Section 5. Participant Follow-up

This section provides information on requirements and procedures for conducting participant follow-up visits in MTN-009.

5.1 Overview of Study Follow-up Plan

MTN-009 follow-up visits are only required for participants who are found to be HIV infected, per Protocol Appendix II, during the screening and enrollment visit. Per protocol, these participants will have a minimum of two follow-up visits. At the first follow-up visit, scheduled to occur (ideally) within two weeks of blood collection (screening and enrollment visit), study staff will provide HIV-infected participants with their CD4-positive T cell count results, and the associated post-test counseling. At the second follow-up visit, scheduled to occur (ideally) within three months of blood collection (screening and enrollment visit), study staff will provide HIV-infected participants with their HIV-1 RNA (viral load) and resistance test results (from the Network Lab), along with the associated post-test results counseling. Test results, counseling and referrals provided at each follow-up visit will vary depending on when the site receives the laboratory results from the Network Lab as well as the need for additional follow-up visits and any additional counseling needed by the participant and offered by the site.

The purpose of follow-up visits in MTN-009 is to provide participants with test results, as well as post-test results counseling and referrals, as needed. No data is collected on CRFs at follow-up visits; thus, no visit codes are provided by the SDMC (SCHARP) for follow-up visits in MTN-009. Study staff may choose to develop and use local visit codes, for follow-up visits only, to label and identify documentation completed for follow-up visits.

Details on required procedures at follow-up visits are described below.

5.2 Types of Follow-up Visits

Two types of follow-up visits may be conducted:

- **Scheduled visits** are those required per protocol as described in Protocol Section 7.2.

- **Interim visits** are those visits that take place between scheduled visits. There are a number of reasons why interim visits may take place, including a participant who has a question for study staff, needs additional counseling, or a participant who is informing study staff of a social harm event. Another reason for an interim visit is if a participant has high HIV-1 RNA levels (viral load), an indication of critical illness. If such a case arises, the NL will flag the participant's record and immediately alert the site to bring the participant in for proper referral for care.

5.3 Follow-up Visit Location

Due to the nature of this study and to ensure participant confidentiality, all follow-up visits will take place at the study clinic. All visits, study contact and contact attempts should be documented in participant study records.

5.4 Follow-up Visit Scheduling

5.4.1 Target Visit Windows

Study sites will schedule follow-up visits to coincide with the receipt of laboratory results:

- First Follow-up (Visit 2): The first follow-up visit will be scheduled approximately two weeks after the date when blood was collected at the screening and enrollment visit. The purpose of this first follow-up visit is to provide each participant with her CD4-positive T cell count result (CD4+) , associated post-test result counseling, and referrals. The visit may be scheduled or rescheduled earlier or later, depending on when the site expects to receive the CD4+ result. However, study staff should make every effort to ensure that the participant completes this visit within two weeks of blood collection, as the participant's CD4+ result will indicate to her primary care physician (or other health care worker to whom she is referred for HIV care) whether or not she should be started on antiretroviral therapy.

- Second Follow-up (Visit 3): The second follow-up visit will be scheduled approximately three months after the blood collection date (Screening and Enrollment visit) or as soon as the site receives both the HIV-1 RNA (viral load) and HIV resistance test results for a given participant from the Network Laboratory. Study staff will provide all HIV-infected participants with their HIV-1 RNA (viral load) if not already provided (see section 5.2 above), HIV resistance test results, associated post-test results counseling, and referrals at this second follow-up visit.

  ***Note**: If the site receives all test results for a given participant before the first follow-up visit takes place, then the site should provide the participant with all of her results during the first follow-up visit. In this case, a second follow-up visit (Visit 3) is not required. However, it is recommended that care be taken at the first follow-up visit to ensure that the participant fully understands all her test results and what they mean in terms of her health and future clinical care. Additional follow-up visits may be scheduled, if needed, to provide the participant with further explanation of the results and counseling.*

5.4.2 Allowable Visit Windows

Follow-up visits are scheduled based on when the site receives laboratory test results. Sites should make every effort to conduct a given follow-up visit as soon as possible after receiving the result(s) required by protocol to be provided at the visit. Test results should be provided to participants, ideally, within the target windows specified above (section 5.4.1). If there is a delay for any reason, and a participant does not complete a follow-up visit within the specified time frame, study staff must clearly document in the participant's chart notes the reason for the delay and all site efforts to minimize the delay.

