Section 6. Study Product Considerations for Non-Pharmacy Staff

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This section provides information and instructions for non-pharmacy staff related responsibilities regarding blinding, transport, receiving the MTN-023/IPM 030 vaginal ring from pharmacy and delivery of the vaginal ring to study participants. Record keeping requirements for non-pharmacy staff also are provided. Associated instructions for pharmacy staff are provided in the MTN-023/IPM 030 Pharmacy Study Product Management Procedures Manual, which will be made available to each MTN CRS Pharmacy by the MTN LOC Pharmacist. Please refer to section 9 of this manual for product use instructions and guidance on study product adherence counseling.

6.1 Responsibilities and Obligations with Regard to Blinding

MTN-023/IPM 030 Investigators of Record (IoRs), and by delegation all MTN-023/IPM 030 study staff members are responsible for maintaining the integrity of the study's blinded design. The identity of the specific study product (Dapivirine Vaginal Ring (VR) or Placebo VR) to which each participant is randomly assigned is double-blinded, meaning that neither study participants nor study staff — including all members of the Protocol Team — will be provided information on the identity of the specific study product to which each participant has been assigned.

Study documentation maintained by clinic staff members — who are responsible for ascertaining primary and secondary study endpoints —will identify the randomization envelope number to which each participant has been assigned. Study documentation maintained by pharmacy staff — who are excluded from ascertaining primary and secondary study endpoints —will include blinded coded information indicating the specific sublot code for the vaginal ring to which participants have been assigned.

Blinding will be maintained throughout the study and until all study endpoint data have been verified and are ready for final analyses. There are no circumstances under which it is expected that unblinding a participant study regimen assignment will be necessary to protect the safety of that individual. In the event that study staff becomes concerned that a participant may be put at undue risk by continuing use of her study product, the IoR may hold or discontinue product use by the participant. However, knowledge of the specific product to which the participant was assigned should not be necessary to guide further follow-up and/or treatment.

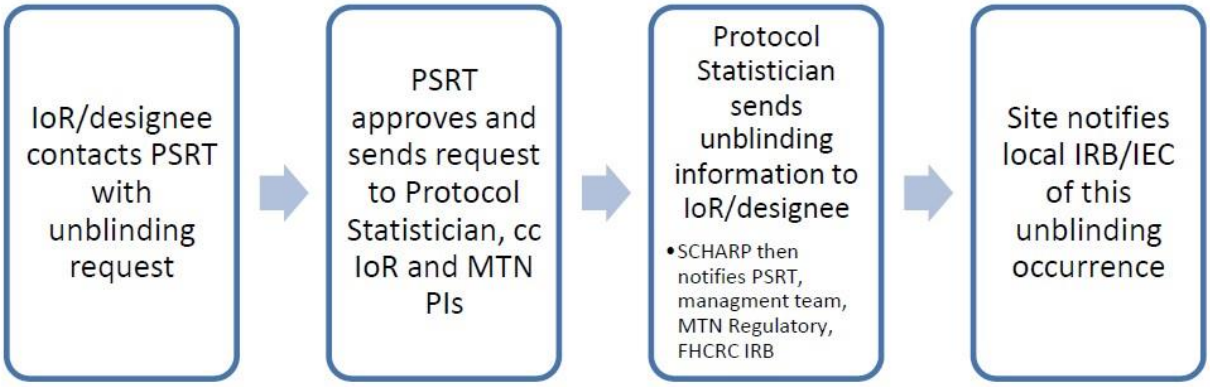
6.1.1 Emergency Unblinding Process

During the trial, an IoR/designee may request that a participant's study regimen assignment be provided (unblinding), if it is essential to protect a participant's safety.

To request the unblinding for a specific participant, the following steps are required:

1. IoR/designee must contact the Protocol Safety Review Team (PSRT) (412-641-8947 or mtn023psrt@mtnstopshiv.org).
2. If the PSRT rules that unblinding is required, the PSRT will send the unblinding request to the Protocol Statistician (Jingyang Zhang), and cc the IoR/designee from the site so that the statistician can send the information to the correct person at the site. The MTN PI and co-PI should also be copied on this request from PSRT.
3. The Protocol Statistician will provide the study regimen assignment to the IoR/designee and will then notify the following: MTN PI and Co-PI, PSRT, the protocol management team and protocol chairs, MTN Regulatory and the Fred Hutchinson Cancer Research Center IRB that this has occurred.
4. The site IoR/designee must notify the local IRB in an expedited manner of this occurrence of unblinding.

