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This publication plan outlines the process by which the MTN and ATN ensures that publications (e.g., journal articles, abstracts, conference presentations and/or posters) resulting from MTN-023 data are developed in a collaborative fashion with all team members actively participating in the design and conduct of the study and study results are published expeditiously and disseminated widely.

## 1.0 MTN-023 Protocol Publication Committee (PPC)

The MTN-023 Protocol Publications Committee (PPC) will oversee the MTN-023 publication process. The PPC will include the following individuals:

* Protocol Chairs: Kathleen Squires and Katherine Bunge
* SDMC: Jingyang Zhang, Marla Husnik, Danny Szydlo, and Melissa Peda
* DAIDS Medical Officer: Lydia Soto-Torres
* NICHD Medical Officer: Bill Kapogiannis
* FHI 360: Lisa Levy

In accordance with CTA requirements, the IND sponsor will be provided the opportunity to review MTN-023 study publications.

**NOTE**: The MTN-023 PPC may ask input from other protocol team members (such as MTN LC or the BRWG) based on content expertise.

MTN-023 PPC responsibilities include, but are not limited to, the following:

* Setting priorities for study data analyses (on a continuous basis and in consultation with the SDMC)
* Planning, reviewing and approving publication concepts for all protocol-related scientific publications (including journal articles and meeting abstracts, poster and oral presentations)
* Establishing and monitoring timelines for publication development and review
* Determining the appropriate composition of analysis and writing teams
* Establishing and agreeing on authorship for all study publications
* Assisting protocol team members in becoming active participants in the writing process
* Reviewing and providing feedback to lead authors on draft publications
* Coordinating and verifying consistency and accuracy between multiple study publications
* Adhering to the publication review procedures as outlined in the MTN Manual of Operational Procedures (MOP)
* Approving all study publications prior to submission to the MTN MRC and subsequent journal and/or conference venue
* Managing required sponsor approvals for study publications, as needed

These responsibilities will be accomplished in accordance with guidance outlined in the MTN MOP Publication Policy (<http://www.mtnstopshiv.org/node/187--> see section 6)

## 2.0 MTN-023 Publication Guidelines

Development of study publications will be coordinated by the PPC. Protocol team members must consult the PPC, using the MTN-023 Concept Proposal Form, to receive approval to develop a publication using MTN-023 study data. The most up-to-date form, can be found on the MTN-023 webpage: (***http://www.mtnstopshiv.org/node/5444***). From these submissions, the MTN-023 PPC will compile a list of all requests for analyses/publications and will work to ensure that each concept on the list is appropriately evaluated. Priority will be given to analyses addressing primary and secondary study objectives of MTN-023; however, other analysis proposals will be considered based on their merits.

Any presentation, abstract, or manuscript must be submitted to the MTN Manuscript Review Committee, DAIDS, NICHD, and IPM for review prior to submission to any journal or conference for publication. See section 4.0 of this plan for further details on the required timelines for review.

**As a general rule, the primary study manuscript must be accepted for publication before any other abstracts or manuscripts using primary study data can be submitted for publication.** Manuscripts focusing on operational issues or contain baseline data may be submitted for publication prior to the primary study manuscript. If an author requests an exception to this rule, it will be considered by the MTN-023 PPC and MTN MRC. To request an exemption from this requirement, the lead author should submit the request in writing to the MTN-023 PPC ([mtn023pubcommittee@mtnstopshiv.org](mailto:mtn023pubcommittee@mtnstopshiv.org)).

## 3.0 MTN-023 Publication Authorship/Sponsorship Guidelines

Authorship should be reflective of the multi-site nature of MTN-023, MTN/ATN publication policies, and generally accepted authorship guidelines. Authorship should be based on the collaborative contributions of all investigators; from conception and design, or acquisition of data, or analysis and interpretation of data; drafting the abstract or revising it critically for important intellectual content; and final approval of the version to be presented/published. **Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work to take public responsibility for appropriate portions of the content.**

The following approach for operationalizing these guidelines will be implemented:

* The person leading the data analysis, data interpretation, and writing of the publication should be the **first author**.
* Team members who contributed substantially to the conceptualization, design, and/or implementation of specific aspects of the study should be included as first author or co-author on publications related to that aspect of the study (e.g., safety measures, behavioral measures).
* The **SDMC statistician** who works with the first author to analyze the data for the publications should be included as a co-author. The protocol statisticians are responsible for designating the most appropriate SDMC staff member to the authorship team.
* **Members of the study management team (from FHI 360, SCHARP, LOC-Pitt, MTN LC, and MTN Pharmacy)** should be considered for authorship on relevant publications (i.e. those presenting primary and secondary study objectives, describing study design and conduct or laboratory or behavioral aspects/assessments of the study)
* **Protocol Chairs** should be given the option of being included as co-authors on all abstracts/manuscripts presenting data on primary and secondary study objectives.
* For **multi-site publications (i.e. if data from more than one site are included in the publication)**, a representative from each site should be included as a co-author whenever possible.

All authorship lists for publications that include data from more than one site should include “***on behalf of the MTN-023 Protocol Team***” at the end of the authorship list.

**NOTE**: Investigators/team members who accept a lead writing assignment will be expected to produce their manuscripts in a timely fashion. For those failing to do so, the MTN-023 PPC has the authority to re-assign lead writing assignments to ensure development stays on track with established timelines developed for each publication.

