

MTN-041 PTID

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SH#

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Date Form Completed

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Social Harms Report (SH)

Instructions: This form is to be completed for any MTN-041 participant who reports a social harm. Interviewer completes form based on report from the participant.

1.	Describe the social harm event:	<p>_____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> Participant declined to describe</p>												
2.	Date of social harm onset:	<table border="1" style="display: inline-table; vertical-align: middle;"> <tr> <td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>dd</td><td>MMM</td><td>yy</td><td></td><td></td><td></td> </tr> </table>							dd	MMM	yy			
dd	MMM	yy												
3.	What type of social harm is this event? (mark all that apply)	<input type="checkbox"/> 1 Physical <input type="checkbox"/> 2 Emotional/Psychological <input type="checkbox"/> 3 Financial <input type="checkbox"/> 4 Other, specify: _____												
4.	Did this event include unwanted disclosure of study participation? (choose one)	<input type="checkbox"/> 1 Yes, specify to whom (record relationship): _____ <input type="checkbox"/> 2 No <input type="checkbox"/> 3 Unknown/information not provided <input type="checkbox"/> 4 Other, specify: _____												
5.	What impact did this situation have on the participant's quality of life? (choose one)	<input type="checkbox"/> 1 No disturbance. <input type="checkbox"/> 2 A minimal disturbance that had no significant impact. <input type="checkbox"/> 3 A moderately upsetting disturbance, but did not have a significant impact. <input type="checkbox"/> 4 A major disturbance that had a significant impact. <input type="checkbox"/> 5 Other (specify) _____ <input type="checkbox"/> 6 Unknown/Declined to provide information												
6.	Other participant comments or remarks:	<p>_____</p> <p>_____</p> <p>_____</p> <p><input type="checkbox"/> 1 None</p>												
7.	What action was taken or recommendations/suggestions were provided to the participant to help resolve or cope with this situation?	<p>_____</p> <p>_____</p> <p>_____</p>												
8.	Referrals made (mark all that apply):	<input type="checkbox"/> 1 Counselor on site <input type="checkbox"/> 2 Other, specify: _____ <input type="checkbox"/> 3 No referrals needed												
7.	Based on your discussion with the participant, do you think this situation is resolved or being sufficiently addressed?	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No <input type="checkbox"/> 3 Other, specify: _____												

Comments:

Social Harms Form (SH) Instructions

Purpose: This form is used to record social harms reported by participants during their MTN-041 participation.

General Information/Instructions: This form should only be completed if a social harm is reported; therefore this form is not required for every participant, or at any specific visit.

Overall Instructions: Enter the PTID in the top left corner of this form and initial and date the bottom right corner of the page. The date the form is completed (not the date of the social harm) should be completed at the top of the form, as well as the social harm number. The SH number should be assigned sequentially for each individual PTID. All items are to be recorded by the Interviewer based on participant description or report and the action(s) taken. Any information recorded or modified on this form after the original date of completion should be initialed and dated, per GCP.

Item-specific Instructions:

Item	Instruction
1	Describe the social harm event in as much detail as possible, including duration, outcome (if applicable), location, individuals involved, action taken, treatment or care sought, etc. If the participant refuses to describe the social harm, check “participant declined to describe” and contact the MTN-041 Management Team (mtn041mgmt@mtnstopshiv.org) as soon as possible to discuss how to complete the rest of this form.
2	Record the date of onset of the social harm.
3	The interviewer should assess what type of social harm the described event is: physical, emotional/psychological, financial and/or other. An event may have implications on all of the above, if so, check all that apply.
4	Record if the social harm was a result of, or resulted in, unwanted disclosure of MTN-041 study participation to another person or group of people and specify who learned of MTN-041 study participation. Record relationships (i.e. MOTHER, HUSBAND), not names.
5	Record how the participant perceives this social harm (and related disclosure about study participation, if applicable) event to have impacted his or her quality of life.
6	Add any other comments about the event that the participant disclosed and that are not already recorded. If there are no further comments mark “NONE”.
7	Record the actions, recommendations, or suggestions provided to the participant to resolve the social harm.
8	Record all referrals made in response to the social harm.
9	This item is to reflect the participant’s (not the interviewer’s) impression of whether the social harm event has been resolved. Ensure date of SH resolution is recorded in item 1 or comments, if known.
Comments	Interviewer should write any other information about the social harm in this section that is not already captured on the form. All comments added after the date the form is initially completed should be initialed and dated per GCP. For instance, follow-up information about the SH obtained at a later date should be recorded in this section and initialed/dated.