
MTN-017 STUDY PUBLICATIONS PLAN

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This publication plan outlines the process by which the MTN ensures that publications (e.g., journal articles, abstracts, conference presentations and/or posters) resulting from MTN-017 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-017 Protocol Publication Committee (PPC)

The MTN-017 Protocol Publications Committee (PPC) will oversee the MTN-017 publication process. The PPC will include the following individuals:

- Protocol Chair(s): Ross Cranston (Protocol Chair) and Javier Lama (Protocol Co-chair)
- SDMC: Barbra Richardson, Karen Patterson, Melissa Peda, Karen Liu and Marla Husnik
- DAIDS Medical Officer: Jeanna Piper
- FHI 360: Sherri Johnson

In accordance with CTA requirements, the IND sponsor and the collaborating pharmaceutical company will be provided the opportunity to review MTN-017 study publications. **NOTE:** The MTN-017 PPC may ask input from other protocol team members (such as MTN LC or the BRWG) based on content expertise.

MTN-017 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 Operations (MOP)
- Approving all study publications prior to submission to the MTN MRC and subsequent journal and/or conference venue
- Managing required sponsor and pharmaceutical company collaborator 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>).

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2.0 MTN-017 Publication Guidelines

Development of study publications will be coordinated by the PPC. Protocol team members must consult the PPC, using the MTN Publication Concept Proposal Form, to receive approval to develop a publication using MTN-017 study data. The most up-to-date form, can be found on the MTN website under the Resources link, within the box labeled Policies/Procedures/Forms (<http://www.mtnstopshiv.org/resources>). From these submissions, the MTN-017 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-017; 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, CONRAD and Gilead 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-017 PPC and MTN MRC. To request an exemption from this requirement, the lead author should submit the request in writing to the MTN-017 PPC (mtn017pubcommittee@mtnstopshiv.org).

3.0 MTN-017 Publication Authorship/Sponsorship Guidelines

Authorship should be reflective of the multi-site nature of MTN-017, MTN 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.**

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- 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-017 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-017 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-017 Publication Review Process

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

1. The proposing author must complete and submit a MTN Publication Concept Proposal Form to FHI 360, by email (sjohnson@fhi360.org). The form can be found on the MTN website under the *Resources* link, within the box labeled Policies/Procedures/Forms (<http://www.mtnstopshiv.org/resources>).
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-017 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-017 PPC.
2. FHI 360 will forward the completed MTN Publication Concept Proposal Form to the MTN-017 PPC for review and approval. The MTN-017 PPC aims to review and provide written comments on concept proposals within 3-5 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-017 PPC decision on whether the concept can move forward to development.
3. Upon receipt of MTN-017 PPC approval of the proposed concept, the lead author will draft and submit the publication (abstract, presentation or manuscript) to FHI 360 by e-mail (sjohnson@fhi360.org), and indicate the target journal or venue (if an abstract and presentation). The publication must be formatted/written in line with target journal or conference requirements.
4. FHI 360 will forward the draft publication to the MTN-017 PPC for review and approval. **Note:** all members of the writing team must review and approve the publication prior to submission to FHI 360 and the MTN-017 PPC. Once the lead author receives comments and feedback, she/he must address these in a timely manner and resubmit to the MTN-017 PPC for review.
5. Once the MTN-017 PPC has approved the abstract/manuscript, FHI 360 will forward the draft publication to CONRAD (IND sponsor) and Gilead (pharmaceutical company collaborator) for review and approval. FHI 360 will compile final comments from all reviewers and submit to the lead author.
6. Once the MTN-017 PPC has approved the abstract/manuscript, FHI 360 will forward the draft publication to CONRAD (IND sponsor) and Gilead (pharmaceutical company collaborator) for review and comment. CONRAD and Gilead will be provided sufficient time review and provide written comments on study publications. For manuscripts, CONRAD and Gilead will be provided no less than 30 working days to review and comment. For abstracts, presentations and posters, CONRAD and Gilead will be provided no less than 7 working days to review and comment. FHI 360 will compile final comments from all reviewers and submit to the lead author.
7. Once PPC, IND Sponsor and Gilead review comments have all been addressed, the lead author will submit a final draft of the abstract/manuscript to FHI 360, who will forward the publication for MRC review. FHI 360 will upload the draft publication to Datavision Review web portal and initiate the MRC review process.

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8. The MTN MRC aims to review manuscripts within 10 working days and within 3-5 working days for abstracts, presentations and posters. Once the review has been completed, the MRC Chair or MTN LOC (Pitt) Manuscript Coordinator will provide comments directly to the lead author, via Datavision. An automated email, generated by Datavision, will be sent to the author providing a link to the review outcome along with the reviewer's comments and suggested revisions. If there are required revisions, these must be addressed before resubmitting for an additional review.
9. After the MRC approves the publication, the lead author may submit it to the journal or conference. The lead author is requested to upload a copy of the final submitted version of the publication to the Datavision Review web portal (It is also recommended that the lead author forward a copy of the conference/journal disposition when received).

Note: In the event an author has intention of developing an approved abstract into a manuscript, the lead author should notify the MTN-017 PPC requesting approval prior to development of the manuscript.

