# Purpose

To describe the process for randomization to study group for MTN-027 study participants

Scope

These procedures apply to all MTN-027 staff members designated by the Site Leader/Investigator of Record to participate in the randomization process for MTN-027. Associated procedures for pharmacy staff are specified in separate SOPs that, for purposes of blinding, are on file in the study pharmacy only.

**Responsibilities**

All MTN-027 staff members, as designed by the Investigator of Record (IoR), who participate in the randomization of MTN-027 study participants, are responsible for understanding and following this SOP.

MTN-027 Site Leader/Investigator of Record (IoR) and the Study Coordinator (SC) are responsible for ensuring that relevant study staff are trained in the randomization process and follow the instructions outlined in the procedures section below.

[MTN-027 Study Coordinator and QA/QC Manager] are responsible for overseeing quality control (QC) and quality assurance (QA) procedures related to this SOP.

MTN-027 Site Leader/Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-027staff members follow this SOP.

**Definitions**

For MTN-027, randomization is defined as the process in which a staff member receives a randomization assignment via the FSTRF web-based system for study participants. The receipt of a randomization confirmation email with a randomization assignment is also is considered the effective act of enrollment into MTN-027 for participants.

Materials

The following materials are used in the process of participant randomization for MTN-027:

* MTN-027 FSTRF Randomization Confirmation Email
* MTN-027 Prescriptions
* MTN-027 Participant-Specific Pharmacy Dispensing Records

The MTN-027 FSTRF Randomization Confirmation Email will be sent to the designated clinic and pharmacy staff once a participant has been randomization to the study. The MTN-027 Prescriptions and Participant-Specific Pharmacy Dispensing Records are provided by the MTN Pharmacist. Use of the first two above-listed items is described in this SOP. Use of the other items is specified in separate SOPs for pharmacy staff that are on file in the study pharmacy only.

Prior to site activation, SCHARP will provide instructions to create FSTRF user accounts to each site clinic in order to randomize participants during the study. Refer to SSP Section 6 for these instructions. Each site clinic and pharmacy will provide SCHARP with a list of designated staff members who will participate in the randomization of study participants and who will receive the FSTRF Randomization Confirmation Email.

**Procedures**

1. Eligibility Determination and Confirmation

Only potential participants who meet the study eligibility criteria will be randomized and enrolled in MTN-027. Eligibility determination and confirmation, including confirmation that the participant was able and willing to provide written informed consent for enrollment in the study, must be completed prior to randomization, per SOP MTN-027-XXX-00, Eligibility Determination for MTN-027.

1. Pre-randomization Enrollment Visit Procedures

After eligibility is confirmed, the following procedures will be performed prior to randomization, i.e., before requesting an MTN-027 randomization assignment to the participant:

* + Administration of Baseline CASI Questionnaire
  + Perform physical exam and pelvic exam
  + Collection of blood for plasma archive

1. Randomization

Once it is determined a participant is eligible for Enrollment, and after required Enrollment procedures are completed, the participant will be assigned a randomization assignment using the FSTRF web-based randomization system. [Insert staff member titles] are authorized to request participant randomization. ***Once randomization has been assigned as documented on the FSTRF Randomization Confirmation Email, the participant is considered enrolled into MTN-027.***

Once the confirmation email has been received, [insert staff member titles] will print two copies of this email and inform the participant of her random assignment. For each participant, [insert staff member titles] will complete the two-part NCR prescription and deliver the prescription together with one copy of the Randomization Confirmation Email to the pharmacy. For all participants, the clinic portion of the prescription (the bottom yellow copy) and the second copy of the Randomization Confirmation Email will be stored in the participant study notebook.

[Insert staff member titles] will complete all prescriptions which contain dispensation instructions for the initial dispensation. Study product resupplies will be requested using the MTN-027 Intravaginal Ring Request Slip. Prescriptions will only be completed by an authorized prescriber, as listed on Form 1572. The pharmacy portion of the completed prescriptions will be faxed or hand-delivered to the pharmacy on the day of completion. If faxed, the hard-copy will be delivered to the pharmacy by the end of the same working day.

If any problems are discovered with the FSTRF Randomization System (e.g. if the site cannot log onto the MTN-027 webpage, or the site is unable to randomize a participant, etc.), site staff will immediately contact the MTN-027 SCHARP Project Manager and the FHI 360 Clinical Research Manager. The site will not proceed with any further randomizations until notified to do so by SCHARP.

Abbreviations and Acronyms

SOP Standard Operating Procedure

SCHARP Statistical Center for HIV/AIDS Research and Prevention

PTID Participant identification

NCR No Carbon Required

**Attachments**

None or [List all relevant attached materials]

**References**

MTN-027 Protocol

MTN-027 Study Specific Procedures Manual, Section 03: Participant Accrual, Screening and Enrollment and Section 6: Web Randomization

[List other site SOPs and documents as applicable]

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| 027-xx | dd MMM yyyy |  | dd MMM yyyy | Initial Release |

Approval

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|  | Author, Author’s Title |  |  | Date: |
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|  | Approver’s Name, Approver’s Title |  |  | Date: |

[Include Attachments here]