20. NETWORK PUBLICATION POLICY 20-1
20.1 Definitions 20-2
20.2 Responsibilities 20-3
20.3 Procedures 20-7
20.3.1 Publication Planning: Publications Concept Development 20-7
20.3.2 Publication Development: Determine Lead Author and List of Co-Authors ... 20-9
20.3.3 Publication Development: Timeline Development and Monitoring 20-9
20.3.4 Publication Review Process 20-10
20.3.5 Publication Submission 20-14
20.3.6 Publication Progression 20-15
20.3.7 Acknowledgments 20-16
20.3.8 NIH Public Access Policy 20-17
20.3.9 Authorship Guidelines 20-17
20.3.10 Writing Guidelines 20-19
20.3.11 Publications of Data from an MTN-Approved Ancillary Study 20-19
20.3.12 Publications of Data from an SDMC-Released Public Use Data Set 20-19
20.3.13 Public Dissemination of Results Being Reported in a Publication 20-19
20.3.14 Conflict of Interest Disclosure 20-19

20. NETWORK PUBLICATION POLICY

All scientific publications (manuscripts, conference abstracts, posters, and oral presentations) that include data from Microbicide Trials Network (MTN) studies are funded by the National Institutes of Health (NIH) through the 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) (excluding posters and oral presentations) and be reviewed by the Product Developer, when applicable, as per the Clinical Trials Agreement (CTA) for the study, as described in Section 20.3.4.

Any scientific publication that is not based on a specific MTN protocol, such as laboratory-related publications, statistical methodology publications and review articles, does not need to undergo PPC review. However, the publication may need to be reviewed by the Product

Developer who provided study product for analysis through a Materials Transfer Agreement (MTA), if applicable.

This section outlines the guidelines and describes the overall 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 Definitions

Datavision/iEnvision (to be referred as "Datavision" throughout Section 20)
A commercial publication planning and tracking software application, used to manage, track and archive MTN publications, including execution of several required MTN publication review steps.

Study-Specific Publication Plan
A document developed by the study PPC, which is based on the MTN Publication Policy but includes additional details and procedures customized to the specific study. A Study-Specific Publication Plan is developed typically for larger studies (Phase III and/or IV clinical trials) or as needed.

MTN Publications
All scientific publications (manuscripts, conference abstracts, posters and oral presentations) that include data from MTN studies, are funded by the NIH through the MTN. All MTN publications must be reviewed and approved by the MTN MRC prior to being submitted for publication or presentation.

MTN Protocol Publication Type Categories (Based on Study Objectives):

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 Statistical and Data Management Center (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 (IRB/IEC).

***MTN Publication Review Process and Management Categories*:**

Protocol-Related Publications
MTN Publications that are related to specific MTN protocols. These publications must undergo the full MTN review process as described in the MTN Publication Policy, including Co-Author, PPC, Product Developer(s) and MRC. The Lead Author is responsible for managing the Co-Author review step, while the Protocol Chair [delegated to the MTN LOC (FHI 360) CRM] is responsible for coordinating the PPC, and/or Product Developer(s), and submitting the publication to MRC review.

Non-Protocol-Related Publications
MTN publications that are not related to specific protocols (for example, laboratory publications that describe a validation process that used samples from multiple protocols). The Lead Author for a non-protocol specific publication is responsible for managing and ensuring that all necessary reviews of the publication have occurred prior to submitting it to MRC review, including Co-Author (always) and Product Developer(s) (if applicable, due to an MTA).

20.2 Responsibilities

Lead Author and Writing Team
The publication's Lead Author is responsible for the life-cycle management (concept submission, development, scientific reviews, finalization and implementation) to ensure the accuracy and integrity of the publication. The Lead Author has the primary responsibility for the content/submission from suggesting a publication concept, writing the publication, ensuring the publication undergoes all MTN-required scientific reviews (including Co-Author and MRC, and PPC and Product Developer(s), as applicable). For publications suggested by an MTN working group (i.e., the Biomedical Science Working Group (BSWG) and others), or by a Clinical Trials Unit/Clinical Research 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 review and approve a publication before it can be submitted to the PPC for review (or to MRC review, for those manuscripts that do not require PPC 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 20.3.9, in consultation with the PPC, if needed
- Developing a publication draft
- Submitting the publication for review by the following groups and reconciling the reviewers' comments within the revised versions of the publication in a timely manner:
  - Co-Authors
  - PPC and Product Developer [if applicable, via the MTN LOC (FHI 360) Clinical Research Manager (CRM)]
  - MRC [via MTN LOC (FHI 360) CRM]
- Tracking, collecting, and maintaining the Co-Authors comments and confirming that all Co-Authors reviewed and approved the publication
- Collecting and/or verifying that conflict of interest information of all Co-Authors is collected/verified, if required by the journal or conference guidelines
- Once all approvals have been obtained, submitting the publication to the target venue
- Communicating with the journal or conference and responding to journal reviewers' comments (following manuscript submission), in cooperation with Co-Authors (and PPC if applicable)
- Communicating all changes in publication status (revise and resubmit, acceptance, rejection, publication) to the MTN LOC (FHI 360) CRM or MTN LOC [University of Pittsburgh (Pitt)] Manuscript Coordinator