5.0 MTN-017 Publication Acknowledgments

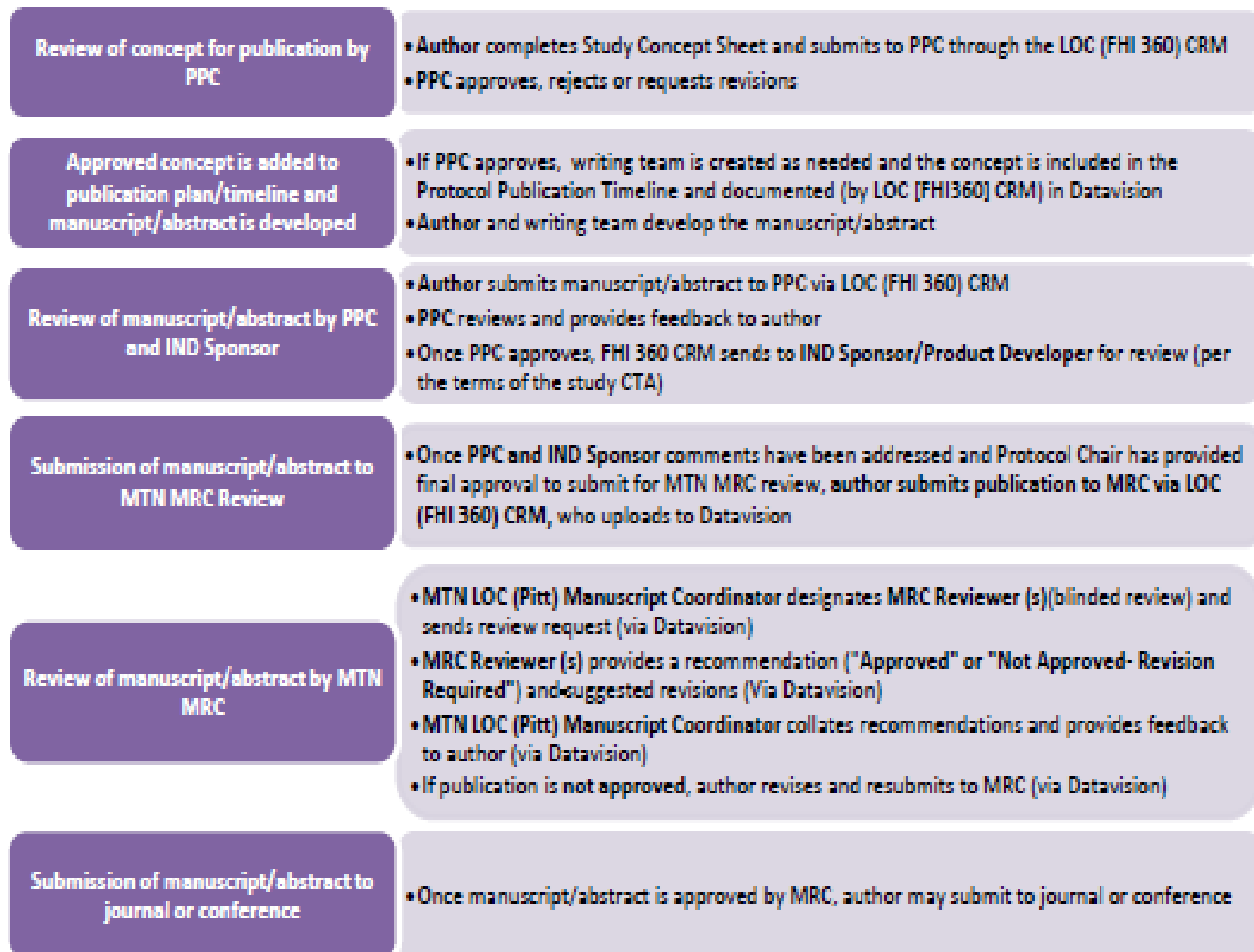
All publications and presentations will include a statement acknowledging MTN and NIH support for the work and listing the applicable cooperative agreement numbers, unless the journal's policy precludes such an acknowledgment.

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

MTN-017 was sponsored by the US National Institutes of Health (NIH) and CONRAD. The study was designed and implemented by the Microbicide Trials Network (MTN). 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 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, CONRAD and the pharmaceutical collaborator, Gilead.

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



*Publications related to specific MTN protocols

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Appendix 6-2: MTN Community Concept Proposal Form

MTN Community Concept Proposal Form
Study Name/Protocol Number:

Date:

Lead Writer Name:

Lead Writer Institution:

Lead Writer Email Address:

Please provide brief answers to the following questions:

1. What is the proposed title for this concept?
2. Please list the names of the co-authors (if known).
3. Briefly describe the rationale/objective for the proposed publication/abstract/poster/presentation. *(Why do you wish to make this information public? What is the added value that the public will gain from this information? What is your goal/aim for this presentation?)*
4. List specific methods or strategies that were or will be used to generate the information that you wish to share? *(How did you learn or plan to gather the information that you will share?)*
5. If you have already collected the data, please provide a summary of the lessons learnt and other outcomes of your intervention. *(Include information on how your strategy may have impacted your goals for community engagement in research, or other relevant goals.)*
6. Are you requesting any data from the MTN Statistical Data and Management Center (SDMC) for this concept? *(If so, please list: be as specific as possible. It is very important that you check any relevant SDMC deadlines before making your request.)*
7. What is your timeline for completion of this abstract or paper? *(Is there a particular meeting or publication that you have in mind? If so, what is the deadline for submission? How long do you think it will take you to complete the writing? What support do you have to write the paper and abstract?)*
8. Are you requesting any support from the MTN Community Resource Working Group to write the abstract or paper? *(If yes, please indicate the support needed)*

Submit this proposal to the relevant publication committee for the study or studies you will discuss in the concept. If you are not sure which committee(s) to contact, please send an email to the FHI 360 Community Program for further guidance.