FORM 07: ADVERSE EVENT FORM

											PAGE OF
PATIENT ID#:								Center: _			
PATIENT INITIALS:					Form completed by:						
								Date asse	essment comple	eted:	_/ /
C SEVERITY: 1 = Mild 2 = Moderate 3 = Severe *4 = Life Threatening	D Serious: *1= Yes 2= No	erious: STUDY DRUG RELATED: 1 = Yes		F ACTION TAKEN REGARDING STUDY DRUG: 1= None 2= Discontinued Permanently 3= Discontinued Temporarily 4= Reduced Dose 5= Increased Dose 6= Delayed Dose			G OTHER ACTION(S) TAKEN: (Code up to 3 actions) 1 = None † 2 = Remedial Therapy-Pharmacologic 3 = Remedial Therapy- Non-Pharmacologic *4 = Hospitalization (New or Prolonged)		H OUTCOME: 1 = Resolved; no sequelae 2 = AE still present - No Treatment 3 = AE still present - Being Treated *4 = Residual Effect(s) Present - No Treatment *5 = Residual Effect(s) Present - Being Treated *6 = Death 7 = Change in Severity 9 = Unknown		
If NO Adverse Events Occurred Check Here:											
A Adverse Event Description (One per line. List syndrome components separately)	Onset Chan	te and Time of / ge in Severity** 4 hour clock)	C Severity	D Serious	E Study Drug	F Action Taken	G Other Action(s)	H Outcome	I. Date and Tin Resolution / Ch Severity** (Use 24 hour clo	ange in	J Description of Action / Comments
1.		<i>!!</i>	_	_					!!		
2.		.:		_				_	!!		
3. Complete Concomitant I	Madication E	:	—	_		_		_	!!_		

Investigator's signature:	Date signed ://
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07_adevent.wpd 01/13/99

^{**} Estimate time to the best of your ability (e.g., if the subject awoke with a headache, enter the time the subject awoke.) If time is unknown, enter 55:55