



MTN-032 V2.0

SSP Updates

May 2018

Section 1: Introduction

- Added LoA#01 for Protocol v2.0, dated 28 March, 2018
- Added guidance outlining Phase 2 readiness process
- Added instructions for requirements prior to beginning activities with male participants

Section 2:

Documentation Requirements

- Clarification: female participant charts should include documentation of permission to contact by HOPE staff
- Added the male partner permission to contact form as part of documentation requirements for male participant charts

Section 3: Participant Accrual and Eligibility Determination

- Added further guidance on male participant recruitment, including additional details about timing for administration of permission to contact requests in light of LoA #01
- Added instruction: sites facing challenges with scheduling a male participant FGD should contact the management team for additional guidance.

Section 3: Participant Accrual and Eligibility Determination

- Clarified that sites should contact management team with recruitment timing questions
- Minor corrections to eligibility criteria verification
- Outlined accrual reporting process using recruitment lists

Section 5: Study Procedures

- Clarified that participants will have received residual drug data feedback up to their 8th month of HOPE participation and that some may have already returned to the clinic to receive their final 3 months of RD feedback.
- Added language to indicate that tools for female FGDs will be provided by the management team if needed.

Section 5: Study Procedures

- Changed Sticker Opinion Tool language from “emoticons” to “emojis”
- Added guidance that pelvic models may be used for male FGDs to demonstrate ring placement
- Added guidance on the provision of HOPE overview information for male partners for men unaware of the basics of the HOPE study

Section 5: Study Procedures

- Added additional guidance that probing for MP FGD/IDI guide question #5 should refer to what they knew prior to their involvement in MTN-032.
- Confirmed guidance that RD feedback from all rings used by the participant must be available prior to her accrual to MTN-032.
- Added guidance for optional use of vulva puppets and penis models during Phase 2 female IDIs

Section 5: Study Procedures

- Added instructions for sites to monitor visit and procedure length for efficiency
- Provided additional guidance for female participants who have already received their final 3 months of RD feedback from the HOPE team

Section 7: Data Collection

- Removed requirement to upload audio files to RTI FTP server
- Changed references from FTP server to SFTP server
- Updated QC review process
- Removed Appendix 7 to standalone document “MTN-032 SFTP Instruction Guide”. Document can be found on MTN-032 site.