

FORM 8: SERIOUS ADVERSE EVENT FORM

PATIENT ID#: _____

PATIENT INITIALS: _____

Center: _____

Form completed by: _____

Date assessment completed: ____/____/____

1. Type of event (check all that apply):

- _____ 1) Death
- _____ 2) Life-threatening
- _____ 3) Hospitalization
- _____ 4) Disability
- _____ 5) Required intervention to prevent permanent impairment/damage
- _____ 6) Other _____

2. Date of Onset: ____/____/____

3. Description of adverse event

-symptoms, course, duration, treatment and sequelae

4. Severity: _____

- 1 = Mild
- 2 = Moderate
- 3 = Severe

5. Study drug related: _____

- 1 = Definitely
- 2 = Probably
- 3 = Possibly
- 4 = Remotely
- 5 = Definitely not

6. Concomitant drug related: _____

- 1 = Definitely
- 2 = Probably
- 3 = Possibly
- 4 = Remotely
- 5 = Definitely not

7. Action Taken: _____

- 1 = None
- 2 = Remedial Therapy-Pharmacologic
- 3 = Remedial Therapy-Non-Pharmacologic
- 4 = Hospitalization (New or Prolonged)

8. Study Drug Action: _____

- 1 = None
- 2 = Discontinued Permanently
- 3 = Discontinued Temporarily
- 4 = Reduced Dose
- 5 = Increased Dose
- 6 = Delayed Dose

9. Outcome: _____

- 1 = Resolved; no sequelae
- 2 = Not Resolved
- 3 = Resulted in sequelae
- 4 = Unknown
- 5 = Death* (complete below)

10. *Date of Death: ____/____/____

11. *Autopsy performed: Yes No

12. *Probable cause of death _____

13. Relevant tests/laboratory data:

14. Describe relevant medical history:

Investigator's signature: _____

Date signed : ___ / ___ / ___