20. THE MICROBICIDE TRIALS NETWORK PUBLICATION POLICY

All scientific publications (manuscripts, meeting abstracts, posters and oral presentations) that include data from Microbicide Trials Network (MTN) studies, or are funded by the National Institute of Health (NIH) through MTN must be reviewed and approved by the MTN Manuscript Review Committee (MRC) prior to being submitted for publication or presentation.

Prior to submission for MRC review, any scientific publication that is based on an MTN protocol must first be approved by the relevant Protocol Publications Committee (PPC) and be reviewed by the Investigational New Drug (IND) Sponsor and/or Product Developer, when applicable, as per the Clinical Trials Agreement (CTA) for the study, as described in Section 20.1.4.

Scientific publications that are not based on a specific MTN protocol, such as laboratory-related publications, statistical methodology publications and review articles, do not need to undergo PPC review.

This section outlines the guidelines and processes by which the MTN ensures that all scientific publications resulting from research conducted by the MTN or involving the use of MTN resources meet the same criteria and standards. All scientific publications must:

- Reflect accurate reporting of design, conduct and analysis of studies
- Be developed in a collaborative fashion with active participation by all investigators involved in the design and conduct of the study
- Be published expeditiously and made available to the scientific community
- Protect the confidentiality of medical, personal or product information in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, the requirements for the protection of human subjects and any applicable CTAs
- Comply with all NIH policies, including the *NIH Public Access Policy*
- Include a statement that acknowledges the MTN and NIH's support for the work and references the applicable NIH cooperative agreement number(s), unless a journal or conference policy precludes such acknowledgement

20.1 Responsibilities

20.1.1 Lead Author and Writing Team

The publication's Lead Author has the primary responsibility for writing the publication and for ensuring the publication undergoes all MTN required reviews (including Protocol Publications Committee (PPC), MRC, and IND Sponsor and/or Product Developer, as applicable). For publications that are suggested by an MTN working group (BRWG, BSWG, and others) or by a clinical site (i.e., a site-specific publication), the Working group or site share the responsibility.

The Lead Author or PPC may choose to identify a writing team. The writing team will consist of a subgroup of protocol team members and be coordinated by the Lead Author. All members of the writing team (i.e., co-authors) must sign off on a publication before it can be submitted to the PPC for review.

The Lead Author (or designee) is responsible for:

- Submitting a completed MTN Publication Concept Form to the PPC for review and approval (not required for primary manuscripts)
- Upon PPC approval, contacting the Protocol Statistician to discuss the analysis plan and develop a timeline for analysis completion
- Following a publication timeline as developed by the PPC
- Determining a co-author list and order according to Authorship Guidelines described in Section 20.3.5, with consultation with the PPC, if needed
- Developing a publication draft and submitting it for review by the following groups as outlined in the MTN Publication Policy:
    - Co-authors (Lead Author maintains co-author sign-off)
    - PPC, IND Sponsor, and/or Product Developer (if applicable) via MTN LOC [FHI 360] CRM
    - MRC (via MTN LOC [FHI 360] CRM)
- Once all approvals have been obtained, submitting to the target venue

20.1.2 Protocol Publications Committee

Once the authors have written a draft publication that has been reviewed and approved by the co-authors, the next step in the review process of MTN protocol publications is a review by the PPC. Each protocol team must have a dedicated PPC. At a minimum, this group will include the following:

- Protocol Chair
- Protocol Co-Chair, when applicable
- Protocol Statistician(s)
- DAIDS MO (and additional NIH MOs, as applicable)
- MTN LOC [FHI 360] CRM
- Other members as needed, such as representatives from the Protocol Management Team

The PPC is responsible for:

- Planning, reviewing and approving publication concepts for all protocol-related scientific publications
- Developing and monitoring publication timelines
- Assigning priorities in the development of publications
- Identifying manuscript writing teams, as needed
- Coordinating between and verifying consistency and accuracy across multiple study publications
- Adhering to the publication review procedures outlined in this policy
- Reviewing the publication to ensure that the publication accurately reports the design, conduct and analysis of the study, prior to submission for MRC review and approval

The PPC should use the checklist below as a tool in its review of all publications.

