

CRF – Protocol Deviation		
No	Question	Response
001	Enter today's date	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
002	Date that site became aware of deviation:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
003	Date that deviation occurred:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
004	Type of deviation:	0 = Enrollment of an ineligible participant 1 = Breach of participant confidentiality 2= Informed consent deviations 3 = Unreported or significant delay in reporting serious adverse events (SAEs) and/or Social Harms (SHs) 4 = Conduct of non-protocol procedure 5 = Study procedure deviation (i.e., missed or incomplete study procedure) 6 = Use of non-approved IRB/IEC materials 7 = Visit completed outside of window 8 = other
005	Please describe the deviation:	

006	Plans or action taken to address the deviation:	
007	Plans or action taken to prevent future occurrences of the deviation:	
008	CRF Notes	