



MTN 015 Data Communiqué #7

August 19, 2013

This is official study documentation for MTN 015. Please circulate it among relevant staff for their review, print it, and place it in your MTN 015 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 015 SSP manual.

UPDATES – Protocol Version 2.0 CRF Changes/Additions

Several new and altered CRFs are being implemented for Version 2.0 of this protocol.

The new CRFs are as follows:

Form Acronym	Form Name	Notes
BQ-1	Abbreviated Baseline Behavioral Questionnaire	<i>Completed by all non-MTN003 participants once site is operating under v2.0</i>
FP-1	Family Planning	<i>Complete once site is operating under v2. To be completed at enrollment and when the participant's method changes</i>
FQ-1	Abbreviated Follow-up Behavioral Questionnaire	<i>Completed by all non-MTN003 participants once site is operating under v2.0; Required at 3, 12 and 24 mns</i>
ACT-1	ACASI Tracking	<i>Completed by all non-MTN003 participants once site is operating under v2.0; Required at screening/enrollment, 3, 12 and 24 mns</i>
PDL-1	Protocol Deviation Log	<i>Complete once site is operating under v2.0.</i>

CLARIFICATIONS –

- 1) The completed PDL-1 forms should be sent to SCHARP via Datafax in the same manner as all of the other CRF forms for this study. iDatafax will not be supported for this study at this time. If/when it does get supported a separate Data Communiqué will be issued with instructions.
- 2) The new BQ-1 and FQ-1 forms will be used for all non-MTN003 participants. All MTN003 participants will continue to use BBQ-1 and FBQ-1. MTN003 participants will NOT be participating in the ACASI either.

REMNDRERS - none