Publication Final Review Checklist:

- Check to ensure accuracy in:
    - Trial design description
    - Results (data analysis)
    - Conclusions (interpretation of results)

- Check to ensure publications (including posters):
    - Meet standard medical writing practices and provide clear and transparent reporting (refer to Section 20.3.6 for specific guidelines)
    - Include the MTN Study Protocol Number
    - Are organized to ensure clarity and meet formatting guidelines

20.1.3 Protocol Chair

In addition to serving as the lead person on the PPC, the Protocol Chair is responsible for the following (or may delegate to the MTN LOC [FHI 360] CRM):

- Ensuring that authors are aware of the MTN Publication Policy and all applicable NIH policies, including the *NIH Public Access Policy* (http://publicaccess.nih.gov)
- Coordinating PPC review of publications prior to their submission to the MRC

- Ensuring necessary reviews (including IND sponsor and/or Product Developer and funders) have occurred before submitting the publication to the MRC
- Consolidating and communicating PPC and IND Sponsor/Product Developer reviewer comments to the authors
- Tracking the status of publications
- Ensuring that the MRC is routinely updated regarding publication status

20.1.4 IND Sponsor and/or Product Development Organization

The IND Sponsor and/or Product Developer, as applicable, must be provided the opportunity to review and comment on manuscripts and abstracts (and possibly posters and oral presentations) according to the terms in the CTA for the study. The IND Sponsor and/or Product Developer reviews the publication either at the same time of the PPC review or following the PPC review, as determined by the Protocol Chair (or the MTN LOC [FHI 360] CRM).

20.1.5 Manuscript Review Committee

The purpose of the MRC review is to ensure that all publications resulting from research conducted by the MTN or involving the use of MTN resources meet high standards of scientific quality and integrity. The MRC review provides an independent review after thorough editing by the co-authors, and for publications that are related to a specific MTN protocol, by the PPC. The MRC review ensures the publication meets the general standards of peer-review journals and ensures the publication correctly acknowledges MTN and funders. The MRC is responsible for ensuring the publication complies with all applicable NIH guidelines.

Membership in the MRC includes the following:

- MRC Chair(s)
- MTN LOC (University of Pittsburgh [Pitt]) Manuscript Coordinator

The MRC will enlist a variety of persons across the MTN as reviewers. Reviewers may include persons from the Statistical and Data Management Center (SDMC), the Laboratory Center (LC), the Behavioral Research Working Group (BRWG), the Biomedical Science Working Group BSWG, Clinical Trials Units/Clinical Research Site investigators as well as *ad hoc* MTN members or non-members who are experts knowledgeable in a particular research area. MTN reviewer guidelines can be found on the MTN website under the "Information for Reviewers" page under the Publication Development and Review section (http://www.mtnstopshiv.org/sites/default/files/mtn_mrc_guidelines_for_mrc_reviewers_final_01mar2017.pdf).

The MRC Chair(s) and MTN LOC (Pitt) Manuscript Coordinator are responsible for managing the MRC peer-review process via Datavision™, a commercial publication planning and tracking software application. This includes the following activities:

- Designating an MRC reviewer for each publication and sending the review request(s) via Datavision
- Tracking MRC reviews to ensure the review process is completed in a timely manner
- Collating and summarizing the MRC reviewer(s) recommendation (i.e., “Approved” or “Not Approved-Revisions Required”) and suggested revisions in Datavision
- Communicating MRC reviewer recommendations to the Lead Author via Datavision

- Serving as the main contact for managing, maintaining and updating Datavision (to be conducted by MTN LOC (Pitt) Manuscript Coordinator)
- Ensuring proper acknowledgement of MTN and its sponsors in all publications

20.2 Definitions

Primary Publications/Manuscripts
Peer-reviewed scientific publications that report the findings of primary study objectives, as described in an MTN study protocol.

