Standard Serious Adverse Event Form

Serious Adverse Event Report Tel: 3505-1574 Fax: 2646-6653	Protocol code (CRE#)	Reported to HA AIRS? ☐ Yes ☐ No	Type of report ☐ Initial ☐ Follow-up (case not completed) ☐ Follow-up (case completed)	Date of this report day / month / year

Patient Identification

Patient No.	Patient Initials			Date of birth			Sex	Date of enrolment		
	first	mid	last	day	month	year	☐ Male ☐ Female	day	month	year

Serious Adverse Event

SAE Start event			SAE stop date		
day	month	year	day	month	year

Description of SAE (use extra paper if necessary; enclose a discharge summary if any)

1. Diagnosis/syndrome:_____
2. Narrative description of SAE

Tick all appropriate to serious adverse event

☐ patient died, date of death: day month year

Autopsy:
- ☐ Yes
- ☐ Planned
- ☐ No

☐ life threatening
☐ required inpatient hospitalization or prolongation of existing hospitalization
☐ persistent or significant disability/incapacity
☐ congenital anomaly/birth defect
☐ other (specify):_____

Outcome of Event to Date

- ☐ complete recovery
- ☐ recovery with sequelae
- ☐ present at time of this report
- ☐ unknown
- ☐ died

If the patient died, cause of death _____

Causal relationship between death and study drug/treatment:
- ☐ associated
- ☐ possible associated
- ☐ not associated --give alternative explanation: _____

Study Drug/treatment Information

Study drug/treatment	Dose, frequency & route used (if applicable)	Indication	Therapy dates [day/month/year] from	Therapy dates [day/month/year] to

Causal relationship between study drug/treatment and event
- ☐ definite associated
- ☐ probable associated
- ☐ possible associated
- ☐ unlikely associated
- ☐ not associated -give alternative explanation:
- ☐ unknown

Action taken with study drug / treatment as a result of the SAE
- ☐ None
- ☐ Dosage adjusted
- ☐ Temporarily interrupted
- ☐ Permanently discontinued

Withdrawn from study as a result of the SAE
- ☐ Yes
- ☐ No

Concomitant Drug/treatment and Relevant Medical History

Relevant medical history [e.g. previous diagnoses, surgery, allergies, pregnancy with date of last period (day/month/year); use extra paper if necessary]

Concomitant drug/treatment (exclude those used to treat the SAE, use extra paper if necessary)

Drug/treatment	Dose, frequency & route used (if applicable)	Indication	Therapy dates [day/month/year] from	Therapy dates [day/month/year] to	Causal relationship to event
					☐ associated ☐ possible associated ☐ not associated
					☐ associated ☐ possible associated ☐ not associated
					☐ associated ☐ possible associated ☐ not associated

Investigator

Name: _____ Signature:_____ Tel: _____ Fax: _____