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: *Event details, cause, including relation to study participation and what happened since the event*	
004	Type of social harm:	Select all that apply 0 = Education 1 = Employment 2 = Housing 3 = Medical/Dental 4 = Partner relationship 5 = Family relationship 6 = Friend/Community relationship 7 = Travel/Immigration 8 = Other | Specify in 005
005	Specify other type of social harm:	Respond only if [004 = 8]
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:	Respond only if [009=0] _ _ / _ _ / _ _ _ _ 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 | Document in Medical Events and Conditions CRF

015	CRF Notes	

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