

## Serious Adverse Event Common Element Form

<b>Serious Adverse Event Report</b> Tel: 3505-1574 Fax: 2646-6653	Reported to HA AIRS? <input type="checkbox"/> Yes <input type="checkbox"/> No	Type of report <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up (case not completed) <input type="checkbox"/> Follow-up (case completed)				
	Protocol Code (CRE#)	Date of this report				
	Patient No.	day	month	year		
Tick all appropriate to serious adverse event  <input type="checkbox"/> patient died <input type="checkbox"/> life threatening <input type="checkbox"/> required inpatient hospitalization or prolongation of existing hospitalization <input type="checkbox"/> persistent or significant disability/incapacity <input type="checkbox"/> congenital anomaly/birth defect <input type="checkbox"/> other (specify): _____	SAE start date		SAE stop date			
	day	month	year	day	month	year
	Causal relationship between study drug/treatment and event <input type="checkbox"/> definite associated <input type="checkbox"/> probable associated <input type="checkbox"/> possible associated <input type="checkbox"/> unlikely associated <input type="checkbox"/> not associated <input type="checkbox"/> unknown					
Description of SAE (use extra paper if necessary; enclose a discharge summary if any)  Diagnosis/syndrome: _____						
<b>Investigator</b> Name: _____ Signature: _____ Tel: _____ Fax: _____						