Secondary Publications/Manuscripts
Peer-reviewed scientific publications that report the findings of secondary study objectives, as described in an MTN study protocol, or other descriptive analyses related to the study objectives (such as a modified analysis of a behavioral objective). Secondary publications may also address scientific questions that are not specified as study objectives in an MTN study protocol, but rely on data collected during the study for additional analyses.

Tertiary Publications/Manuscripts
Peer-reviewed scientific publications resulting from research conducted in support of MTN activities that do not rely on MTN data (for example, literature reviews).

Publications Based on Public Use Data Sets
Publications based on MTN study data that are made available to the public in special data sets prepared by the SDMC expressly for broad dissemination. In general, all identifying information is stripped out of Public Use Data Sets so they may be used without consulting the relevant Institutional Review Board/Independent Ethics Committee.

20.3 Procedures

Table 20.1 Overview of Publication Development and Review Procedures*

Review of concept for publication by PPC	• **Lead Author** completes MTN Publication Concept Proposal Form and submits to PPC via **LOC (FHI 360) CRM** • **PPC** approves, rejects or requests revisions
Approved concept is added to publication plan/timeline and manuscript/abstract is developed	• If **PPC** approves, writing team is created as needed and the concept is included in the Protocol Publication Timeline and documented (by **LOC [FHI360] CRM**) in Datavision • **Lead Author** and writing team develop the manuscript/abstract
Review of manuscript/abstract by PPC and IND Sponsor/Product Developer	• **Lead Author** submits manuscript/abstract to **PPC** via **LOC (FHI 360) CRM** • **PPC** reviews and provides feedback to **Lead Author** • Upon PPC approval, **Lead Author** submitts to **IND Sponsor/Product Developer** review (per the terms of the study CTA) via **LOC (FHI 360) CRM**
Submission of manuscript/abstract to MTN MRC Review	• Once **PPC and IND Sponsor/Product Developer (per CTA)** comments have been addressed and Protocol Chair has provided final approval to submit for MTN MRC review, **Lead author** submits publication to **MRC** via **LOC [FHI 360] CRM,** who uploads to Datavision
Review of manuscript/abstract by MTN MRC	• **MTN LOC (Pitt) Manuscript Coordinator** designates **MRC Reviewer(s)** (blinded review) and sends review request (via Datavision) • **MRC Reviewer (s)** provides a recommendation ("**Approved" or "Not Approved- Revision Required**") and suggested revisions (Via Datavision) • **MTN LOC (Pitt) Manuscript Coordinator** collates recommendations and provides feedback to **Lead Author** (via Datavision) • If publication is **not approved**, **Lead Author** revises and resubmits to MRC (via Datavision)
Submission of manuscript/abstract to journal or conference	• Upon MRC approval **Lead Author** may submit publication to target journal or conference

*Publications related to specific MTN protocols

20.3.1 Publication Planning: Publications Concept Development

A primary manuscript (or possibly two primary manuscripts for studies with multiple primary endpoints) will be developed for each protocol. No concept submission is required for *primary* manuscripts or abstracts; however, a completed publication concept is required to be submitted to the PPC for any other manuscripts or meeting abstracts for the study (i.e., secondary and tertiary publications). If the proposed concept requires the use of data from multiple MTN studies, the concept proposal needs to be submitted to all relevant MTN LOC [FHI 360] CRMs. MTN LOC [FHI 360] CRMs will then coordinate and manage the concept submission to all relevant PPCs. The concept must be approved by all the applicable PPCs before moving forward.

- Development of the concept and submission to PPC for approval is the responsibility of the publication Lead Author. The MTN publication concept form must be used for this purpose. This is a universal form to be used across all MTN protocols. The form, "MTN Publication Concept Proposal Form", is available on the MTN website (http://www.mtnstopshiv.org/research/publications/publication-development-and-review/support-materials-and-guidelines) - see form posted under the "Policies, Guidelines and Forms" heading. Once a concept has been approved by the relevant PPC(s), it is the Lead Author's responsibility to contact the Protocol Statistician(s) to discuss the analysis plan and develop a timeline to complete the analysis.