## 4.0 MTN-023 Publication Review Process

The following steps must be followed by all team members proposing a publication:

1. The proposing author will complete and submit the MTN-023 Concept Proposal Form to the MTN-023 PPC, by email ([mtn023pubcommittee@mtnstopshiv.org](mailto:mtn023pubcommittee@mtnstopshiv.org)).

**Note**: A concept proposal form is not required for primary manuscript(s). However, prior to any other protocol team member drafting a publication (e.g. manuscripts, abstracts, posters or oral presentations) using MTN-023 study data, he or she must submit a concept proposal form to the PPC. Site-specific proposals must be reviewed and approved by the site Investigator of Record (IoR) prior to submission to the MTN-023 PPC.

1. The MTN-023 PPC aims to review and provide written comments on concept proposals within 3 working days. FHI 360 will compile and provide final comments from all reviewers to the lead author and/or will notify the lead author of the MTN-023 PPC decision on whether the concept can move forward to development.
2. Upon receipt of MTN-023 PPC approval of the proposed concept, the lead author will contact the SDMC statistician, if needed, and work together to draft the publication. All members of the writing team must review and approve the publication prior to submission to the MTN-023 PPC. Once the lead author receives comments from co-authors, they will submit the publication to the MTN-023 PPC for review.
3. Once the MTN-023 PPC has approved the abstract/manuscript, FHI 360 will forward the draft publication to IPM (IND sponsor) for review and approval. FHI 360 will compile final comments from all reviewers and submit to the lead author.
4. Once PPC and IPM review comments have all been addressed, the lead author will receive approval to submit the publication for MTN MRC review. FHI 360 will upload the publication for review to the MRC publication software system (datavision) on behalf of the lead author.
5. The MTN MRC aims to review manuscripts within 10 working days and within 4 working days for abstracts, presentations and posters. The MTN MRC review recommendation will be provided to the lead author using Datavision. One of the following two review outcomes will be provided:
   1. *Approved*: The publication is approved as is (if no comments were provided) or with minor comments. If minor comments were suggested, the author will address the comments and revise the publication. NO NEED to submit for any additional MRC review cycles.
   2. *Not Approved - Revision Required*: The current version of the publication is not approved and major revisions are necessary. Author will address the necessary revisions, revise the publication and then resubmit for an additional MRC review cycle.
6. Once the MTN MRC approves the publication, the author may submit the publication to the target journal or conference.

Please note that an abstract/manuscript may be submitted for publication only after it has been approved by the MTN-023 PPC, IPM and MTN MRC. Once it is submitted for publication, the lead author is responsible for informing the MTN-023 PPC and MTN MRC of the result of the review and the publication’s status. It is also recommended that the lead author forward a copy of the conference/journal disposition when received.

## 5.0 MTN-023 Publication Acknowledgments

All publications and presentations will include a statement acknowledging MTN, ATN, and NIH support for the work and listing the applicable cooperative agreement numbers, unless the journal's policy precludes such an acknowledgment.

The acknowledge section for publications should include the following statement of support:

**MTN-023/IPM 030 was sponsored by the US National Institutes of Health (NIH) and International Partnership for Microbicides (IPM). The study was designed and implemented by the Microbicide Trials Network (MTN) and the Adolescent Trials Network (ATN). The MTN is funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. The ATN is funded by through the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, with supplemental funding from National Institute on Drug Abuse and National Institute of Mental Health (5 U01 HD 40533 and 5 U01 HD 40474). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health. The study product used in this study were supplied by the IND sponsor, IPM.**

## Appendix 6-1: Publication Development and Review Process (At-A-Glance)

## Appendix 6-2: MTN-023 Concept Proposal Form

|  |  |
| --- | --- |
| MTN-023 CONCEPT PROPOSAL FORM  This concept proposal should be brief (1-2 Pages in length) | |
| Submission Date: | **Lead Author/Writer Name:** |
|  |  |
| Lead Author/Writer Institution: | **Lead Author/Writer Email Address:** |
|  |  |
| Lead Author/Writer Role on MTN-023: | |
|  | |
| Target Venue:  (Journal, conference, etc.) | **Submission Deadline (to target venue), if applicable** |
|  |  |
| Type of publication:  (e.g., manuscript or abstract)  Note: If the lead author intends to develop an approved abstract into a manuscript, the lead author should email the MTN-023 PPC requesting approval prior to manuscript development. | |
|  | |
| Name of Potential Co-Authors/Writing Team (if known): | |
|  | |
| 1. Proposed Publication Title: | |
|  | |
| 1. Briefly describe the rationale/hypothesis/objectives for the proposed publication:   Note: If related to the protocol’s study objectives, please explain | |
|  | |
| 1. Provide a summary of the analysis plan.   Note: If the study is ongoing, no post-enrollment data will be made available per the MTN publication policy, so please do not submit concepts with requests for data from the MTN SDMC. | |
|  | |
| 1. Is data needed from the MTN Statistical Data and Management Center (SDMC)?   No 🡪 specify below what data will be used and how such data will be generated.  Yes🡪 provide a summary of data needed (e.g., lab assay data, ACASI, CRF, etc.): | |
|  | |
| 1. Is assistance needed with the statistical analysis?   No  Yes: A statistician will be assigned to be a member of the writing team once a concept has been reviewed and approved by the MTN-023 PPC. | |
| 1. Provide the proposed timeline for completion of analysis and subsequent submission of draft publication to MTN-023 PPC. | |
|  | |
| Submit this Concept Proposal Form to the MTN-023 PPC (mtn023pubcommittee@mtnstopshiv.org). | |