Section 1. Introduction

This section specifies the sources of procedural information available to study staff, the responsibilities of the Investigator of Record (IoR) and the process by which each site will be approved to initiate implementation of MTN-029/IPM 039.

1.1 Current Protocol Specifications

The table below documents the history of the MTN-029/IPM 039 protocol, along with any Clarification Memos, Letter of Amendments, and Full Amendments, if applicable, all of which are considered Essential Documents. A copy of each document should be available to staff and a copy should be maintained in site essential files.

Document	Date
MTN-029/IPM 039 Protocol, Version 1.0	30 June 2015
Clarification Memo #01	16 February 2016

Sites are expected to operate under the protocol version and associated Clarification Memos and/or Letters of Amendment that are currently approved by the local institutional review board/ethics committee (IRB/EC). To ensure this section reflects the current specifications of the protocol, upon issuance of any future protocol Clarification Memo (CM), Letter of Amendment (LoA), or Protocol Amendment, specifications listed above will be updated accordingly. These documents are available on the MTN-029/IPM 039 webpage (http://www.mtnstopshiv.org/studies/6411)**.** Further information on the content and required handling procedures for these documents is available in the Microbicide Trials Network (MTN) Manual of Operational Procedures (MOP), which is located on the MTN webpage (http://www.mtnstopshiv.org).

1.2 Procedural Information

The Study Specific Procedures (SSP) Manual serves to supplement the protocol. It does not replace or substitute the protocol or its contents. In the event this manual is inconsistent with the information and guidance provided in the protocol, the specifications in the protocol will take precedence. In the event study implementation questions are not adequately addressed by the study protocol or this manual or if any inconsistencies between the two documents are identified, please notify the MTN-029/IPM 039 Study Management Team at **mtn029mgmt@mtnstopshiv.org**.

The MTN-29/IPM 039 Study Management Team consists of the Protocol Chairs, and representatives from MTN Pharmacy, MTN Leadership and Operations Center (LOC)-University of Pittsburgh (Pitt) and FHI 360, the Statistical and Data Management Center (SDMC), and the MTN Laboratory Center (LC). Sites should contact this group for general questions on protocol implementation or study procedures, including clinical, lab, product, and/or CRF procedures.

Contact details for all of the above listed individuals are listed in the MTN-029/IPM 039 protocol and are also available in the MTN Directory (http://www.mtnstopshiv.org/people/directory), which can be accessed via the MTN webpage.

1.3 Investigator of Record (IoR) Responsibilities

MTN-029/IPM 039 must be conducted in accordance with the United States (US) Code of Federal Regulations (CFR) and the International Conference on Harmonization Consolidated Guidance for Good Clinical Practice (GCP). In addition, MTN-029/IPM 039 must be implemented in accordance with all site-specific regulations, policies, and guidelines applicable to human subjects research in general and/or the conduct of study procedures in particular. Copies of all such regulations, policies, and guidelines should be maintained in on-site essential document files.

The Division of AIDS (DAIDS) policies '*Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*' and '*Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials*' are useful for interpreting and operationalizing the applicable regulations and guidelines in accordance with DAIDS expectations. These resources are available on the NIAID website (http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/ClinicalSite.aspx) as well as on the MTN website under 'Resources and Links' (http://www.mtnstopshiv.org/resources).

The IoR at each study site must sign an Investigator Signature Form (protocol signature page) and a U.S. Food and Drug Administration (FDA) Form 1572 to formally indicate his/her agreement to conduct MTN-029/IPM 039 in accordance with the provisions of the study protocol, applicable US regulations, and MTN policies. An IoR may delegate their obligations and responsibilities for conducting MTN-029/IPM 039 to other study staff members. However, in doing so, this delegation does not relieve the IoR of his/her ultimate responsibility for all study procedures performed and all study data collected. Delegation of IoR responsibilities must be formally documented throughout the period of study implementation on the site's Delegation of Authority (DoA) log. The obligations and responsibilities assumed by the IoR when signing the FDA Form 1572 are listed on the form itself, which is available on the DAIDS Regulatory Support Center (RSC) website. Note that no staff member should fulfill the IoR role in the IoR's absence. Full responsibility and authority over the protocol by anyone other than the IoR may only take place if an additional 1572 is completed and submitted to DAIDS.

Consistent with the regulations, guidelines, and policies cited above, the site IoR must obtain and maintain IRB/EC approval of MTN-029/IPM 039 throughout the period of study implementation. Detailed information on IRB/EC submission, review, approval, and documentation requirements is located in the MTN MOP. All sites are encouraged to request an acknowledgement of receipt for all documents submitted to their IRBs/ECs and to request that IRBs/ECs note the effective and expiry dates of all approvals. Documentation of all correspondence to and from all responsible IRBs/ECs (i.e., complete copies of all submissions, responses, and approvals) must be maintained in on-site essential document files. Documentation of all IRB/EC approvals may also be requested by the MTN LOC.

Note: Staff regularly involved in the source documentation of safety data or are delegated to perform critical trial related procedures should be included on the FDA Form 1572 as a sub-investigator. Such components may include, but are not limited to, adverse event (AE) assessment, collection of participant safety information, confirmation of participant eligibility, or dispensation of study product.

1.4 Study Activation Process

Prior to commencing active recruitment activities and undertaking any study procedures, each study site must complete the following:

- obtain approval to conduct MTN-029/IPM 039 from all required local regulatory authorities and IRBs/ECs,
- complete protocol registration procedures with the DAIDS RSC Protocol Registration Office (PRO), and
- complete study activation requirements, and be issued a Site-specific Study Activation Notice from MTN LOC.

Information on these procedures can be found in the MTN MOP. Detailed information on the requirements of pre-implementation steps are summarized in the MTN-029/IPM 039 Activation Checklist. MTN LOC will notify sites (on a site-by-site basis), when all activation requirements have been met by issuing a Site-Specific Study Activation Notice.