Table 20.2 outlines the sections of the MTN MOP pertaining to the processes involved for various types of publications and data requests.

Table 20.2 Applicable MOP Sections for MTN Data Publication, Ancillary Study, Secondary Data Analysis, and Dataset Requests: Where to Look

	Publication Process (MOP Section 20)	Ancillary Study Request Process (MOP Section 21.1)	Secondary Data Analysis Request Process (MOP Section 21.2)	Dataset Request Process (MOP Section 21.3)
Are you a member of the Protocol Team requesting SDMC analysis of study data?	X			
Are you *not* a member on the Protocol Team requesting SDMC analysis of study data?			X	
Are you requesting approval for new data collection, data abstraction from participant records (for data that is not in the study database), or additional analyses done on lab specimens?		X		
Are you requesting a dataset (no analysis by SDMC needed) for purposes of conducting protocol-specified primary and/or secondary endpoint analyses (e.g., A/CASI dataset releases to the MTN BRWG)?	X			
Are you requesting a dataset (no analysis by SDMC needed) to conduct your own analyses *outside* of what is specified in the protocol for primary and secondary endpoint analyses?				X

For approved concepts, the PPC may assist the Lead Author in identifying other writing team members.

20.3.2 Publication Timeline Development and Monitoring

Primary study results

The PPC develops a publication timeline prior to initiating publication development. The Protocol Statistician, as a member of the PPC, coordinates with others at the SDMC to ensure timelines are feasible. Ideally, primary results should be presented at a key medical/scientific

meeting as soon as possible once the data are analyzed, which is determined by the Protocol Chair(s), Lead Author [if other than the Chair(s)], and Protocol Statistician.

The primary results manuscript should be submitted to MRC review within approximately **six months** following study database lock date. This allows for timely reporting of study outcomes.

Typically, primary results abstract/s must be accepted for presentation before other abstracts related to the protocol can be submitted to any meeting. Similarly, primary results manuscripts must be accepted for publication before manuscripts containing primary study data can be submitted for publication. However, publications that do not report study results, such as baseline data or operational issues, may be submitted to a meeting or a journal prior to submission of a the primary abstract or manuscript, with approval from the MTN MRC. To obtain approval from the MRC, the Lead Author should email the MTN LOC (Pitt) MRC Coordinator with this request (mtnMRCcoordinator@mtnstopshiv.org).

General Guidelines for Publication Timelines

Ideally, the PPC develops a publication timeline prior to initiating publication development. In developing the timeline for any publication, it is imperative that the Protocol Statistician provide input to the PPC from SDMC colleagues to ensure the timelines are feasible.

At a minimum, a publication timeline should contain the following information:

- MTN protocol number
- Expected date of last participant follow-up visit (for primary manuscript/abstract)
- Expected date that data will be locked (for primary manuscript/abstract)
- Expected date for completion of SDMC analysis
- Start date of manuscript preparation
- Expected date of publication submission to the PPC for review
- Expected date of publication submission to the IND Sponsor and/or Product Developer for review according to the timeline specified in the study CTA
- Expected date of submission to the MRC
    - Abstracts must be submitted to the MRC at least two weeks prior to the conference-specified abstract submission date
    - Posters must be submitted to the MRC at least two weeks prior to the conference date
    - Oral presentations must be submitted to the MRC approximately one week prior to the conference date
- Deadline for submission to the conference or journal, if applicable

The PPC is responsible for monitoring the timelines set forth in the manuscript concept and for reporting to the MRC. The Protocol Chair or MTN LOC (FHI 360) CRM shares the study's publication timeline with the MRC Chair(s) and MTN LOC (Pitt) Manuscript Coordinator.

