

CRF – Social Harm		
No	Question	Response
001	Enter today's date:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
002	Date of event was initially brought to team's awareness:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
003	Description of event: <i>Event details, cause, including relation to study participation and what happened since the event</i>	
004	Type of social harm:	<b>Select all that apply</b>  0 = Partner relationship 1 = Family relationship 2 = Education 3 = Employment 4 = Housing 5 = Medical/Dental 6 = Friend/Community relationship 7 = Travel/Immigration 8 = Other   <b>Specify in 005</b>
005	Specify other type of social harm:	<b>Respond only if [004 = 8]</b>
006	Event start date:	_ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y

007	Did the event involve physical harm?	0 = No 1 = Yes 2 = Not known
008	Event's impact on quality of life:	0 = Minimal 1 = Moderate 2 = Major 3 = Not known
009	Is event ongoing?	0 = No 1 = Yes
010	Event end date:	<b>Respond only if [009=0]</b>  _ _ / _ _ / _ _ _ _ D D / M M / Y Y Y Y
011	Event outcome:	0 = Unresolved 1 = Resolved
012	Is follow-up from study staff needed?	0 = No further action needed 1 = Yes, continue to follow-up
013	Actions taken to address social harm:	
014	Is this social harm reportable as a Social Adverse Event (SAE)?	0 = No 1 = Yes   <b>Document in Medical Events and Conditions CRF</b>

015	CRF Notes	
-----	-----------	--