Protocol Publications Committee

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)
- Division of AIDS (DAIDS) Medical Director (MO) (and additional NIH MOs, as applicable)
- The MTN LOC (FHI 360) CRM is a non-voting member but sits on the PPC to manage the publication process
- Other members may also participate 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
- Develop a Study-Specific Publication Plan (for Phase III or IV clinical trials, or as needed)
- Identifying manuscript writing teams, as needed
- Recommending a mentor for the Lead Author, if requested
- Coordinating between and verifying consistency and accuracy across multiple study publications
- Adhering to the publication review procedures outlined in this section
- 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

- Reviewing major revisions made to a publication in response to journal reviewers' comments or made for submission to a new journal. "Major revisions" are those that affect the essential components of the publication (i.e., main analyses or conclusions)

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

Publication Final Review Checklist:

Check to ensure accuracy of:

- 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 20.3.10 for specific guidelines)
- Include the MTN Study Protocol Number
- Are organized to ensure clarity and meet formatting guidelines

The PPC reviews the draft publication only after it has been reviewed and approved by the Co-Authors.

Protocol Chair

In addition to serving as the lead person on the PPC, and therefore responsible for all PPC-related responsibilities, the Protocol Chair is responsible for the following:

- Signing the approved Publication Concept Form to indicate PPC approval of the concept

The following additional Protocol Chair responsibilities can be delegated to the MTN LOC (FHI 360) CRM:

- Coordinating PPC review of publication concepts and publications in process
- Coordinating Product Developer review of publications in process
- Ensuring necessary reviews (including Co-Authors, PPC and Product Developer) have occurred before submitting the publication to the MRC
- Collecting, consolidating and communicating PPC and Product Developer reviewers' comments to Lead Author and documenting the comments/approval in Datavision
- Adding new publication files (following publication concept approval) in Datavision and activating relevant review activities, when applicable, in Datavision
- Tracking the status of publications after MRC approval and subsequent submission to journal or conference until publication
- Coordinating publication review timelines and other relevant issues with MTN LOC (Pitt) Manuscript Coordinator and ensuring that the MRC is routinely updated regarding publication status
- Ensuring that the Lead Author/Co-Authors are aware of the MTN Publication Policy and all applicable NIH policies, including the NIH *Public Access Policy* (http://publicaccess.nih.gov)

Product Developer

The Product Developer, as applicable, must be provided the opportunity to review and comment on publications (including manuscripts, abstracts, and posters and oral presentations), according to the terms in the CTA for the study.

Manuscript Review Committee

The MRC is responsible for developing policies and procedures related to MTN publications and for management of the MRC review step.

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 and comply with all applicable NIH guidelines, including acknowledgment of the MTN and its federal research funders. The MRC review provides an independent review after thorough editing by the Co-Authors, and for publications related to a specific MTN protocol, by the PPC and Product Developer.

Membership in the MRC includes the following:

- MRC Chair
- MTN LOC (Pitt) Manuscript Coordinator

The MRC will enlist a variety of persons across the MTN as MRC reviewers. Reviewers may include persons from the SDMC, MTN Laboratory Center (LC), BSWG, Clinical Trials Units/Clinical Research Site investigators as well as *ad hoc* MTN members or non-members who are experts in a relevant research area. MTN MRC Review 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 review is blinded – the reviewer's name is typically not revealed to the Lead Author. The MRC review is conducted per the MTN MRC review Guidelines (see MTN website https://mtnstopshiv.org/sites/default/files/mtn_mrc_guidelines_for_mrc_reviewers_final_01mar2017.pdf)

