



## MTN-024/IPM 031 Operational Guidance #1: Clarifications to Study Specific Procedures (SSP) Manual

This operational guidance to MTN-024/IPM 031 sites is intended to provide clarification on how to document screening laboratory results and protocol guidance stipulating that participants abstain from inserting anything into their vagina for 72 hours prior to each clinic visit, including abstaining from the use of study approved lubricant and vaginal intercourse.

### **SSP section 9.5 (Protocol Adherence Counseling):**

Site staff will counsel participants to refrain from engaging in certain practices and/or using prohibited medications during the course of study participation, which could potentially increase the possibility of adverse events due to agents other than the study vaginal ring.

Protocol adherence counseling is required at Enrollment and the 4-Week and 8-Week visits. Per protocol section 6.7, participants should be counseled to avoid the following practices:

- Refrain from using non-study provided or approved vaginal products or objects during study participation
- Refrain from inserting study approved lubricant 72 hours (3 days) prior to each scheduled visit.
- Refrain from engaging in vaginal intercourse 72 hours (3 days) prior to each scheduled visit.

In addition to the above mentioned protocol requirements, per Section 6.7, participants should abstain from inserting anything into the vagina for 72 hours prior to each clinic visit, including abstaining from the use of study approved lubricant and vaginal intercourse. Therefore, participants should be counseled at the Screening visit to refrain from the aforementioned practices for 72 hours (3 days) prior to the Enrollment visit to ensure the cervicovaginal lavage (CVL) and vaginal swabs for biomarker testing are not impacted. Should a participant report engaging in the abovementioned practices during the prohibited period, the visit need not be rescheduled. Any reported practices should be documented on the Vaginal Practices CRF.

### **Per SSP section 3.4.5 (Screening Procedures):**

At screening, participants will undergo testing for the following sexually transmitted infections (STIs): GC/CT, Syphilis, Trichomonas, and HIV. The following laboratory evaluations are conducted: AST, ALT, Creatinine, and a complete blood count with platelets. If indicated, participants may be tested for bacterial vaginitis, vaginal candidiasis, or herpes simplex virus. If required for eligibility or clinically-indicated, a Pap smear specimen will also be done.

Hematology tests (CBC with Platelets) and chemistry tests (AST, ALT and Creatinine) results are documented on the Safety Laboratory Results (SLR-1) CRF. HIV test results are documented on the HIV Results (HIV-1) CRF. Vaginal wet prep, GC/CT, Trichomonas rapid test and other if indicated test results are documented on the STI Test Results (STI-1) CRF.

Note that the follicle-stimulating hormone test (FSH), urine pregnancy and Syphilis RPR test results are maintained at the site in local testing logs, lab results report and/or chart notes. These results are not documented on a CRF.

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