After a concept is approved, the protocol LOC (FHI 360) CRM will enter the publication concept details and suggested timelines into Datavision. The PPC and the MRC Chair(s) [or MTN LOC (Pitt) Manuscript Coordinator on behalf of the MRC Chair(s)] are responsible for routinely tracking progress on manuscript development from the time of concept review through submission for MRC review. The MTN LOC (Pitt) Manuscript Coordinator tracks progress of publications from the time of submission to MRC through approval by MRC. The PPC and MTN

LOC (Pitt) Manuscript Coordinator track and document progress of publications from the time of submission to target journal/meeting through presentation/publication in Datavision. The MRC Chair(s) or MTN LOC (Pitt) Manuscript Coordinator will provide progress reports across protocols to MTN Leadership, as requested.

20.3.3 Publication Review Process

1. Co-Author Review
   After the concept has been approved by the PPC, the Lead Author, and the writing team/co-authors, if applicable, develop a 1st draft publication and follow the publication timeline developed by the PPC.

   All co-authors must review the publication and sign off on the publication (abstract, presentation or manuscript) before it can be submitted to the PPC for review; the Lead Author must maintain co-author sign-off approvals before submitting to PPC.

2. PPC and Sponsor Review
   The Lead Author submits the publication to the PPC (via the MTN LOC [FHI 360] CRM), indicating the target venue (journal or meeting) and noting associated deadlines. In the case of abstracts, posters and oral presentations, the authors should confirm the poster or presentation has been formatted according to the guidelines for that meeting.

   The MTN LOC (FHI 360) CRM submits the draft publication to the PPC members for review and comment. The LOC (FHI 360) CRM consolidates and communicates PPC comments to the Lead Author.

   A representative from the protocol's IND Sponsor and/or Product Developer organization must also review the publication as defined in the CTA for the study. The protocol team may include the IND Sponsor and/or Product Developer organization representative in the PPC review (i.e., simultaneous review by PPC and Sponsor) or send the publication to the Sponsor and/or Product Developer representative after PPC approval is in place (sequential review). Again, the MTN LOC (FHI 360) CRM consolidates and communicates IND sponsor and/or Product Developer organization comments to the Lead Author.

   After the Lead author has addressed all the PPC and IND Sponsor and/or Product Developer review comments and revised the publication accordingly, the Lead Author sends the revised publication to MRC review via the MTN LOC (FHI 360) CRM. The revised publication is not sent back to the PPC at this stage, unless there are substantial changes or the PPC requests this additional review step.

   Note: A publication should not be submitted to the MRC until it has been formatted to the style designated by the conference or journal.

3. MRC Review
   The MTN LOC (FHI 360) CRM uploads the draft publication to Datavision and initiates the MRC review process (activates the "MRC Coordinator Review and Assign the MRC Reviewer" step). The MRC Chair(s) or MTN LOC (Pitt) Manuscript Coordinator then designates an MRC reviewer and activates an "MRC Review/Approval" step. The MRC reviewer receives an email notification (generated by Datavision) with a web link to the publication available for review on the secure Datavision Reviewer's web portal

(https://mtn.envisionpharma.com/dv_mtn/) with step-by-step instructions explaining how to download the publication document, and upload the revisions and comments. Additional instructions on the use of Datavision are available on the MTN website at (http://www.mtnstopshiv.org/sites/default/files/datavision_use_instructions_reviewer_and_author.pdf).

The MRC reviewer will conduct a review based on MTN guidelines available on the MTN website (see the Information for Reviewers page posted under the Publication Development and Review section - http://www.mtnstopshiv.org/sites/default/files/mtn_mrc_guidelines_for_mrc_reviewers_final_01mar2017.pdf) and will provide a recommendation (APPROVED or NOT APPROVED-REVISION REQUIRED) as well as comments and possibly specific suggested revisions within the publication document.

Once the review has been completed, the MRC Chair(s) or MTN LOC (Pitt) Manuscript Coordinator reviews the recommendation and comments and provides these to the Lead Author, via Datavision. An automated email, generated by Datavision, is sent to the Lead Author providing a link to the recommendation along with the reviewer's comments and suggested revisions.

