] No [ ] N/A