The MRC review is managed by the MRC Chair or MTN LOC (Pitt) Manuscript Coordinator and conducted via Datavision. 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 the MRC reviewer recommendation (i.e., "Approved with No Comments", "Approved with Minor Revisions" or "Not Approved- Major Revisions Required") and suggested revisions and communicating them to the Lead Author via Datavision
- Ensuring proper acknowledgement of MTN and its federal research funders in all MTN publications

The MRC Chair and the MTN LOC (Pitt) Manuscript Coordinator are responsible for managing the overall MTN publication processes and procedures by:

- Tracking [via collaboration with MTN LOC (FHI 360) CRMs for protocol-specific publications] and disseminating the status of MTN publications to MTN Leadership and DAIDS
- Coordinating and archiving protocol-specific publication documents in Datavision, in collaboration with Lead Author and MTN LOC (FHI 360) CRMs (to be conducted by MTN LOC (Pitt) Manuscript Coordinator)
- Serving as the main contact for managing, maintaining and updating Datavision (to be conducted by MTN LOC (Pitt) Manuscript Coordinator)

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 MTN **LOC (FHI 360) CRM** • **PPC** approves (and **Protocol Chair** signs concept), 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 **MTN LOC (FHI360) CRM]** in Datavision • **Lead Author** and writing team develop the manuscript/abstract
Review of manuscript/abstract by PPC and Product Developer	• **Lead Author** submits manuscript/abstract to **PPC** via **MTN LOC (FHI 360) CRM** who sends review request (via Datavision) • **PPC** reviews and provides feedback (Approval and comments) , via **Datavision. MTN LOC (FHI 360) CRM** provides feedback to **Lead Author.** • Upon PPC approval and addressing PPC comments, **Lead Author** submits to **Product Developer** review (per the terms of the study CTA) via **LOC (FHI 360) CRM,** who sends review request (via Datavision)
Submission of manuscript/abstract to MTN MRC Review	• Once **Product Developer** comments have been addressed, the **Lead Author** submits publication to **MRC** via MTN **LOC (FHI 360) CRM,** who sends review request (via 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 with No Comments", "Approved with Minor Revisions" or "Not Approved- Major Revisions 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** submits publication to target journal or conference

*Publications related to specific MTN protocols

20.3.1 Publication Planning: Publications Concept Development

The PPC develops, approves and maintains a master list of all planed study-related publications.

Primary Publications
A primary manuscript (or possibly two primary manuscripts for studies with multiple primary endpoints) will be developed for each MTN protocol. The development of primary manuscripts or abstracts does not require the submission of a publication concept form. This may include a primary publication based on data from an MTN-approved ancillary study.

Secondary Publications and any other MTN publications
For any other manuscript or conference abstract for the study (i.e., secondary and tertiary publications), a publication concept is required to be submitted by the protocol team member (and/or other individuals interested in a leading the development of a secondary publication – see Table 20.2) to the PPC via the study MTN LOC (FHI 360) CRM. 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 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), posted under the "Policies, Guidelines and Forms" heading. Each concept must be approved by the relevant PPC(s) and signed by all relevant Protocol Chairs. The signed concept is archived in a new record in Datavision by the MTN LOC (FHI 360) CRM.

Once a concept is approved, 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.

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

Table 20.2 outlines the sections of the MTN MOP pertaining to the processes involved for various types of publications and data requests. Publications based on secondary data analysis should undergo the same process as any MTN protocol-related publication. Details pertaining to the required process for publications based on an ancillary study are included in Sections 20.3.11 and 21.1.7 of this Manual. Details pertaining to the required process for publications based on public datasets are included in Sections 20.3.12 and 21.3.2 of this Manual.

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	X			

(e.g., A/CASI dataset releases to the MTN Behavioral Consultant)?				
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

20.3.2 Publication Development: Determine Lead Author and List of Co-Authors

Upon PPC approval of the publication concept, the Lead Author selects the Co-Authors/Writing Team. The Lead Author is typically the investigator who plans and submits the publication concept. For primary publications, the Lead Author is typically the Protocol Chair or Co-Chair.

The selection of Co-Authors/writing team by the Lead Author, in conjunction with members of the PPC, as appropriate, is based on pre-established criteria as described in section 20.3.9, Writing Guidelines, and if applicable, in the Study-Specific Publication Plan document. Authors are identified to ensure fair representation and participation across the protocol team.

For development of the first draft of the publication, the Lead Author and Co-Authors/writing team are to follow standard scientific guidelines and study-specific standards, as specified in section 20.3.10, and in Study-Specific Publication Plans. In addition, the Lead Author/Co-Authors must refer to the required publication guidelines/format of the targeted peer-reviewed journal(s) and conferences.

