Adverse Event Form

Complete and submit to <u>researchreview@ucmo.edu</u> and in the subject line put *Attn: Research Compliance Officer.*

Protocol Title:			
Protocol #:			
PI Name:			

Severity	Study Intervention Relationship	Action Taken Regarding Study Intervention	Outcome of AE	Expected	Serious Adverse Event (SAE)
1 = Mild	0 = Not related	0 = None	1 = Resolved	1 = Yes	1 = Yes
2 = Moderate 3 = Severe	1 = Unlikely related 2 = Possible related	1 = Study modification	2 = Improve with modification3 = Improve with intervention	2 = No	2 = No
4 = Life- Threatening	3 = Probably related 4 = Definitely related	 2 = Intervention 3 = Hospitalization 4 = Intervention discontinued 5 = Other 	 4 = Ongoing/Continuing intervention 5 = Condition worsening 6 = Death 7 = Unknown 		(if yes, complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Relationship	Action Taken	Outcome of AE	Expected	SAE