

Date assessment completed: ____/____/____

C SEVERITY:	D Serious:	E STUDY DRUG RELATED:	F ACTION TAKEN REGARDING STUDY DRUG:	G OTHER ACTION(S) TAKEN: (Code up to 3 actions)	H OUTCOME:
1 = Mild 2 = Moderate 3 = Severe *4 = Life Threatening	*1 = Yes 2 = No	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 9 = Unknown	1 = None 2 = Discontinued Permanently 3 = Discontinued Temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None † 2 = Remedial Therapy-Pharmacologic 3 = Remedial Therapy- Non-Pharmacologic *4 = Hospitalization (New or Prolonged)	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: ☐

[illegible]

† Complete Concomitant Medication Form

** 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**

Investigator's signature: _____

Date signed : / /