Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-032

Assessment of ASPIRE and HOPE Adherence

DAIDS Protocol #: 12058

A Non-IND Study

Version 1.0 / 20 August 2015
Letter of Amendment #01 / 26 October 2015

Clarification Memo Date: 9 November 2016

Section 1: Summary of Clarifications and Rationale

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB/IEC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/IEC overseeing the study at their site for information. This CM is official MTN-032 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-032. No change in informed consent is necessitated by or included in this CM.

This document corrects one mention of Phase 2 eligibility criteria language for consistency with Phase 2 eligibility criteria language throughout the rest of the protocol. This document also modifies language to reduce redundancy of qualitative data collection efforts between MTN-032 and MTN-025, the Phase 2 parent protocol. Additionally, this document updates the location of DAIDS policy and guidance documentation, and the Protocol Team Roster.

Section 2: Implementation

With the exception of updates to the protocol team roster, text to be deleted is noted below with a ~~strikethrough~~ and text to be added is in **bold.**

1.) The following modifications have been made to Section 7.2, *Phase 2,* to make Phase 2 eligibility criteria language in this section consistent with Phase 2 eligibility criteria language throughout the rest of the protocol:

Approximately 84 former Phase 1 participants who ~~completed~~ **participated in** HOPE will be enrolled into Phase 2 (see Section 10.3 for sample composition details).

2.) The following modifications have been made to Section 7.2, *Phase 2,* to reduce redundancy of qualitative data collection efforts between this study and its parent protocol, MTN-025, but still allow for following up with participants likely to yield interesting data, as well as for consistency with above modification:

~~Whenever possible~~ **At sites that implement the HOPE qualitative component and at the discretion of the Protocol Team**, effort will be made to enroll eligible ~~former~~ HOPE participants who took part in the HOPE qualitative component.

3.) The following modifications have been made to update the URLs where current DAIDS guidance documents can be found:

a) Section 11.2, *Source Documents and Access to Source Data/Documents*, has been modified to update the URL where the current Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials policy and appendices can be found:

All study sites will maintain source data/documents in accordance with Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials

~~(http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/sourcedocpolicy.pdf)~~**(https://www.niaid.nih.gov/sites/default/files/documents/daids-sourcedocpolicy.pdf)** and the relevant appendix regarding source documentation (~~http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/sourcedocappndx.pdf~~)**(https://www.niaid.nih.gov/sites/default/files/documents/sourcedocappndx.pdf)**.

b) Section 11.3, *Quality Control and Quality Assurance*, has been modified to update the URL where the current Requirements for Clinical Quality Management Plans at DAIDS Funded and/or Supported Clinical Research Sites policy can be found:

All study sites will conduct quality control and quality assurance procedures in accordance with Requirements for Clinical Quality Management Plans at DAIDS Funded and/or Supported Clinical Research Sites (~~http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/qmppolicy.pdf~~)**(https://www.niaid.nih.gov/sites/default/files/documents/qmppolicy.pdf)**.

c) Section 13.5, *Informed Consent Process*, has been modified to update the URL where the current Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials policy can be found:

Study staff must document the informed consent process in accordance with the Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (~~http://rsc.tech-res.com/policiesandregulations/~~)**(https://www.niaid.nih.gov/sites/default/files/documents/daids-sourcedocpolicy.pdf)**.

4.) Protocol Team Roster – Removals: Beth Galaska, Ian McGowan, Kat Calabrese.

5.) Protocol Team Roster – Updates:

a) Luis Duran's credentials changed to DrPH, and title changed to Protocol and Regulatory Specialist.

b) Rhonda White's address edited to add FHI 360 and remove P.O. Box 21059.

6.) Protocol Team Roster – Additions:

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The above information will be incorporated into the next version of the protocol at a later time if it is amended.