MTN-036/ IPM 047 Operational Guidance #1:
Guidance on Documenting Previous Ring Use

This operational guidance to MTN-036/IPM 047 sites is intended to provide further guidance on how to document participants' previous use of an investigational vaginal ring (IVR) in a clinical study.

Clarifying Question on Enrollment CASI Questionnaire

The CASI Questionnaire at enrollment asking, "Have you ever in your life used any of the following: Vaginal ring (such as NuvaRing, Estring, Femring)," is intended to capture all vaginal ring use, including previous use of an IVR, such as the dapivirine ring through participation in a clinical trial. Prior to administering the survey, site staff should make this clarification to participants.

Tracking Participation in Previous IVR Studies

The study team would like to track prior participation in an IVR study. Sites should collect this information based on their records of a participant having participated in a previous IVR study at the site. Upon completing participant follow-up, sites should provide the behavioral team a list of MTN-036 PTIDS known to have been in previous IVR studies with the associated study name(s) indicated.

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