If the MTN MRC recommendation is APPROVED:

- If APPROVED but no comments are provided, the Lead Author may submit the publication as-is to the target venue.
- If APPROVED but minor comments were provided, the author may revise the publication based on the suggested comments and then submit the publication to the target venue.

If the MTN MRC recommendation is NOT APPROVED- REVISIONS REQUIRED:

- The author needs to revise the document based on MRC reviewer comments and then resubmit the publication for an additional MRC review. Only upon obtaining a final "APPROVED" recommendation may the author submit the publication to the target venue.

The target timeline for reviewer's comments to be available to the Lead Author of a manuscript is 10 working days. The target timeline for the review of abstracts, posters, and presentations is four working days. If the MRC provides a "NOT APPROVED-REVISIONS REQUIRED" recommendation, the Lead Author must address comments before resubmitting the publication for another MRC review.

After the MRC approves the publication, the Lead Author may submit it to the target venue (journal or conference).

For publications that are not protocol-specific (for example, laboratory publications that describe a validation process that used samples from multiple protocols), the Lead Author will ensure that all necessary reviews of the publication have occurred prior to submitting it to MRC for review. For instance, reviews may be required by IND Sponsors and/or Product Developers who provided study product for analysis through a Materials Transfer Agreement (MTA). The Lead Author will forward the publication via email to the MTN LOC (Pitt) Manuscript Coordinator. Then the MTN LOC (Pitt) Manuscript Coordinator will assign an MRC reviewer(s) and forward the publication for MRC review as described above.

Disputes: Disputes with respect to the manuscript development and preparation process should be addressed within the PPC and writing teams. Failing resolution at this stage, the issue may be raised with the MRC. If the MRC cannot resolve the dispute, the MRC Chair(s) will refer it to the MTN EC for final resolution. If suggestions from the MRC reviewer conflict with the PPC's directives, the Lead Author should refer the matter to the MRC Chair(s) who will communicate with the Protocol Chair to resolve the conflict.

Third-Party Agreements: Third-party agreements with IND Sponsors and/or Product Developers will include an agreement on publications policy and authorship in accordance with the guidelines set forth in the study's relevant MTA or CTA.

20.3.4 Publication Submission

Abstracts or manuscripts may not be submitted for publication without review by the PPC, the MRC, funders, the IND Sponsor and/or Product Developer, as applicable and as described in Sections 20.3.1 – 20.3.3. Typically, primary study manuscripts must be accepted for publication before other abstracts or manuscripts containing primary study data can be submitted. (Publications that do not report results, such as those using baseline data only or reporting operational issues may be published prior to the primary manuscript). If an author requests an exception to this rule, it will be considered by the PPC and MRC.

At the time the abstract or manuscript is submitted for publication, the Lead Author provides a copy of the submitted version to the PPC and, via Datavision, to the MRC for tracking purposes. The Lead Author uploads a copy of the submitted version to Datavision via a link that is provided in the MTN MRC approval email notification or in a separate Datavision email notification titled "Upload Submitted Document". Copies of the submitted publication will be provided to the IND-Sponsor/Product Developer, via Datavision, by the MTN LOC (Pitt) Manuscript Coordinator.

Lead Authors should notify the Protocol Chair(s), MTN LOC (FHI 360) CRM and MTN LOC (Pitt) Manuscript Coordinator of any updates regarding the journal or conference review outcome and the status of the publication (i.e., accepted for publication, revision required, rejected, resubmitted to new journal, published).

For journal submission, response to any feedback and/or request for revisions required by the journal editor or reviewer will be provided by the Lead Author, in consultation with the writing team. If the requested changes to the manuscript are not substantive and do not modify the analyses or conclusions, the Lead Author can revise the manuscript and resubmit without additional PPC or MRC reviews, but the author must inform the PPC that this is being done. However, if journal review feedback indicates the need to revise the paper's essential components, the author may not resubmit the revised manuscript to the journal until both the PPC and MRC have completed second reviews. The same is true if the manuscript is submitted to another journal with minimal changes; in this case, the author should notify the PPC and MTN LOC (FHI 360), who will notify the MRC of the change in the target journal. It is the responsibility of the PPC to determine if edits are substantive enough to modify the analyses and/or conclusions of the manuscript previously endorsed by the MRC. The publication file should be updated within Datavision to reflect the new manuscript version and the name of the new target journal.

