**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: 560-18 Managing Fatigue Using Virtual Reality for Post-Operative Lung Cancer Patients: Understanding the Post-Surgical Non-Small Cell Lung Cancer Patient's Symptom**

**Report date:** Click or tap to enter a date.

**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. Date of Report: Click or tap to enter a date.

Description of Event:

Click or tap here to enter text.

1. Event: Click or tap here to enter text. Grade: Choose an item.
	1. Relationship:Choose an item.
	2. Expected (currently in ICF): [ ] Yes [ ] No
	3. Does the event require a change in the ICF? [ ] Yes [ ] No
	4. Serious: [ ]  Yes [ ]  No

Comments: Click or tap here to enter text.

1. Event: Click or tap here to enter text. Grade: Choose an item.
2. Relationship: Choose an item.
3. Expected (currently in ICF): [ ] Yes [ ] No
4. Does the event require a change in the ICF? [ ] Yes [ ] No
5. Serious: [ ]  Yes [ ]  No

Comments: Click or tap here to enter text.

1. Event: Click or tap here to enter text. Grade: Choose an item.
2. Relationship:Choose an item.
3. Expected (currently in ICF): [ ] Yes [ ] No
4. Does the event require a change in the ICF? [ ] Yes [ ] No
5. Serious: [ ]  Yes [ ]  No

Comments: Click or tap here to enter text.

1. Event: Click or tap here to enter text. Grade: Choose an item.
	1. Relationship:Choose an item.
	2. Expected (currently in ICF): [ ] Yes [ ] No
	3. Does the event require a change in the ICF? [ ] Yes [ ] No

Comments: Click or tap here to enter text.

In the case of more than four (4) SAEs, please contact the PRMS Office and you will be sent a copy of the form with the number of events you require.

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 MedWatch form was completed for these events, please include it in the submission.

 Click or tap here to enter text. Click or tap to enter a date.

Name of person completing report Date

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