MTN-015 Operational Guidance:
Exiting ASPIRE and HOPE participants from MTN-015

The purpose of this Operational Guidance document is to outline procedures for exiting participants from the ASPIRE/MTN-015 and the HOPE/MTN-015 cohorts from MTN-015, and to note study close out considerations. **Reference MTN-015 Data Communique #13 for CRF completion guidance related to study exit of ASPIRE and HOPE participants from MTN-015.**

Completion of MTN-015 Accrual from MTN-025/HOPE

- Notify the MTN-015 management team if there are any participants potentially eligible for MTN-015 that are still pending enrollment.
- New enrollments into MTN-015 may occur through 31DEC2018. No additional enrollments into MTN-015 will be permitted after this date.

Timeframe for MTN-015 Study Exit Visits

- PTID listings of all ASPIRE/015 and HOPE/015 participants in follow-up will be provided by SCHARP to sites to facilitate tracking and scheduling of MTN-015 study exit visits. The following study exit timelines should be followed:
    - ASPIRE/MTN-015 Cohort: Conduct the Study Exit/Termination visit at the participant's next scheduled study visit that occurs between **01NOV2018 – 30JUN2019**.
    - HOPE/MTN-015 Cohort: Conduct the Study Exit/Termination visit at the participant's last scheduled study visit that occurs *before* 30JUN2019.
        - Note: Sites should aim to have all MTN-015/HOPE participants who have initiated ART complete a minimum of one year of follow-up on ART. Notify the MTN-015 study management team if the participants last scheduled study visit before 30JUN2019 does not align with at least 1 year of ART follow-up, in which case, PTID-specific guidance may be provided regarding study exit timeframes.
- All MTN-015 participants should be exited no later than **30JUN2019**. Should participants not present to clinic within this timeframe to complete study exit procedures, they will be terminated in absentia following the guidance outlined below.

Procedural Requirements/Counseling Considerations

- Sites are encouraged to contact participants and inform them of their pending study exit in advance of the scheduled study exit visit. Additional counseling related to the end of MTN-015 participation can be provided as part of interim visits at the discretion of the site, as needed.
- Procedural requirements for conducting the Study Exit/Termination Visit are specified in protocol Section 7.2.3; further procedural guidance is incorporated in Section 5.9 of the SSP Manual and the updated Final Visit checklist, v2.0, dated 31OCT2018, located on the MTN website under study implementation materials: http://www.mtnstopshiv.org/node/468.
    - Sites are encouraged to review current MTN-015 study exit checklists and update as needed in advance of conducting MTN-015 study exit visits for ASPIRE/HOPE participants.
- A Sample Study Exit Script template, v2.0, updated 31OCT2018, and certificate of completion are also available on the MTN-015 website under study implementation materials—sites are encouraged to adapt and implement use of these tools.
- Sites should provide available MTN-015 study results to participants at their MTN-015 exit visit. Messages related to available study results are as follows *(also provided on template Study Exit Script):*
    - The study is ending because researchers have collected enough follow-up information to answer the study questions. All MTN-015 participants will exit the study by 30JUN2019.

- I would like to share with you the results we have from the MTN-015 study to date that are relevant to former ASPIRE/HOPE participants. Among participants enrolled from the ASPIRE/MTN-020 trial:
  - **Dapivirine ring use did not impact HIV disease progression.** In other words, the health of women after their HIV infection was similar regardless of whether they used the dapivirine or placebo ring around the time of their HIV infection.
  - **Dapivirine ring use did not impact the effectiveness of medications similar to dapivirine that are used to treat HIV**. In other words, the bodies of women responded the same to HIV treatment regardless of whether they used the dapivirine or placebo ring around the time of their HIV infection.
  - **Dapivirine ring use did not cause HIV drug resistance.** There was no difference in the frequency of drug resistance between dapivirine and placebo groups. Drug resistance is when one or more medicines that usually work to treat HIV, called antiretrovirals or ARVs, no longer work as well.
- You will be contacted if results change significantly based on additional analysis of MTN-015 data. In order for us to share any updated results, we need to be able to keep in touch with you. Therefore, we ask you to please inform us if you move to a new home, change your phone number, or have any other new details that would help us keep in touch with you.

Lab Considerations

- Sites should contact the MTN-015 Management Team as soon as possible if there are any unreceived pending HIV resistance reports.
- MTN leadership is working on plans for biological samples in storage. The MTN Laboratory Center will contact your site with guidance once plans are finalized. Samples will stay in storage on site until further notice.

Exiting Participants in Absentia

Should a participant fail to present for her study exit visit by the cutoff date (30JUN2019), sites should move forward with terminating the participant in absentia. For these participants:

- Notify the MTN-015 management team that a study exit visit was unable to be completed.
- Record the reason(s) for not completing the study exit visit in the participant study records.
- Reference Data Communique #13 for CRF completion guidance related to terminating participants in absentia.

MTN-015 Study Close Out

- Sites may proceed with MTN-015 study closure once all MTN-015 participants have been exited at their respective sites.
- Complete all items as outlined on the MTN-015 Close Out Checklist, v2.1, 30OCT2018. Contact the MTN-015 management team with any questions.
- Sites should aim to complete study close out activities within approximately 6 months of the final MTN-015 participant visit.

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

DocuSigned by:
Ashley J. Mayo
E35C3483DC334F6...

Ashley J. Mayo, MSPH
Sr. Clinical Research Manager, FHI 360

31OCT2018
Date