Figure 6-1. Flow Chart of Emergency Unblinding Process



6.2 Randomization Assignment

The MTN Statistical Data Management Center (SDMC) will generate and maintain the study randomization scheme and associated materials, which consist of the following:

- MTN-023/IPM 030 Randomization Envelopes

- MTN-023/IPM 030 Randomization Envelope Tracking Record (Appendix 6-1)
- MTN-023/IPM 030 Prescription (Appendix 6-2)
- MTN-023/IPM 030 Vaginal Ring Request Slip (Appendix 6-3)
- MTN-023/IPM 030 Randomization Number Tracking Record for Pharmacy
- MTN-023/IPM 030 Participant-Specific Pharmacy Dispensing Records

Randomization Envelopes will be shipped from the MTN SDMC to each study clinic. They will be stored in the clinic and assigned in sequential order (via increasing envelope number) to participants who have been confirmed as eligible and have provided written informed consent to take part in the study. Envelopes must be assigned in sequential order, and only one envelope may be assigned to each participant. Once an envelope is assigned to a participant, it may not be re-assigned to any other participant. All envelopes are sealed with security tape that, when opened reveals the word “OPENED” or “SECURITY TAPE” in the residue of the tape.

Envelope assignment to eligible participants will be documented on the Randomization Envelope Tracking Record (Appendix 6-1) that will accompany each envelope shipment to each site. The act of assigning a Randomization Envelope to a participant is considered the effective act of randomization and enrollment into the study. Once a Randomization Envelope is assigned, the participant is considered enrolled in the study.

Each Randomization Envelope will contain a prescription (Appendix 6-2). Prescriptions will be produced as two-part no carbon required (NCR) forms preprinted with the CRS name, CRS ID, CRS Location, Randomization Number, and randomization status for the in-depth interview. After recording the PTID and other details on the prescription, clinic staff will separate the two sheets of the form, and the white original will be delivered to the pharmacy. The Randomization Envelope and the yellow copy will be retained in the participant’s study notebook in the clinic. Only one prescription may be assigned to each participant. Once a prescription is assigned to a participant, it may not be re-assigned to any other participant. A prescription must be signed by an authorized prescriber as designated on FDA Form 1572.
If pharmacy staff identify possible errors on the original prescription, they will return the prescription to clinic staff for clarification or correction. If corrections are required, corrections must be made on both the white original prescription and the yellow copy by the authorized prescriber. A signed and dated note explaining the corrections also should be recorded on both copies. Identical corrections and notes should be recorded on both copies, on the same date, by the same person. Corrections should only be made by study staff authorized to complete original prescriptions.

6.3 Dispensing Study Product

Each participant is assigned to either 25 mg dapivirine vaginal ring or a placebo vaginal ring based on the randomization number pre-printed on the prescription (see Appendix 6-2).

Each vaginal ring will be dispensed in its original sealed pouch. The pharmacist/designee will also dispense an amber or white participant vaginal ring return bag. The pharmacist/designee will complete the PTID and date the bag was dispensed, and clinic staff will complete a contact name and phone number on the label of the return bag. Clinic staff must be sure to provide the participant with the correct vaginal ring and the return bag. Clinic staff should instruct the participant that the ring should be rinsed and dried and placed in the bag if the used ring is removed prior to the next scheduled visit so that it can be returned to the clinic. Although participants are encouraged to not remove the ring, they may also rinse and dry the ring and place it in this bag for storage if there is a need to temporarily remove the ring. The ring should always be rinsed with clean water before reinserting the ring. Participants may request a new bag at clinic visits as needed if the bag is used or misplaced.

