

MTN-003D

Social Harms

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What is a Social Harm?



Social Harm

- Social harm = non-medical adverse consequence of study participation
- For example:
 - Difficulties in personal relationships with partners, family members, friends
 - Stigma or discrimination from family or members of the community



Required Preparation

- Before study initiation:
 - Discuss as a staff team, and with community representatives, what issues and problems are most likely to be encountered by participants
 - Agree on how issues and problems should be handled if reported
 - Define roles and responsibilities so each staff member is aware of what actions he/she can appropriately take and what actions should be referred to other team members
 - Specify roles, responsibilities, and procedures in SOPs



Reporting Social Harms

- Any social harm reported by participants during study participation or up to 30 days afterwards, should be fully documented in the participant file
- Social harms related specifically to the MTN-003D study documented on the Social Harms CRF

Social Harms Report (SH)

Instructions: This form is to be completed for any MTN-003D participant who reports a social harm. Interviewer completes form based on report from the participant.

1.	Describe the social harm event: _____ _____	
2.	Date of social harm onset	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> dd MMM yy
3.	What type of social harm is this event? <i>(mark all that apply)</i>	<input type="checkbox"/> ₁ Physical <input type="checkbox"/> ₂ Emotional <input type="checkbox"/> ₃ Financial <input type="checkbox"/> ₄ Other, specify: _____
4.	Did this event include unwanted disclosure of study participation?	<input type="checkbox"/> ₁ Yes, specify to who: _____ <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?	<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:	_____ _____ _____ <input type="checkbox"/> ₁ None
7.	Based on your discussion with the participant, do you think this situation is resolved?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No <input type="checkbox"/> ₃ Other, specify: _____
8.	What action, recommendation or suggestion was provided to participant to help resolve this situation?	_____ _____ _____



Reporting Social Harms

- Use as much detail as possible to describe the event, including a full description of the event, severity of the event, action taken, approximate onset and resolution dates
- Make every effort to provide appropriate referrals as needed



Reporting Social Harms

- While only those social harms reported up to 30 days after study participation will be recorded and reported, every effort will still be made to provide appropriate care, counseling, and referrals to those presenting after this period.



Reporting Social Harms

- Each site will provide listings of social harms related to MTN-003D participation that are reported by study participants to the MTN-003D Protocol Team at a minimum of every month.
- Social harms related to this study that result in AE(s) should be reported within **three** working days of site awareness.



Scenario 1

During the in-depth interview, a participant reports that during VOICE she was not able to use the study gel because her husband thought the wetness of the gel meant that she was not being faithful. He was very upset and slapped her several times. She was afraid of telling him she was participating in the study, so she stopped using the gel.



Scenario 1 Questions

- ❑ Is this a social harm?
- ❑ Is this social harm related to MTN-003D?
- ❑ How and where would you document this event?
- ❑ What steps would you take to address this event?




Scenario 2

A participant presents to the site a few days after her MTN-003D visit. She reported that her partner got very upset because she was late arriving home on the day of her study visit.



Additional Information?

- What additional information would you ask?



Scenario 2 (cont.)

They had an argument that was so loud the neighbors got involved. Participant reported that this affected her emotionally a lot and she was embarrassed to face her neighbors.



Additional Information?

- What additional information would you ask?



Scenario 2 (cont.)

Participant reported that partner is still upset with her, but he is not as mad as before. She had to tell her partner where she was that day and explain what the study was about.



Scenario 2 Questions

- ❑ Is this a social harm?
- ❑ Is this social harm related to MTN-003D?
- ❑ How and where would you document this event?
- ❑ What steps would you take to address this event?

Social Harms Report (SH)

Instructions: This form is to be completed for any MTN-003D participant who reports a social harm. Interviewer completes form based on report from the participant.

1. Describe the social harm event:

₁ Participant declined to describe

2. Date of social harm onset

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
dd		MMM		yy	


3. What type of social harm is this event? (*mark all that apply*)

- ₁ Physical
₂ Emotional
₃ Financial
₄ Other, specify: _____

4.	Did this event include unwanted disclosure of study participation?	<input type="checkbox"/> ₁ Yes, specify to who: _____ <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?	<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:	<hr/> <hr/> <hr/> <input type="checkbox"/> ₁ None

7.	Based on your discussion with the participant, do you think this situation is resolved?	<input type="checkbox"/> ₁ Yes <input type="checkbox"/> ₂ No <input type="checkbox"/> ₃ Other, specify: _____
8.	What action, recommendation or suggestion was provided to participant to help resolve this situation?	<hr/> <hr/> <hr/>
9.	Referrals made (<i>mark all that apply</i>): <input type="checkbox"/> ₁ Counselor on site <input type="checkbox"/> ₂ Other, specify: _____ <input type="checkbox"/> ₃ No referrals needed	

Comments:



What are your questions about reporting social harms?