Since the purpose of MTN-009 follow-up visits is to provide participants with HIV-related test results and counseling, there is no protocol-specific allowable visit window for follow-up visits. Rather, sites must make every effort to have participants' complete follow-up visits, even if it means completing a visit outside of the target window. Sites should follow their local SOP with regards to efforts to retain participants and schedule follow-up visits. If a site is unable to contact a participant for a follow-up visit after multiple attempts, and the site has made all reasonable efforts to contact the participant as specified in the relevant SOP, then the site may cease further retention efforts for that participant as specified in the SOP. In

addition, if a participant withdraws consent and refuses further participation in the study, study staff will cease retention efforts for that participant and will clearly document the participant's refusal in her chart notes.

5.4.3 Missed Visits

For participants who do not complete scheduled follow-up visits within the specified timeframe, the visit will be considered missed and relevant documentation will be completed (e.g. chart notes, site-specific forms). A missed visit will not be considered a protocol deviation if it is missed because a participant did not keep her appointment. However, the site should make a reasonable effort, as defined in a site SOP, to make up the visit in order to provide the participant with her test results and the appropriate post-test counseling. If a participant misses a visit and does not return to the site after adequate follow-up per site SOP, the site must inform the MTN-009 management team. All efforts to contact the participant should be included in the communication with the management team. If the visit is missed because of a site's oversight, it will be considered a protocol deviation and reported as such. Follow-up visits should be conducted and results provided to the participant as soon as possible once results are received at the site.

5.5 Follow-up Visit Procedures

The administrative and counseling procedures required to be performed at each scheduled follow-up visit are specified in Section 7.2 of the MTN-009 protocol. These procedures are also listed on the Counseling Considerations, Section 6 and follow-up visit checklists in Section 7 of this manual.

5.6 Updating Locator Information

Collection of locator information from each participant is required at the screening and enrollment visit (See Section 4.5 of this manual). Study staff should review this information with participants at each follow-up visit, and should update the locator information as needed.

When reviewing a participant's locator information with her during follow up, 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.

5.7 Reporting of Social Harm

Participants may experience social harms, non-medical adverse consequences, as a result of their participation in the study. For example, participants could experience difficulties in their personal relationships with partners, family members, and friends. They also could experience stigma or discrimination from family members and members of their community. In the event that any social harms occur, study staff should fully document the issues or problems and make every effort to facilitate their resolution.

Social harms that are judged by the Investigator of Record (IoR) to be serious or unexpected will be reported to responsible site Ethics Committees (EC) at least annually, or according to their individual requirements. Every effort will be made by study staff to provide appropriate care and counseling to the participant, and/or referral to appropriate resources for the safety of the participant as needed.

Relationship to study participation or procedures will be assessed by the site IoR, or designee according to current DAIDS guidelines.

Any unanticipated problems will be reported to the DAIDS Medical Officer and the MTN-009 management team at the same time as the problems are reported to the responsible site ECs overseeing the research according to pre-established procedures as required by 45 CFR 46.

Prior to study initiation, study staff teams at each site should discuss as a group, and with community representatives, what issues and problems are most likely to be encountered by participants at their site, and should agree upon how these issues and problems should be handled if reported. Roles and responsibilities should be defined for all staff members, such that each staff member is aware of what actions he/she can appropriately take, and what actions should be referred to other members of the team. During study implementation, staff teams at each site should continue to discuss actual participant experiences, successful and unsuccessful response strategies, and other lessons learned among themselves and with community representatives. Based on these discussions and lessons learned, procedures for responding to issues and problems should be reassessed and updated as needed throughout the study.

The following are suggested strategies for responding to social harms that may be adapted and tailored to best meet participant needs:

- When first responding to an issue or problem, actively listen to the participant's description of the problem and ask questions to elicit as much detail as possible about the problem, including the participant's perception of the severity of the problem. Record all pertinent details in signed and dated chart notes.

- Ask the participant for her thoughts on what can/should be done to address the problem, including what she would like study staff to do in response to the problem (if anything).

- Discuss with the participant any additional or alternative strategies that you might suggest to address the problem and collaborate with her to develop a plan to try to address the problem. Document the plan in signed and dated chart notes.

- Take all possible action to try to address the problem, per the plan agreed upon with the participant. Document all action taken, and outcomes thereof, in signed and dated chart notes.

- Follow all problems to resolution or stabilization and document in chart notes.

- Provide referrals as needed/appropriate to other organizations, agencies, and service providers that may be able to help address the problem. All referrals and follow-up should be documented in a chart note.