Icahn School of Medicine at Mount Sinai

Conduits
The Institutes for Translational Sciences

Adverse Event Log

Protocol: ____

Subject # ______________ **Subject Initials** _____________ **GCO#**__________ **PI:** ____

Please check if the patient *did not* experience any adverse events: ☐

Adverse Event Term (Diagnosis if known or sign/symptom) (One diagnosis/sign/ symptom per row)	**Serious Adverse Event** 1=Yes* 2=No	**Date of Onset** dd/mm/yyyy	**Outcome** **1**=Ongoing **2**=Recovery, no Sequelae **3**=Recovery, with Sequelae **4**=Not resolved, but f/u not necessary per PI **5**=Subject died **6**=Unknown	**Date AE Ended** dd/mm/yyyy	**Duration** [If < 24hrs provide: minutes hours]	**Intensity** **1**=Mild **2**=Moderate **3**=Severe	**Action Taken re: Study Medication** **0**=No change **1**=Dose increased **2**=Dose decreased **3**=Discontinued & reintroduced **4**=Permanently discontinued	**Other Action Taken Due to AE** **0**=None **1**=Concomitant Medication/ Treatment** **2**=Discontinued from study	**Causality** Is there a reasonable possibility that the study medication caused the event? **0**=No **1**=Unlikely **2**=Possibly **3**=Probably **4**=Definitely
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Form version date: 7/2/13

* IND holder must Complete MedWatch Form (FDA 3500a)
** Complete Concomitant Medications Log