



MTN-038 Operational Guidance #1: Revised Product Use Instructions and Important Information

The MTN-038 management team provides a double-sided resource with illustrated Vaginal Ring Insertion Instructions on one side and Vaginal Ring Important Information on the other. These materials are used to help guide protocol counseling and are offered as a printed resource for MTN-038 participants to take home with them as well. The first version of this document was finalized on 10SEP2018. Based on new information from CONRAD about the tenofovir vaginal ring and placebo ring in MTN-038, a revised version 1.1 was finalized on 03May2019. Sites should add their contact information to the document and submit it for IRB review and approval.


The following instructions provide guidance on implementation of the updated Vaginal Ring Insertion Instructions and Vaginal Ring Important Information sheet, V1.1, dated 03May2019, once IRB approved for use:

- For participants who have already completed PUEV, no action is needed.
- For new screening and enrollments, utilize the updated V1.1 Vaginal Ring Insertion Instructions and Vaginal Ring Important information sheet during participant education and protocol counseling at these visits. Participants should also be offered a copy to take home.
- For participants in active follow-up, review the updated V1.1 Vaginal Ring Insertion Instructions and Vaginal Ring Important Information sheet at their next regularly scheduled visit during protocol counseling, making sure to highlight the following updates:
 - Vaginal Ring Insertion Instructions: The original instruction to twist the ring into a figure 8 shape during insertion has been modified based on participant experiences and guidance from CONRAD. The new guidance is to pinch the sides of the ring together.
 - Vaginal Ring Important Information:
 - Guidance in the “If the ring falls or is taken out somewhere dirty” and “Storage” sections has been updated to instruct participants to seal the return bag with the ring inside, which will help prevent the ring from drying out.
 - A message about “Ring Appearance” has been added to the form to educate participants about expected changes in the ring’s appearance based on use.

Site staff should document this review and any participant questions that arise in the participant’s protocol counseling notes. Participants should also be offered a copy to take home.

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

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