20.3.3 Publication Development: 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 conference 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. The MTN Steering Committee (SC) tracks the progress of primary manuscripts monthly, based on a report provided by the MTN LOC (Pitt) Manuscript Coordinator.

Typically, primary results abstract/s must be accepted for presentation before other abstracts related to the protocol can be submitted to any conference. 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 conference or a journal prior to submission of a the primary abstract or manuscript, with approval from the study PPC and MTN MRC. To obtain approval from the PPC and MRC, the Lead Author should email the study PPC (via email to study CRM) and MTN LOC (Pitt) MRC Coordinator (mtnMRCcoordinator@mtnstopshiv.org) with this request.

General Guidelines for Publication Planning and Timelines
The PPC may develop a Study-Specific Publication Plan that will highlight the MTN Publication Policy and include additional details and guidelines specific to the study, such as standard language/phrases to be used consistently across all study-related publications to describe the study, etc.

Ideally, the Lead Author 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 Lead Author to ensure the timelines are feasible. Timelines are developed based on the following information:

- 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 Product Developer for review according to the timeline specified in the study CTA
- Expected date of submission to the MRC for review
    - 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 Lead Author is responsible for monitoring the timelines set forth in the manuscript concept and for reporting timeline updates and/or delays to the MRC and the MTN LOC (FHI 360) CRM.

After a concept is approved, the protocol LOC (FHI 360) CRM (or designee) will enter the publication concept details and suggested timelines into Datavision. The PPC and the MRC Chair [or MTN LOC (Pitt) Manuscript Coordinator on behalf of the MRC Chair] 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/conference through presentation/publication in Datavision. The MRC Chair or MTN LOC (Pitt) Manuscript Coordinator will provide progress reports across protocols to MTN Leadership, as requested.

20.3.4 Publication Review Process

1. Co-Author Review
   After the concept has been approved by the PPC, the Lead Author, and the Co-Authors/writing team, if applicable, develop a 1st draft of the publication and follow the publication timeline developed by the PPC. In the development of the 1st draft, the Lead Author follows standard scientific guidelines and study-specific standards, as specified in the MTN Publication Policy and in the Study-Specific Publication Plan, if available. In addition, the Lead Author must refer to the required publication guidelines/format of the targeted peer-reviewed journal(s) and conference(s).

The Lead Author provides the first complete draft of the publication for review to the Co-Authors/Writing Team via email. All Co-Authors must review and approve the draft of the publication. The Lead Author integrates input from the Co-Authors/Writing Team into the publication, and retains all input received from Co-Authors. Co-Author comments should be ideally provided within approximately five business days (for abstracts and posters/oral presentations) and within approximately 10 business days (for manuscripts); however, these timelines may be adjusted according to the Lead Author and writing team as needed. All Co-Authors must review the publication and approve the publication (abstract, presentation or manuscript) before it can be submitted to the PPC for review; the Lead Author must maintain Co-Author approvals before submitting to PPC.

2. PPC Review

The Lead Author submits the draft publication (Co-Author approved version of the publication) to the PPC [via the MTN LOC (FHI 360) CRM], indicating the target venue (journal or conference) 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 conference.

The PPC review is coordinated by the MTN LOC (FHI 360) CRM as follows: The MTN LOC (FHI 360) CRM (or designee) submits the draft publication for PPC review via Datavision (i.e., uploads the publication to the relevant Datavision file, tags the version as “PPC” and initiates the “PPC review” step in Datavision). Each PPC reviewer receives an email (generated by Datavision) with a web link to the publication available for review on the secure MTN-customized Datavision website: (https://mtn.envisionpharma.com/ienv_mtn/desktop/login.xhtml?windowId=e8f). Approval and comments from each PPC are typically provided directly within Datavision or occasionally via email. If provided via email, the comments are manually archived in Datavision by the MTN LOC (FHI 360) CRM (or designee). If a member of the PPC does not respond within a specified deadline, and does not request more time for review, the MTN LOC (FHI 360) will close this review step and consolidate and communicate available PPC comments to the Lead Author via email.

If PPC members are also Co-Authors on the publication, the PPC review may occur during the Co-Author review step.

The PPC conducts a review and provides the feedback within Datavision:

- Recommendation as—
  - (1) Approved with No Comments or
  - (2) Approved with Minor Revisions or
  - (3) Not Approved - Major Revisions Required.
- May provide comments in the comments box and/or may suggest specific revisions provided within the publication document.

