## **Adverse Event Reporting Form**

Investigator:	Pho	ne #		
	(Print Name)			
Protocol Title :				
Date of Adverse Event : Time of Event :				
Location of the Adver	rse Event :			
Concomitant Med	ications			
Length of time on	study medication			
Is the event being rep	oorted (check all that apply):			
Unexpected	- the specificity or severity of the adverse event is not consist investigator's brochure or with the other current risk information		ırrent	
Related (Or) Possibly Related	drug or intervention OR it is possible that the adverse eve	re is a reasonable possibility the adverse event may have been caused by the g or intervention OR it is possible that the adverse event may have been caused g intervention but there is insufficient information to determine the kelihood of this possibility.		
☐ Serious	- (1) results in death, or (2) is life-threatening, or (3) require continuance of existing hospitalization, or (4) results in persistent disability or incapacity, or (5) is an overdose, or (6) any medical erequires treatment to prevent one of the medical outcomes listed	pacity, or (5) is an overdose, or (6) any medical event which		
Not Serious	- Does not meet the criteria for classification as serious.			
Describe the adverse	event :			
Medical treatment pr	rovided to subject :			
Subject's prognosis :				
Is the risk of the adverse event contained in the current consent form?		☐ Yes	□ No	
Should the consent for of this event?	orm or any portion of the study be revised as a result	☐ Yes	□ No	
If Yes, provide a revised consent form with all revisions highlighted.		☐ Yes	□ No	
Will currently enrolled individuals be notified of this event?		☐ Yes	□ No	
	he method of notification			
•	ith all applicable reporting requirements (i.e., FDA, OHRP, etc)?			
If No, explain wh	ny:			
Investigator's Signature			Date	