MTN-023/IPM 030 Data Communiqué #4

2 October 2015

This is official study documentation for MTN-023/IPM 030. Please circulate it among relevant staff for their review, print it, and place it in your MTN-023/IPM 030 SSP Manual in the Data Communiqués section. This document is considered part of the MTN-023/IPM 030 SSP manual.

REMINDERS

None.

CLARIFICATIONS

Documenting Abnormal and Normal Findings due to Unexpected or Expected Bleeding

Observation of any unexpected genital blood or bleeding is considered an abnormal finding. For example, bleeding that is prolonged or heavier than usual, per clinical judgment of the IoR or designee, this would be considered an abnormal finding. See SSP sections 7.9 and 8.2.1 for further guidance and clarification. "Abnormal findings" should be marked in Item 2 of the Pelvic Exam CRF and any associated findings should be marked in Item 2a. Unexpected genital bleeding should be documented as a reportable AE as well and an Adverse Experience Log (AE-1) CRF should be completed.

However, any genital blood or bleeding that is expected, per clinical judgment of the IoR or designee, is not considered an abnormal finding. In addition, any finding that is considered normal, per clinical judgment of the IoR or designee, is not reported as an abnormal finding. For example, menstrual blood or cervical bleeding associated with speculum insertion or a vaginal swab and/or specimen collection judged to be within the range of normal, per clinical judgment of the IoR or designee, would not be reported as an abnormal finding. Thus, this is not a reportable adverse event. With expected bleeding, "no abnormal findings" can be marked on the Pelvic Exam (PE-1) CRF.

This guidance supersedes the current form instructions on the back of the Pelvic Exam CRF and should be used moving forward.

UPDATES

None.