ICCTG PROTOCOL #1

Adverse Events and Serious Adverse Events

Patient ID: __ __ __ __ __ __ __
Patient Initials: __ __ __
Clinical Center: __
Contact Week: __ __
Date: __ __ / __ __ / __ __
month day year
RC ID: __ __ __ __

This form is to record any adverse events and serious adverse events during the study, regardless of the relationship to the study drug.

Adverse Event(s) and Date of Onset: (Specify Event - One per line)		Duration: 1=Hours 2=Days 3=Minutes 8=Unknown	Frequency: 1=Once 2=2 or 3 Episodes 3=Several Episodes 4=Daily 9=Not Applicable	Grade: 0=None 1=Mild 2=Moderate 3=Severe 4=Life Threatening 5=Fatal 9=Not Applicable	Relationship to Study Drug: 1=Related 2=Possibly 3=Not Related 4=Undetermined	Treatment for Adverse Event? 0=No 1=Yes	Did Reaction Abate After Stopping Drug? 0=No 1=Yes 9=Not Applicable	Did Reaction Reappear After Stopping Drug? 0=No 1=Yes 9=Not Applicable	Outcome: 1=Recovered 2=No follow-up 3=On-going/Follow-up needed *4=Death *5=Life-threatening *6=Resulted in or prolonged inpatient hospitalization *7=Do not use *8=Resulted in persistent or significant disability/incapacity *9=Congenital anomaly/ birth defect *10=Requires intervention to prevent permanent impairment or damage	Was the Event Serious? (See Asterisks in "Outcome" column) 0=No 1=Yes If **YES,** see MOP for reporting procedures.
Adverse Event Number	Date of Onset m / d / y	Record only one	Record only one	Record only one	Record only one	Record only one	Record only one	Record only one	Record most appropriate	Record only one
AE _ _ _										
Event Code: _ _ _ _ _ _	Specify Event::			Description of Event / Comment:						
AE _ _ _										
Event Code: _ _ _ _ _ _	Specify Event::			Description of Event / Comment:						
AE _ _ _										
Event Code: _ _ _ _ _ _	Specify Event::			Description of Event / Comment:						
AE _ _ _										
Event Code: _ _ _ _ _ _	Specify Event::			Description of Event / Comment:						
AE _ _ _										
Event Code: _ _ _ _ _ _	Specify Event::			Description of Event / Comment:						

* Serious Adverse Event (requires P.I. signature)

P.I. Signature: ____________________________

Date: __ __ / __ __ / __ __
month day year

*Did the P.I. sign this form? ❐$_1$ Yes ❐$_0$ No