Section 6. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN-012/IPM 010.

6.1 Retention Definitions

The term "retention" generally refers to completion of follow-up visits and procedures as specified in a study protocol. This definition must be operationalized for any study, and operational definitions usually reflect the primary objectives and endpoints of a study. For MTN-012/IPM 010, retention will be defined based on whether participants complete the scheduled final clinic visit (Day 7) within the allowable visit window. Participants who complete their scheduled visits within the allowable visit window will be considered "retained" for the study. Additional retention measures may be defined and used during the study if desired by the Protocol Chair and/or Protocol Statistician.

The MTN Statistical and Data Management Center (SDMC) will post reports on their ATLAS portal presenting retention rates throughout the period of study implementation. The SDMC also will generate a final end-of-study retention rate after the study is completed. All reports will include site-specific and cross-site information. Please see Section 13 of this manual for more information on the study reporting plan.

6.2 Retention Requirements

As this is a short-term Phase 1 study, a retention rate of 100% is targeted across sites.

The purpose of the 100 percent retention target is to ensure the accuracy of study results. The safety of the study products tested in MTN-012/IPM 010 will be estimated by comparing evidence of Grade 2 or higher male genitourinary adverse event(s) observed among participants assigned to the active product group to the rates observed among participants assigned to the placebo control groups. To avoid bias in the study results, high participant retention rates must be maintained throughout the study.

6.3 Retention SOPs

Site staff are responsible for establishing a standard operating procedure (SOP) for participant retention, and for updating the SOP and retention efforts undertaken to meet the study retention goal of 100 percent. The SOP should minimally contain the following elements:

- Site-specific retention goals
- Methods for tracking actual retention versus retention goals
- Procedures for completing and updating participant locator information
- Site-specific definition of "adequate" locator information (for purposes of determining participant eligibility)
- Visit reminder methods and timeframes
- Methods and timeframes for identifying when a visit has been missed
- Planned retention methods, including what outreach/locator efforts are taken after a missed visit
- Methods for timely evaluation of the utility of retention methods

- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

6.4 Obtaining and Updating Locator Information

Successful retention begins with collection of exhaustive locator information from each study participant. All study participants will be asked to provide locator information during the study screening visit, and to review/update this information at the enrollment and final clinic visits. Provision of "adequate" locator information during screening is a study eligibility requirement and each site must specify its definition of adequate locator information in its retention SOP.

Each study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. Potential locator items include:

- Participant's full name, alias, and/or nickname; government-issued identification number; home address; home phone number; mobile phone number; pager number; work address; work phone number; fax number; e-mail address.

- Name, address, telephone number, and/or other contact information for stable community contacts (i.e., participant family members and friends) who typically know the whereabouts of the participant.

  Note: *Although contact information for a participant's current primary partner likely will be useful, contact information for other contacts also should be collected, since the participant's relationship with this partner could change during the course of the study.*

- Name, address, telephone number, and/or other contact information for the participant's health care provider, school or training program; church or other place of worship; social service case worker; counselor, etc; participant's child's school and health care provider.

- Name, address, telephone number, and/or other contact information for support groups, shelters, food pantries, and other social service organizations used by the participant.

During the informed consent process and when collecting locator information, study participants must be informed that their locator sources will be contacted if study staff are unable to locate the participant directly. Study staff will negotiate with the participant how they will identify themselves when locator sources are contacted. Arrangements agreed upon with the participant should be documented on the locator form.

Study staff should view every participant contact as an opportunity to update the participant's locator information. When updating locator information, actively review each item on the locator form to determine whether the information is still current (i.e., rather than simply asking "Has any of your information changed since your last visit?"). Also probe for additional information that the participant was not able or willing to provide at previous visits.

6.5 Retention Tips

Some general strategies for maximizing participant retention are as follows:

- Dedicate adequate staff time and effort to retention efforts.
- Work with community members to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
- Keep participants and community members up-to-date on study progress to foster a sense of partnership and ownership of the study
- Inform local service providers who interact with the local study population about the study, so that they also can express their support for the study.
- Actively review clinic flow to minimize participant waiting time.
- Develop rapport and ensures participants feel welcome and comfortable during their visits.
- Emphasize the value of the participant's involvement in the study during the study informed consent process.
- Use tracking systems to identify when participants' scheduled visits are due and/or overdue. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled visits.
- Schedule the Final Clinic Visit at the participant's enrollment visit. Give the participant an appointment card with the scheduled visit date and time noted.
- Pay close attention to the allowable visit window and prioritize retention efforts for participants nearing the end of the window. Organize daily caseloads and work assignments based on these priorities.
- Follow-up on missed appointments with an attempt to re-contact/re-schedule within 24 hours (preferably on the same day). Continue these efforts per site retention SOPs until contact is made.
- Keep locator information up-to-date and maintain thorough documentation of all efforts to contact the participant. Keep all this information in an organized manner, so that different staff members can easily review the information and contribute to re-contact efforts when necessary.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
- If a participant wishes to discontinue participation in the study, his wishes must be respected. At the time when the participant states that he wishes to discontinue participation, study staff must document the participant's stated wishes in detail, together with the following information:
    - Why the participant wishes to leave the study.

- Whether the participant is willing to have any further contact with study staff in the future and, if so, through what methods.

- If the participant has any pending laboratory test results, whether and how he is willing to be contacted for purposes of receiving his results.