6.3.1 Chain of Custody

For MTN-023/IPM 030, the vaginal rings and return bag will only be dispensed from the pharmacy directly to a clinic staff member who will then deliver the participant-specific study product to the participant. If staffing issues make it impossible for a clinic staff member to pick up the ring from the pharmacy, a designated transport staff member (runner or courier) may pick up the vaginal ring and bag, and then transfer the study product to a designated clinic staff member who will then provide the participant the study product. The MTN-023/IPM 030 Chain of Custody (Pharmacy) SOP provides documentation regarding who receives the vaginal ring from the pharmacist. Responsibilities and procedures from the time of product receipt from the pharmacy until delivery to participant, including procedures for participant identity verification prior to ring provision, should be outlined in the Clinic Study Product Accountability and Destruction SOP. The SOP should be developed with input from both pharmacy and clinic staff to ensure smooth on-site clinic flow. This SOP must be approved by the MTN LOC Pharmacist prior to study activation and may only be modified after consultation with the MTN LOC Pharmacist.

6.3.2 Initial Vaginal Ring Dispensing - Prescription Overview

All prescriptions will have the assignment “MTN-023/IPM 030 Vaginal Ring (25 mg dapivirine or placebo)”, as all participants will be randomized to vaginal ring. The randomization number pre-printed on the prescription (which is the same as the randomization envelope number) will indicate to the pharmacy which MTN-023/IPM 030 Participant-Specific Pharmacy Dispensing Record should be used to instruct the pharmacy staff as to which ring sub-lot should be dispensed to the participant. Note that only one vaginal ring may be dispensed at each visit.

The in-clinic procedures are listed below.

6.3.2.1 In Clinic (procedures C1-C5):

C1. Obtain the next sequentially-numbered Randomization Envelope which contains a MTN-023/IPM 030 prescription. Assign the Randomization Envelope to the participant by documenting the PTID, date assigned, time assigned, and the designated clinic staff initials on the MTN-023/IPM 030 Randomization Envelope Tracking Record in the row corresponding to the assigned Randomization Envelope Number. The person who marks the informed consent check box is responsible for confirming the presence of a properly signed/marked and dated informed consent form for enrollment prior to recording his/her initials beside these boxes.

C2. The middle section of the prescription must be completed by a study staff member designated in the site’s delegation of duties as an authorized prescriber of study product. This person also must be listed as an investigator (either the Investigator of Record or Sub-Investigator) on the current FDA Form 1572.

C3. The bottom section of the prescription requires clinic staff initials and the date once all of the above is completed. This should be completed by the clinic staff member who verifies that the participant signed the informed consent form and completed the top part of the prescription.

C4. Double-check the accuracy of all entries and then separate the two parts of the completed prescription. Retain the yellow (clinic) copy in the participant study notebook.

C5. Deliver the white (pharmacy) original prescription to the study pharmacy.

6.3.2.2 In Pharmacy (procedures P1-P3):

P1. Upon receiving the completed MTN-023/IPM 030 Prescription (at enrollment), the pharmacist will review the document for completion and accuracy. In the event that pharmacy staff identifies possible errors on the original prescription, they will return the original prescription to clinic staff for clarification or correction. If corrections are required, corrections must be made on both the white original prescription and the yellow copy. A signed and dated note explaining

the corrections also should be recorded on both copies. Identical corrections and notes should be recorded on both copies, on the same date, by the same person. Corrections to original study prescriptions should only be made by an authorized prescriber and fully documented in the participant's chart notes.

P2. Receipt of the MTN-023/IPM 030 Prescription will be documented on the Randomization Number Tracking Record for Pharmacy. The PTID, pharmacy staff initials, and date the prescription is received must be recorded for the corresponding Randomization Number.

P3. Following review of the signed MTN-023/IPM 030 Prescription pharmacy staff will dispense the study product for participants per instructions in the MTN-023/IPM 030 Pharmacy Study Product Management Procedures Manual and in accordance with the site pharmacy Chain of Custody SOP.

