Microbicide Trials Network

CLARIFICATION MEMO #01 TO:

MTN-045

Dual Purpose Prevention (DPP) Product Preferences among Couples

DAIDS Protocol #: 38598

A Non-IND Study

Version 1.0 / 25 February 2019

Clarification Memo Date: 27 May 2020

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-045 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-045. No change in informed consent is necessitated by or included in this CM.

This document includes information related to COVID-19's impact on study implementation. This document clarifies that the content of the planned behavioral assessments may include questions related to the impact of the COVID-19 pandemic on the context of participants' HIV prevention product use. This document also clarifies that the overall study duration at study sites may be affected by COVID-19 closures, and that changes to procedures may be implemented to mitigate potential hazards to participants or due to public health emergencies at the study sites. This document also updates RTI International's address 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~~, text to be added is in **bold**, and text in ***bold italics*** is not to be added, but to serve as a clarification of the implementation item in question. This information will be included in the protocol the next time the protocol is updated.

1.) The following clarification applies to Section 7.2, *Behavioral Evaluations*:

Additional questions may be asked related to COVID-19's potential influence on the context of participants' HIV prevention product use, in order to explore the impact of the pandemic on couples' product preferences.

2.) The following clarification applies to Protocol Summary, *Study Duration*, and Section 4.3, *Time to Complete Accrual*:

Overall study duration - from first enrollment through closure of all follow-up - may be longer than planned if temporary site closures due to the COVID-19 pandemic cause delays or pauses in enrolling participants at one or more research sites.

3.) The following clarification applies to Section 13, *Human Subjects Protections*:

Changes to this protocol may be implemented by investigators prior to IRB/IEC approval, if those changes are required to eliminate apparent immediate hazards to the study participant. [See 45 CFR 46.108(a)(3)(iii) under the 2018 Requirements and 45 CFR 46.103(b)(4)(iii) under the pre-2018 Requirements.] These changes must be documented as Protocol Deviations and reported to the Protocol Team and IRB/IEC as soon as possible. [See ICH E6(R2), Good Clinical Practice, Section 4.5.4.] In the event of a public health emergency, investigators should adhere to the recommendations of their local institutions, IRB/IEC and local health departments. When conflicts exist between local directives, MTN, Protocol Team and/or DAIDS policies or guidance, sites should follow the requirement that is most protective of study participants and site staff. [See DAIDS Guidance,

Coronavirus Disease (COVID-19) and DAIDS HIV/AIDS Network Clinical Research Studies, Page 3, dated March 13, 2020.]

4.) Section 1.4, *Data Center*, and Section 1.5, *Study Operations*:

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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.