Email notifications will be provided, via Datavision, to the MTN LOC (Pitt) Communications and External Relations Team when abstracts, presentations or manuscripts are accepted for publication or presentation.

Upon publication, the MTN LOC (Pitt) Manuscript Coordinator is responsible for routinely updating MTN PIs and DAIDS of published manuscripts and posting MTN publication information to the MTN website.

20.3.4.1 Oral and Poster Presentations

The PPC and MRC, and if necessary, the IND Sponsor and/or Product Developer, must review and approve final drafts of oral and poster presentations in advance of the conference deadline and prior to their submission.

20.3.4.2 Acknowledgments

All publications (i.e., manuscripts, abstracts, oral and poster presentations) and data dissemination documentation should include both an acknowledgement of the MTN and NIH's support for the work, with reference to the applicable award numbers, and a disclaimer (unless the journal's policy precludes such an acknowledgment). The following language should be used:

> The study was designed and implemented by the Microbicide Trials Network (MTN) funded by the National Institute of Allergy and Infectious Diseases through individual grants (UM1AI068633, UM1AI068615 and 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 (NIH). [*Optional sentence:* The work presented here was funded by NIH grants UM1AI068633 [*and UM1AI068615 or UM1AI106707, as relevant]*. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

The MTN LOC, LC and SDMC each have a different award number: *LOC: UM1AI068633; SDMC: UM1AI068615; LC: UM1AI106707*. The Lead Author or MTN LOC (FHI 360) CRM should consult with the Protocol Chair and DAIDS MO for the study in question to determine the correct cooperative agreement number(s) to be cited and advise the MTN LOC (Pitt) Manuscript Coordinator of this information. If not all three award numbers are relevant to the publication, use the following optional sentence and cite the relevant award numbers: "The work presented here was funded by NIH grants UM1AI068633 and UM1AI068615" *or* "The work presented here was funded by NIH grants UM1AI068633 and UM1AI106707" *or* "The work presented here was funded by NIH grants UM1AI068633".

20.3.4.3 Requirement to Post Journal Articles to PubMed Central (NIH Public Access Policy)

The *NIH Public Access Policy* requires that all publications resulting from NIH-funded studies be accessible to the public via PubMed Central (PMC) no later than 12 months after publication. PMC is the NIH digital archive of biomedical and life sciences journal literature. It is free and accessible at http://www.ncbi.nlm.nih.gov/pmc/. Final, peer-reviewed manuscripts must be submitted to the NIH Manuscript Submission System (NIHMS) upon acceptance for publication, and be made publicly available on PMC no later than 12 months after the official date of publication.

Because the MTN is funded by the NIH, any publication resulting from an MTN study must meet the *NIH Publication Access Policy*.

It is the responsibility of the Lead Author to ensure that a journal article be posted on PMC. While many journals/publishers automatically post the final published version of an NIH-funded article directly to PMC on behalf of the author, some journals require the author to make special arrangements to post directly to PMC or that the author or designee submit the publication to the NIHMS. Detailed submission instructions are available online at: http://publicaccess.nih.gov/index.htm.

20.3.5 Authorship Guidelines

Roles of authors and contributors in manuscripts submitted to peer reviewed journals are defined by the International Committee of Medical Journal Editors (ICMJE) — *Recommendations for the Conduct, Reporting,* Editing and *Publication of Scholarly Work in Medical Journals (ICMJE).* As noted in section II of the ICMJE recommendation, (http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html), authorship should be based on **all four** of the following criteria:

- Contributes substantially to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafts the abstract or revises it critically for important intellectual content; AND
- Provides final approval of the version to be presented or published, AND
- Agrees to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors. Alone, acquisition of funding, collection of data or general supervision of the research group does not justify authorship. Each author should have participated sufficiently in the work to take public responsibility and credit for certain portions of the content. Those who do not meet all four authorship criteria but provided substantial contribution should be named in the acknowledgement section.