6.4 Study Product Accountability

Study product will be dispensed to clinic staff and provided to the participant in the clinic. Used study product will be returned by the participant and given to the clinic staff (rather than the pharmacy). Therefore, accommodation must be made to allow for documentation of distribution, collection, and removal of study product at the site clinic. A standardized process of tracking and accountability must be followed by all MTN-023/IPM 030 sites. A sample Participant-Specific Clinic Study Product Accountability Log is available on the MTN-023/IPM 030 website under Study Implementation Materials. This log includes tracking the date it is distributed to the study participant, the date of ring return to the clinic, and the final status of each ring (used ring for storage, used ring for destruction, unused ring to pharmacy, or ring not returned). Sites will be provided an SOP template which should be modified to reflect the specific processes at the site.

6.4.1 Documentation of Ring Provision and Ring Collection

6.4.1.1 Clinic Participant-Specific Vaginal Ring Accountability Record

This log should be maintained and completed as outlined in the SOP for Clinic Vaginal Ring Accountability and Destruction (template is available on the MTN-023/IPM 030 website under Study Implementation Materials). This SOP should define who is responsible for updating this log, when it is updated, where it is stored, how and when it will be QC'd, and who is responsible for the QC procedures. It must be updated at least daily and indicated in the Source Document SOP whether any of the data points will collect source data.

6.4.1.2 Ring Collection and Insertion CRF

Site staff must document all vaginal ring returns on the Ring Collection and Insertion CRF, as well as the Participant-Specific Clinic Study Product Accountability Log described above.

After documenting the return of used rings on the CRF and clinic log, clinic staff should proceed to follow the directions outlined in SSP Section 10.9 (Testing of Intravaginal Ring (IVR)). The placement of the used ring in the biohazard bag (supplied by Laboratory Center) that is to be stored is also documented on the Participant-Specific Clinic Study Product Accountability Log.

In the unusual event that a vaginal ring was dispensed but never inserted, the returned (unused) vaginal ring must be returned to the clinic and documented by study staff on the Ring Collection and Insertion CRF and the Participant-Specific Clinic Study Product Accountability Log. The unused vaginal ring should be returned to the pharmacy for quarantine. Only unused vaginal rings may be returned to the pharmacy. Clinic staff and pharmacy staff will complete the Pharmacy Record of Returns.

6.4.1.3 Clinic Study Product Destruction Log

In the rare event that a ring must be destroyed, this log (also available on the MTN-023/IPM 030 website under Study Implementation Materials) should be completed to document the

destruction of the specific biohazard waste container/bin. This will be the final documentation required for recording the accountability of any used ring that is not destined for further testing. If a ring is inserted in the clinic and then removed, during the same visit, due to an adverse event or error subsequently discovered, the ring would be placed in the container for destruction.

6.5 Duration of Use of Each Vaginal Ring

Participants should be counseled to refrain from removing the ring until the next scheduled visit (approximately 28 days) unless instructed otherwise by the study clinic. The ring should be replaced after 28 days. If this is not possible, every effort should be made to replace the ring within the next 7 days. Sites must consider this when developing visit scheduling and tracking systems.

If the next scheduled visit is greater than 35 days from the current visit, the participant should be counseled to use the ring as usual and the ring will be replaced when she comes in for her next scheduled visit. IoR discretion must be used regarding ring use depending on the length of time until this next visit. If the ring is used >35 days, attempts should be made to contact the participant and retrieve the study product as soon as possible.

6.6 Vaginal Ring Re-supply During Follow-up

While conducting all visit procedures for each scheduled visit is ideal, it is acknowledged that this might not always be possible. At a minimum, all of the following procedures must be conducted in order to dispense study product:

- AE assessment and clinical management, in accordance with sections 8 and 9 of the protocol (verbal report of symptoms is acceptable; if symptoms indicate that further evaluation is necessary, this must be conducted prior to dispensing study product).
- Pregnancy test: participant must have a documented negative pregnancy test prior to dispensing product
- Collection of used vaginal ring (and unused, if applicable), if available.
- Adherence Counseling/Vaginal Ring Use Instructions, as needed.

The above listing of procedures is also required in the event that a participant returns to the clinic for an interim visit to resupply study product. The MTN-023/IPM 030 Vaginal Ring Request Slip, which will be produced as two-part NCR forms, (see Appendix 6-3) will be used by clinic staff to communicate that a new vaginal ring should be resupplied to a participant, either for a scheduled study visit or for an interim visit. The slip is also used to communicate clinic staff decisions to temporarily hold, permanently discontinue, or resume (after a hold) vaginal ring use. Further, the slip is used to communicate to the pharmacy of a participant's refusal to accept a new vaginal ring and to communicate when the product use period is completed.

