Form 9 Adverse Event

Participant ID (participantid)

_____

Date Form Completed: (ae_fdate)

_____
(mm-dd-yyyy)

1. Briefly describe the adverse event: (ae_desc)

_____

2. What was the date of the adverse event? (ae_date)

_____
(mm-dd-yyyy)

3. Action taken regarding adverse event: (ae_action)

4. Was this an expected adverse event or an unexpected adverse event? (ae_ue)

◯ Expected (1)
◯ Unexpected (0)

5. Relationship to research protocol: (ae_rel)

◯ Not related (0)
◯ Possibly related (1)
◯ Probably related (2)
◯ Definitely related (3)

6. Was this a Serious Adverse Event? (ae_sae)

◯ Yes --> Complete Serious Adverse Event Form (1)
◯ No (2)

Additional notes (ae_notes)

_____

Study Personnel Initials (ae_init)

_____

Date data entered (ae_edate)

_____
(mm-dd-yyyy)

Serious Adverse Event (A-7)

1. Did the subject experience a serious adverse event during the course of the study? (sae_study)

◯ Yes (1)
◯ No (0)

2. Is this an initial report or a follow-up to an ongoing event? (sae_init)

◯ Intial (1)
◯ Follow-up (2)

Follow-up #: (sae_fu)

_____

3. Subject's age at time of event (sae_age)

_____
(age)

4. Event occurrence: (sae_date)

_____
(mm-dd-yyyy)

Location: (sae_loc)

_____

5. Describe Event: (sae_desc)

_____

6. Actions Taken: (sae_act)

_____

7. Is this event: (sae_ue)

◯ Expected (1)
◯ Unexpected (0)

8. Relationship to research protocol: (sae_rel)

◯ Not related (0)
◯ Possibly related (1)
◯ Probably related (2)
◯ Definitely related (3)

9. Seriousness of the event: (sae_ser)

◯ Death (1)
◯ Resulted in a life-threatening illness or injury (2)
◯ Resulted in a permanent impairment of a body structure or body function (3)
◯ Resulted in a hospitalization or prolongation of an existing hospitalization (4)
◯ Required medical or surgical intervention to prevent permanent impairment or damage (5)
◯ Congenital anomaly or birth defect in offpsring of the subject (6)

10. Did the event result in hospitalization? (sae_hosp)

◯ Yes (1)
◯ No (0)

Number of in-patient days: (sae_ip)

_____

11. Outcome: (sae_out)	◯ Onging (1) ◯ Resolved (2) ◯ Resolved with sequelae (3) ◯ Death (4)
If this is a follow-up report, specify: (sae_on)	◯ Improved (1) ◯ Unchanged (0) ◯ Worsened (2)
12. Date of outcome (sae_odate)	_____ (mm-dd-yyyy)