

MTN-045 (CUPID): Social Harms Report

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PTID

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Staff initials

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Date of report (dd/mmm/yyyy)

Social Harms Report (SH)

Instructions: This form is to be completed for any MTN-045 participant who reports a potential social harm event. Staff member completes form based on report from the participant.

1.	Describe the reported event: _____ _____ _____																																
		<input type="checkbox"/> ₁ Participant declined to describe																															
2.	Date of occurrence/onset	<table style="display: inline-table; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> <tr> <td style="text-align: center;">dd</td> <td></td> <td style="text-align: center;">MMM</td> <td></td> <td style="text-align: center;">yy</td> <td></td> <td></td> </tr> </table>								dd		MMM		yy			(use best estimate if exact date is unknown)																
dd		MMM		yy																													
3.	Who did this (who perpetrated the harm)?	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">a. Sex partner:</td> <td style="width: 20%; text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="width: 20%; text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>b. Family members:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>c. Friends or neighbors:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>d. Health worker:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>e. Classmates:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>f. Co-workers:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>g. Church member:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>h. Community member, known to you:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>i. Stranger:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>j. Other:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes, specify: _____</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> </table>		a. Sex partner:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	b. Family members:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	c. Friends or neighbors:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	d. Health worker:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	e. Classmates:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	f. Co-workers:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	g. Church member:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	h. Community member, known to you:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	i. Stranger:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	j. Other:	<input type="checkbox"/> ₁ Yes, specify: _____	<input type="checkbox"/> ₂ No
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4.	Was the event due to participant's involvement in the study?	<input type="checkbox"/> ₂ No → End of Form. Document in chart notes and offer referrals. <input type="checkbox"/> ₁ Yes, explain: _____ _____																															
5.	What type of harm resulted from this event? (mark all that apply)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 60%;">a. Physical:</td> <td style="width: 20%; text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="width: 20%; text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>b. Emotional:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>c. Financial:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>d. Sexual:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> <tr> <td>e. Other:</td> <td style="text-align: center;"><input type="checkbox"/> ₁ Yes, specify: _____</td> <td style="text-align: center;"><input type="checkbox"/> ₂ No</td> </tr> </table>		a. Physical:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	b. Emotional:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	c. Financial:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	d. Sexual:	<input type="checkbox"/> ₁ Yes	<input type="checkbox"/> ₂ No	e. Other:	<input type="checkbox"/> ₁ Yes, specify: _____	<input type="checkbox"/> ₂ No															
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e. Other:	<input type="checkbox"/> ₁ Yes, specify: _____	<input type="checkbox"/> ₂ No																															
6.	Did this event include unwanted disclosure of study participation?	<input type="checkbox"/> ₂ No <input type="checkbox"/> ₁ Yes, specify to who: _____ <input type="checkbox"/> ₆₆ Unknown/Declined to provide information <input type="checkbox"/> ₈₈ Other, specify: _____																															

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7.	What impact did this situation have on the participant's quality of life (according to the participant's perspective)?	<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"/> ₆₆ Unknown/Declined to provide information <input type="checkbox"/> ₈₈ Other (specify) _____																
8.	Other participant comments or remarks:	_____ _____ _____ <input type="checkbox"/> ₁ None																
9.	Based on your discussion with the participant, does participant think this situation is resolved?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No, not yet resolved <input type="checkbox"/> ₃ No, unable to be resolved																
9a.	If resolved or unable to be resolved, enter closure date:	<table style="width: 100%; border: none;"> <tr> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> <td style="border: none; text-align: center;"> <table border="1" style="width: 25px; height: 25px;"></table> </td> </tr> <tr> <td style="border: none; text-align: center;">dd</td> <td style="border: none; text-align: center;">MMM</td> <td style="border: none; text-align: center;">yyyy</td> <td colspan="5" style="border: none; text-align: right;">(use best estimate if exact date is unknown)</td> </tr> </table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	<table border="1" style="width: 25px; height: 25px;"></table>	dd	MMM	yyyy	(use best estimate if exact date is unknown)				
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dd	MMM	yyyy	(use best estimate if exact date is unknown)															
10.	What action, recommendation or suggestion was provided by study staff to the participant to help resolve this situation?	_____ _____ _____																
11.	Referrals made (<i>mark all that apply</i>):	a. Counselling: <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No b. Medical care: <input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No c. Other: <input type="checkbox"/> ₁ Yes, specify: _____ <input type="checkbox"/> ₂ No																
12.	What action, recommendation or suggestion will be taken by study staff to prevent the same situation from reoccurring and to minimize the possibility of others experiencing the same?	_____ _____ _____ _____																
Comments: _____ _____ _____ _____																		

Social Harms (SH) Instructions

Purpose: This form is used to record social harm events reported by participants up to 30 days following their MTN-045 participation. Social harms, which are deemed related to a participant’s study participation, should be reported to the protocol team and/or ethical review boards according to the reporting guidelines outlined in the SSP Manual.

General Information/Instructions: This form is only completed in full if a harmful event is reported and determined to be study related; therefore this completed form is not required for every participant, or at any specific visit.

Overall instructions: Enter the PTID, your initials, and date the report is made at the top of every page of this form. All items are to be recorded by the Interviewer based on participant description or report and the action taken. Any information recorded or modified on this form after the original date of completion should be initialed and dated.

Item-specific Instructions:

Item	Instruction
1	Describe the reported 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 event, check “participant declined to describe” and contact the protocol team as soon as possible to discuss how to complete the rest of this form.
2	Record the date the social harm occurred. If the participant is unsure of the exact date, use their best estimate.
3	Record who perpetrated the harm.
4	The interviewer is to make an assessment of whether the harm was related to study participation. If it unrelated to the study, they should end the form.
5	The interviewer is to make an assessment of the type of harm the described event is: physical, emotional, financial, sexual, and/ or other. An event may have implications on all of the above. Physical can include beating/hitting/slapping, shoving/tripping, cutting/burning/shooting, withholding basic needs (food, water, shelter, clothing, medicine). Emotional may include yelling/shouting, shunning/ignoring, gossiping, emotional, physical or financial harm to others (e.g. children, family members). Financial may include loss of source of income, loss of resources, lost home, victim of theft, cost of care for physical or emotional harm. Sexual harm can include unwanted sexual advances, unwanted sexual touching, rape, or attempted rape.
6	Record if the event was a result of, or resulted in unwanted disclosure of MTN-045 study participation to another person or group of people and specify who learned of MTN-045 study participation. Record relationships (i.e. MOTHER), not names.
7	Record how the participant perceives this event (and related disclosure about study participation, if applicable) to have impacted their quality of life.
8	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”.
9	This item is to reflect the participant’s (not the interviewer’s) impression as to whether the event is resolved. If the event is “unable to be resolved”, provide an explanation in the comments. Examples of this could be that the relationship with the primary partner ended or the participant lost her job and there was no opportunity of getting it back.
9a.	Provide the date that the event was resolved, per participant report, or the date at which it was determined that the event could not be resolved.
10	Record the actions, recommendations, or suggestions provided to the participant to resolve the event.
11	Record all referrals made in response to this event.
12	Record the actions, recommendations, or suggestions provided to prevent reoccurrence of the event for this participant and/or to minimize the chances of a similar event occurring for other participants.
Comments	Interviewer should write any other information about the event 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. For instance, follow-up information about the event obtained at a later date should be recorded in this section and initialed/dated.