Bulk supplies of the slips will be provided to the clinic staff by SCHARP. Sites will identify the individual responsible for receiving the slips and for contacting the SCHARP Project Manager should additional slips be needed during the study. Instructions for completion of the MTN-023/IPM 030 Vaginal Ring Request Slips are printed on the slips themselves. Additional guidance for clinic staff is as follows:

- Record the CRS name, the participant's ID number (PTID) and the Randomization Number assigned to the participant in the boxes provided at the top of the slip.
- Mark the box for RESUPPLY, HOLD, RESUME, PARTICIPANT DECLINE, PERMANENT DISCONTINUATION, or PRODUCT USE PERIOD COMPLETED.
- If RE-SUPPLY or RESUME is marked, only one (1) vaginal ring is dispensed.
- Mark RESUME only after a HOLD has been lifted.
- Only mark the HOLD or PERMANENT DISCONTINUATION box for clinical (site-initiated) hold/permanent discontinuations. This includes any time the participant is directed by the clinician to remove the ring. Additionally, PERMANENT DISCONTINUATION should be marked for participants who decide to terminate from

the study early. Record the reason for the hold or discontinuation on the line provided.

- If a participant declines to be issued a new vaginal ring for any reason, mark the PARTICIPANT DECLINE box. For participants who decline study product, a ring request slip should be completed each month to document the continued refusal. If the participant agrees to start receiving product again, mark the RE-SUPPLY box to indicate she is restarting product.
- At the scheduled 24-Week/Final Clinic Visit, mark the PRODUCT USE PERIOD COMPLETED box. This will indicate that no more vaginal rings will be provided for the participant.
- The clinic staff printed name, signature, and signature date must be completed by a clinic staff member authorized to order study product for participants during follow-up. When marking RESUME, this clinic staff member must be an authorized prescriber. In all other circumstances, the slips do not need to be signed by an authorized prescriber; however site-specific pharmacy regulations and procedures may be more stringent. All sites must comply with their local requirements.
- Double-check the accuracy of all entries. The MTN-023/IPM 030 Vaginal Ring Request Slip is a two-part NCR form. Retain the yellow copy in the participant study notebook, and deliver the white original to the pharmacy.
- The pharmacist must review the slip for completion and consistency. In the event that pharmacy staff identify possible errors on the slip, they will return the original slip to clinic staff for clarification or correction. If corrections are needed, the corrections must be made on both the white original sheet and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both copies. Identical corrections and notes should be recorded on both copies, on the same date, by the same person. Corrections should only be made by study staff authorized to complete the requested action on the original request slip. See above.

Once a ring is dispensed, clinic staff will document on the Ring Collection/Insertion CRF the needed details regarding the dispensation of the vaginal ring.

6.6.1 Vaginal Ring Hold and Resumption

Protocol Section 9 (Clinical Management) and SSP Section 7 (Clinical Considerations) specify the circumstances under which use of study product may be held or permanently discontinued. A product hold can occur for a number of reasons, as described throughout Protocol Section 9. Holds may be placed either in the clinic or over the phone.

If a product hold is instituted **during a clinic visit or over the phone**, an MTN-023/IPM 030 Vaginal Ring Request Slip marked HOLD should be completed and delivered to the pharmacy, and a Product Hold/Discontinuation Log CRF should also be completed and faxed to SCHARP. A Product Hold/Discontinuation Log CRF should be completed for each clinical product hold, even if the participant is already on a hold for another reason. There is no need to send pharmacy an additional MTN-023/IPM 030 Vaginal Ring Request Slip if a product hold is already in place.

If product hold is instituted **over the phone**:

- Request that the participant remove the vaginal ring, rinse the ring with clean water, pat dry with a paper towel and place it in the study-provided return bag until further instructions are available.
- Follow-up as clinically appropriate per protocol, SSP and/or site SOPs.
- The participant should not resume vaginal ring use until it is determined safe by the IoR/designee. Vaginal ring use may be resumed by asking the participant to come to the clinic for a new vaginal ring.

