

Investigational Title: \_\_\_\_\_ COMIRB # \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Participant ID: \_\_\_\_\_

**ADVERSE EVENT and  
 INTERCURRENT ILLNESS LOG**

Seriousness Criteria	Action Taken	Outcome
1. Life Threatening 2. Hospitalization 3. Congenital Anomaly/Birth Defect 4. Persistent or Significant Disability or Incapacity 5. Other Medically Important Event 6. Death	1. None 2. Concomitant medication (add to ConMeds) 3. Procedure 4. Subject discontinued 5. Other, specify	1. Ongoing 2. Recovered 3. Recovered with sequelae 4. Death 5. Not Recovered 6. Unknown

AE # (1, 2, 3...)	Adverse Event /Intercurrent Illness (enter diagnosis)	Start Date (dd/mmm/yyyy)	Stop Date (dd/mmm/yyyy)	Serious <input type="radio"/> Yes <input type="radio"/> No	Seriousness Criteria	Severity <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Death	Relationship to Study Drug/Device <input type="radio"/> Not Related <input type="radio"/> Possible <input type="radio"/> Probable <input type="radio"/> Definite	Action Taken (list all that apply)	Outcome	PI Initials & Date
				<input type="radio"/> Yes <input type="radio"/> No		<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Death	<input type="radio"/> Not Related <input type="radio"/> Possible <input type="radio"/> Probable <input type="radio"/> Definite			
				<input type="radio"/> Yes <input type="radio"/> No		<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Death	<input type="radio"/> Not Related <input type="radio"/> Possible <input type="radio"/> Probable <input type="radio"/> Definite			
				<input type="radio"/> Yes <input type="radio"/> No		<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Death	<input type="radio"/> Not Related <input type="radio"/> Possible <input type="radio"/> Probable <input type="radio"/> Definite			
				<input type="radio"/> Yes <input type="radio"/> No		<input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe <input type="radio"/> Life Threatening <input type="radio"/> Death	<input type="radio"/> Not Related <input type="radio"/> Possible <input type="radio"/> Probable <input type="radio"/> Definite			

To be signed by Principal Investigator at End-of-Study or once all events have stabilized/resolved.

Principal Investigator Signature: \_\_\_\_\_ Date: \_\_\_\_\_