The following approach should be considered to operationalize these authorship guidelines:

- The first author should be the person who is leading the data analysis and interpretation and is writing the abstract/manuscript. It is the responsibility of the Lead Author to ensure and document that all co-authors have reviewed and approved the manuscript/abstract prior to submission and to maintain documentation of any forms the journal requires authors/co-authors to complete.
- Team members who contributed substantially to the conceptualization, design and/or implementation of specific aspects of the study should be included as an author or co-author on abstracts/manuscripts related to that aspect of the study (for example, safety measures, behavioral measures or informed consent issues).
- If data from more than one site are included in a publication, a representative from each site should be included as a co-author whenever possible. When abstract submission guidelines limit the number of co-authors, the Protocol Chair/PPC will facilitate site representation/authorship decisions, making every effort to ensure parity across sites over time.

- All authorship lists for abstracts/manuscripts that include data from more than one site should include the wording “on behalf of the MTN-XXX Protocol Team for the Microbicide Trials Network” at the end of the authorship list.
- The SDMC statistician who works with the first author to analyze the data for the abstract (if applicable) should be included as a co-author. The Protocol Statisticians are responsible for designating the most appropriate SDMC staff member to the authorship team.
- Representatives from the BRWG, BSWG, Community Working Group (CWG) and members of the study management team (i.e., MTN LOC (FHI 360), MTN SDMC, MTN LOC (Pitt), and MTN LC) who have contributed substantially to the writing of the publication or to the conduct of the study should be given consideration for inclusion as co-authors on publications that present data on the primary and secondary study objectives and/or describe the study design and conduct.
- For publications presenting data on primary and secondary study objectives, the Protocol Chair should be given the option of being included as a co-author.
- When U.S. Government staff (for example, employees from the NIH and the Centers for Disease Control and Prevention) are co-authors, the pertinent organization must approve manuscripts, and the U.S. Government staff person is responsible for obtaining the necessary approvals.

20.3.6 Writing Guidelines

Authors should follow standard guidelines for medical writing and manuscript preparation, including:

- ICMJE manuscript guidelines (http://www.icmje.org/recommendations/browse/manuscript-preparation/).
- Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines and checklist (http://www.consort-statement.org/consort-2010), when reporting on randomized controlled studies.

20.3.7 Publications of Study Data from an SDMC-Released Public Use Data Set

Federal research sponsors often require that data be made available to the public in the form of public use data sets. Public use data sets for MTN studies are prepared by the SDMC expressly for this purpose. If study data have been released by the SDMC as a public use data set, concepts and manuscripts may be developed independent of MTN oversight and do not require a review by the PPC, BSWG, BRWG or MRC. The MTN is not responsible in any way for the content of manuscripts developed using these data.

20.3.8 Public Dissemination of Results Being Reported in a Manuscript or Abstract

Some manuscripts or abstracts may contain results that are considered newsworthy or are of interest to external stakeholders. NIAID, and, when applicable, the National Institute of Mental Health (NIMH) and/or the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), are responsible for determining the way results are publicly disseminated and ensuring that the process meets the terms of a study’s specific CTA. When MTN study results are being published in a journal or presented at a scientific meeting, the NIAID Office of Communications and Government Relations, the DAIDS Workforce Operations, Communications and Reporting Branch, and the MTN Communications and External Relations Team coordinate media outreach and public dissemination. They work with the study’s Lead Author, the Protocol Chair, MTN Principal Investigator (PI), MTN co-PI and others at the discretion of NIAID and in accordance with relevant embargo policies (see Section 8 of this

manual for further information about Public Information Policy and Press Releases/Public Statements).

20.3.9 Conflict of Interest Disclosure

Journals and meetings often require submission of conflict of interest statements. See the ICMJE guidelines and sample forms at http://www.icmje.org/conflicts-of-interest.