A vaginal ring should not be removed for a hold and later reinserted for reuse.

Once an MTN-023/IPM 030 Vaginal Ring Request Slip is completed and a "HOLD" is marked, regardless of the reason or duration, no further vaginal rings will be dispensed for that participant until another slip is marked "RESUME" and signed by an authorized prescriber.

For the first dispensation after a hold, complete an MTN-023/IPM 030 Vaginal Ring Request Slip marked RESUME. The Product Hold/Discontinuation Log CRF documenting the hold should be updated and re-faxed to SCHARP when the participant resumes study product.

6.6.2 Permanent Discontinuation

If it is determined by the site clinician that vaginal ring use will be permanently discontinued, site staff will complete an MTN-023/IPM 030 Vaginal Ring Request Slip marked PERMANENT DISCONTINUATION. No further Vaginal Ring Request Slips need to be completed after this visit. A Product Hold/Discontinuation Log CRF must also be completed and faxed to SCHARP. If the participant opts to remain in follow-up, follow guidance per SSP Section 5 (Study procedures) regarding visit procedures for participants who have discontinued use of study product.

6.7 Study Product Retrieval

Protocol Section 6.4.4 specifies the circumstances under which study product must be retrieved from participants who are required to hold or discontinue vaginal ring use. Because participants are expected to have the vaginal ring in place at the time of their clinic visit, the need for product retrieval is expected to be rare. When product retrieval is required, retrieval may occur by the participant returning the product to study staff. Only unused vaginal rings are brought to the pharmacy for quarantine.

Figure 6-2 specifies the circumstances and timeframes with which vaginal rings must be retrieved. If the vaginal ring cannot be retrieved (i.e., participant disposed of it or product was lost after removal) this must be documented on the Ring Collection and Insertion CRF and the related details and counseling on the need to ensure return of product to site should be detailed in the participant's chart notes.

Figure 6-2. Requirements for Retrieval of Study Product Due to Temporary Hold or Permanent Discontinuation

	Retrieve Study Product
Permanent discontinuation or temporary hold due to potential HIV	Within 24 hours
Permanent discontinuation for any	Within 5 working days
Temporary hold for reasons with expected duration of at least 7	Within 7 working days

For all product holds requiring product retrieval, if the vaginal ring is not retrieved within the time frame listed in Figure 6-2, the PSRT must be informed.

In addition to the above, all vaginal rings should be retrieved from all participants at their 24-Week/Final Clinic Visit. If the participant does not bring her vaginal ring to this visit, study staff must arrange to retrieve the vaginal ring within 2 working days. If the vaginal ring is not retrieved within this timeframe, the PSRT must be informed. The retrieved vaginal ring must be documented by clinic staff on the Ring Collection and Insertion CRF.

6.8 Study Product Considerations During Split Visits

In cases where follow-up visit procedures are split across more than one day, every effort should be made to complete pregnancy testing and all other safety evaluations required for product

dispensation (as listed in Section 6.6 of this manual), and product dispensation on the first day of the split visit. If safety testing cannot be performed, the IoR or designee should determine if a new ring should be provided to the participant at that visit.

6.9 Study Product Considerations During Missed or Late Visits

In the event of a missed or late visit, staff members should immediately assess the amount of time that has passed since the participant was last dispensed a vaginal ring. The IoR or designee should determine the next steps to follow, and consult the PSRT as needed.

6.10 Study Product Complaints

During the study, a problem or concern may be observed with an IVR. A problem may be noted by the pharmacy staff, clinic staff, or the participant. These complaints may concern the dosage form (ring), packaging (overwrap pouch), or other aspects of the study product. Clinic staff should make thorough record of complaints of participants and clinic staff. The clinic staff member will notify (via email) the site PoR and other designated site pharmacy staff of the study product complaint. This notification should include as much detail as possible and pictures (if necessary). The following information should be provided in the email: date of the observed issue, date that the issue was reported, date IVR was dispensed, did an adverse event occur, description of the nature of the issue, and any other details deemed necessary. The site PoR will forward (via email) this information to the MTN LOC Pharmacist. The MTN LOC Pharmacist will forward the study product complaint to IPM. If the complaint/issue is concerning an unused IVR, then the unused IVR should be held in the pharmacy. If the complaint/issue is concerning a used IVR, then the clinic staff should process this IVR per standard operating procedures for used IVRs.

