Sample Outside Safety Report Log

IRB#: _____

OSR/INDSR#:	Adverse Event (include NCI toxicity grading if applicable)	Start/Stop Dates	Frequency 1=Once 2=Intermittent 3=Continuous	Severity 1=Mild 2=Moderate 3=Severe 4=Life threatening 5=Death	Treatment 0=None 1=Medicated 2=Non-medicated 3=Both 1&2 4=Hospitalized	Effects on Dosing 0=N/A 1=Drug withheld 2=Discontinued 3=Dose adjusted	Related to the study 0=Unrelated 1=Unknown 2=Related 3=Possibly related	Unanticipated Event 0=No 1=Yes	Serious* (FDA definition) 0=No 1=Yes	Serious** (VU IRB definition) 0=No 1= Yes
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***** Serious (FDA) = death, life-threatening AE, hospitalization, a significant disability/incapacity, or an AE (based on medical judgment) prevented by medical or surgical intervention

** Serious (VU IRB) = the event implies an adverse alteration in the risk-potential benefit profile of the research

SAMPLE