FORM 9: ADVERSE EVENT

Participant ID: _____ - ___ ___ ___

Date: ___ ___ / ___ ___ / ___ ___ ___ ___
MM DD YYYY

1. Briefly describe the adverse event: _____

_____

2. What was the date of the adverse event? ___ ___ / ___ ___ / ___ ___ ___ ___
MM DD YYYY

3. Action taken regarding adverse event: _____

_____

4. Was this an expected adverse event or an unexpected adverse event?*

- ☐ Expected
- ☐ Unexpected

**If unsure, the research center PI will make the determination as to the nature of relatedness*

5. Relationship to research protocol:

- ☐ Not related
- ☐ Possibly related
- ☐ Probably related
- ☐ Definitely related

6. Was this a Serious Adverse Event?**

- ☐ Yes → Complete Serious Adverse Event Form (next page)
- ☐ No

***Serious Adverse Events (SAE) are defined to include any adverse experience resulting in the following:*

- *Persistent or significant disability or incapacity*
- *Hospitalization*
- *Life threatening situation*
- *Death*

Additional Notes: _____

_____

SERIOUS ADVERSE EVENT NOTIFICATION FORM (page 1 of 2)

Participant Number: ☐☐☐-☐☐☐

1. Did the subject experience a serious adverse event during the course of the study? ☐$_1$ Yes* ☐$_0$ No

** If Yes, complete remainder of this form*

2. Is this an initial report or a follow-up to an ongoing event? ☐$_1$ Initial ☐$_2$ Follow-up, #_____

3. Subject's age at time of event: ☐☐

4. Event occurrence: Date: ☐☐/☐☐/☐☐☐☐ Location_____

EVENT DETAILS

5.Describe Event:

6. Actions Taken:

7. Is the event: ☐$_1$ Unexpected ☐$_0$ Expected

8. Relationship to research protocol:

☐$_0$ Not related
☐$_1$ Possibly related
☐$_2$ Probably related
☐$_3$ Definitely related

9. Seriousness of the event:

☐$_1$ Death
☐$_2$ Resulted in a life-threatening illness or injury
☐$_3$ Resulted in a permanent impairment of a body structure or body function
☐$_4$ Resulted in a hospitalization or prolongation of an existing hospitalization
☐$_5$ Required medical or surgical intervention to prevent permanent impairment or damage
☐$_6$ Congenital anomaly or birth defect in offspring of the subject

10. Did the event result in a hospitalization? ☐$_1$ Yes ☐$_0$ No

If Yes, provide number of in-patient days: ☐☐☐

11. Outcome: ☐$_1$ Ongoing

If this is a follow-up report, specify: ☐$_1$ Improved ☐$_0$Unchanged ☐$_2$Worsened

☐$_2$ Resolved

☐$_3$ Resolved with sequelae

☐$_4$ Death

12. Date of outcome: ☐☐/☐☐/☐☐☐☐

M M D D Y Y Y Y

INVESTIGATOR SIGNATURE

Principal Investigator Name (print) _____

Principal Investigator Signature: _____

Date: ☐☐/☐☐/☐☐☐☐

M M D D Y Y Y Y