

MTN-034 Data Communiqué #4 – November 12, 2019

This is official study documentation for MTN- 034. Please circulate it among relevant staff for their review, print it, and place it in your MTN-034 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-034 SSP manual.

Social Benefits Form

The purpose of this document is to provide new guidance on the completion of the Social Benefits Form in MTN-034. This information was first presented in an MTN-034 training on 09 September 2019 at the MTN Regional Meeting.

The Social Benefits Form is completed when a participant affirms that they have experienced a positive change, event, or experience in their life related to their study participation or product (ring or tablet) use in the past 3 months during the administration of the Social Benefits and Impacts CRF at select visits. A form should also be completed if a participant spontaneously reports a benefit at other times during a study visit.

After concisely describing the social benefit and indicating the visit at which the benefit was reported, the Form administrator is instructed to categorize the social benefit. However, there may be some commonly reported social benefits that do not clearly fit into the pre-defined categories. The following guidance is provided to ensure that all social benefits are categorized consistently across sites.

New Social Benefit Form Guidance

When selecting from the list of potential categories the social benefit relates to, Form administrators are advised to:

- Use the “*Staying HIV free*” category for any feelings of having a peace of mind, stress relief, alleviated worries, etc., from product use reported by the participant
- Use the “*Other*” category for increased sexual pleasure reported by the participant
 - However, try not to use the “*Other*” category when the benefit could fit into another category.
- Ensure that the description of the social benefit explains why the category was selected.
 - E.g.: If a participant states that they are happy about the counselling she receives at the clinic, describe why the counselling made the participant happy and categorize the social benefit accordingly. For example, if the counseling makes her happy because she knows her status, it could be categorized as “*HIV Testing*”. If it made her happy because it helped her improve communication with her partner, it could be categorized as “*Improved communication*”. In either case, the description should reflect why that category was chosen.

If there is any uncertainty on how to categorize a social benefit reported by a participant, form administrators may contact the BRWG for additional guidance.

Site IoRs and/or Study Coordinators are instructed to train all relevant staff/form administrators on the Social Benefit Form procedures using the materials shared at the MTN Regional Meeting training and this additional guidance. Please document training per site SOPs and inform your FHI site representative when it is completed.

REMINDERS

None