

MTN-032 Operational Guidance #3: Debriefing Reports and Drug Detection Level for IDI Participants Pre-Selected for an FGD

The purpose of this guidance document is to provide information on: 1) Types and purpose of the MTN-032 debriefing reports and; 2) Determining drug detection level when switching pre-selected FGD participants to receive an IDI.

1) MTN-032 debriefing reports types and purpose

There are three debriefing report templates for MTN-032:

- 1) IDI Debriefing Report – completed for each IDI participant.
- 2) FGD Debriefing Report – completed for each FGD to provide an overall summary of the group discussion.
- 3) Individual FGD Debriefing Report – completed for each individual who will be participating in an FGD to provide a report of her reaction to her individual drug adherence results.

Purpose for adding Individual FGD Debrief Report. For FGD participants, the presentation and discussion of individual drug level results will occur after the informed consent process and prior to the start of the FGD. Unlike the FGD, this portion of the interview will not be audio-recorded. Therefore, the Individual FGD Debriefing Report has been added to capture a detailed summary of participant reactions when receiving her individual drug adherence results.

2) Determining drug detection level when switching pre-selected FGD participants to receive an IDI

Randomly selected subgroups for IDI were stratified by age group and the quantity of dapivirine detected in plasma at Month 3. Ideally sites should aim to recruit the target number of total women in each age and drug detection level group that is designated in the SSP. When IDI participants are recruited from FGD recruitment lists (e.g. young women at some sites as per Operational Guidance #2), the image for Month 3 blood plasma on the participant's individual drug level visual results should be used to determine the participant's drug detection level. If the image is green then she is in the "high drug detection" group, if the image is white she is in the "low drug detection" group.

Note that this drug detection level determination should be used solely for recruitment purposes, and not explicitly discussed with participants as their adherence level. Please refer to SSP Section 5, and SSP Appendix 5-1 for details on instructions for using the visual tools during the discussion with participants.

All Operational Guidance documents must be printed and filed with regulatory documentation