Appendix 6-1: MTN-023/IPM 030 Randomization Envelope Tracking Record

CRS	<pre-fill>	CRS ID:	<pre-
CRS	<pre-fill>		

Instructions: Complete one row each time a randomization envelope is assigned to an MTN-023/IPM 030 study participant. All entries must be made in blue or black ink. Corrections may be made by drawing a line through incorrect entries, entering correct information, and initialing and dating the correction.

Randomization	Envelope Assigned to	Date Assigned	Time Assigned (hh:mm)	Clinic Staff Initials
101				
102				
103				
104				
105				
106				
107				
108				
109				
110				
111				
112				
113				
114				
115				
116				
117				
118				
119				
120				

Appendix 6-2: MTN-023/IPM 030 Prescription

Instructions: All entries must be made in dark ink. Press firmly when completing this form. Corrections may be made by drawing a single line through incorrect entries, recording correct information, and initialing and dating the correction.

CRS Name:	**Pre-fill**	**CRS ID:**	**Pre-fill**
CRS Location:	**Pre-fill**	**Randomization #:**	**Pre-fill**
Participant selected to complete the in-depth interview at Week 12?	**Pre-fill**		

Participant ID: ☐☐☐–☐☐☐☐☐–☐

Did the participant provide written informed consent for enrollment into MTN-023/IPM 030? . . . . . Yes ☐ No ☐

Clinic Staff Initials _____

MTN-023/IPM 030 Vaginal Ring (25 mg dapivirine or placebo)

Sig: Insert one ring into the vagina.

Quantity: One vaginal ring. May be refilled as needed per request by designated clinic staff on MTN-023/IPM 030 Vaginal Ring Request Slip for duration of participation in the study

Authorized Prescriber Name (please print):

_____

Authorized Prescriber Signature:

_____

Date: ☐☐–☐☐☐–☐☐
dd MMM yy

Clinic Staff Instructions: Complete all items on this prescription. After initialing and dating below, deliver original white copy (labeled "Pharmacy") to pharmacy. File yellow copy (labeled "Clinic") in participant study notebook.

Clinic Staff Initials: _____

☐☐–☐☐☐–☐☐
dd MMM yy

Appendix 6-3: MTN-023/IPM 030 Vaginal Ring Request Slip

CRS Name:

Participant ID: ☐☐☐–☐☐☐☐☐☐–☐

Randomization Number: ☐☐☐

Clinic Staff Instructions: Mark whether this is a study vaginal ring re-supply, clinical hold, resume (after a clinical hold), clinical permanent discontinuation, participant decline, or product use period completion notification. Only an authorized prescriber can indicate product resumption. Deliver the original white copy (labeled "Pharmacy") to the pharmacy. File the yellow copy (labeled "Clinic") in the participant's study notebook.

☐ **RE-SUPPLY** → **Pharmacy:** Dispense 1 vaginal ring.

☐ **HOLD** → **Reason**: _____

Pharmacy: Do not dispense further vaginal rings to the participant until another MTN-023/IPM 030 Vaginal Ring Request Slip marked "RESUME" is received.

☐ **RESUME** → **Pharmacy:** Dispense 1 vaginal ring.

☐ **PARTICIPANT DECLINE** → **Pharmacy:** Do not dispense at this visit – participant is refusing vaginal ring.

☐ **PERMANENT DISCONTINUATION** → **Reason:** _____

Pharmacy: Do not dispense any further vaginal rings to the participant.

☐ **PRODUCT USE PERIOD COMPLETED** → **Pharmacy:** Do not dispense any further vaginal rings to the participant.

Clinic Staff Name (please print): _____

Clinic Staff Signature: _____

Date: ☐☐–☐☐☐–☐☐
dd MMM yy