Following PPC review, the Lead Author addresses all PPC reviewer comments, revises the publication accordingly and submits the draft publication to Product Developer review (if applicable) 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.

If the publication is not approved by the PPC, the Lead Author re-sends the revised publication to MTN LOC (FHI 360) CRM for a PPC re-review.

Note: A publication should not be submitted to the Product Developer and MRC review until the primary author has confirmed it has been formatted to the style designated by the conference or journal.

Note: PPC review will not be required for posters and oral presentations. Instead, a copy of the draft version of the poster/oral presentation should be sent to the PPC (along with a deadline for comment) when it is sent for final co-authors review. The final publication (following review of the draft publication by the Product Developer (If applicable) and MRC review) should be sent to the PPC as a courtesy.

3. Product Developer Review

The Lead Author submits the draft publication (PPC approved version of the publication or Co-Author approved version for posters and oral presentations) to the MTN LOC (FHI 360) for Product Developer review. Typically, for manuscripts and abstracts, the PPC and Product Developer reviews are conducted as a sequential review (first PPC, then Product Developer). However, occasionally, due to time constraints, a simultaneous review may be conducted, as determined by the MTN LOC (FHI 360) CRM.

If the Product Developer is also a Co-Author on the publication, the Product Developer review may occur during the Co-Author review step.

The Product Developer review is coordinated by the MTN LOC (FHI 360) CRM via Datavision: The MTN LOC (FHI 360) CRM (or designee) submits the draft publication [PPC approved version of the publication (or Co-Author approved version for posters and oral presentations)] for Product Developer review via Datavision (i.e., uploads the publication to the relevant Datavision file, tags the version as “Drug Developer” and initiates the “Drug Developer review” step in Datavision, thereby initiating an automated email with a web link to the publication available for review on the secure MTN-customized Datavision website). Comments from the Product Developer are provided either directly within Datavision or via email. If provided via email, the comments are manually archived in Datavision by the MTN LOC (FHI 360) CRM (or designee). The MTN LOC (FHI 360) CRM (or designee) consolidates and communicates Product Developer organization comments to the Lead Author.

After the Lead Author has addressed the 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.

4. MRC Review

The MTN LOC (FHI 360) CRM (or designee) uploads the draft publication (Drug Developer reviewed/revised version of the publication or PPC approved version if no Drug Developer review is required) to Datavision, tags it as “MRC” and completes and ends the CRM Pre-Submission Checklist in Datavision.

The MTN LOC (Pitt) Manuscript Coordinator or MRC Chair (s) receives an automated email notice (automatically generated by ending the CRM Pre-Submission Checklist) that the draft publication is ready for MRC review. The MRC Chair or MTN LOC (Pitt) Manuscript

Coordinator then designates an MRC reviewer and initiates the “MRC Review/Approval” review step in Datavision.

The MRC reviewer receives an email (generated by Datavision) with a web link to the publication available for review on the secure MTN-customized Datavision website. Additional instructions for MRC reviewers on the use of Datavision are available on the MTN website at (https://mtnstopshiv.org/sites/default/files/ienvision_mrc_review_instructions_19aug21.pdf). The MRC reviewer conducts a review based on MRC review 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 provides the feedback within Datavision:

- Recommendation as—
    - (1) Approved with No Comments or
    - (2) Approved with Minor Revisions or
    - (3) Not Approved – Major Revisions Required.
- May provide comments in the comments box and/or may suggest specific revisions provided within the publication document.

Once the MRC review has been completed (i.e., an automated message indicating review completion is sent via Datavision to the MTN LOC (Pitt) Manuscript Coordinator), the MRC Chair or MTN LOC (Pitt) Manuscript Coordinator verifies that the standard MTN acknowledgment statement is included (for manuscripts and presentations/posters) and revises the statement, as needed. Then the MRC Chair or MTN LOC (Pitt) Manuscript Coordinator adjudicates comments with the MRC reviewer and provides both the recommendation and comments using the “Manuscript Review Committee Status and Approval Form” as well as providing the tracked changed MRC approved version of the publication, as applicable, to the Lead Author, via an email using a standard email template available within Datavision.

If the MTN MRC recommendation is APPROVED:

- If Approved with No Comments, the Lead Author may submit the publication as-is to the target venue (journal or conference).
- If Approved with Minor Revisions, the author may revise the publication based on the suggested comments and then submit the publication to the target venue.

Note: No resubmission to MRC is required.

If the MTN MRC recommendation is NOT APPROVED – MAJOR REVISION REQUIRED:

- The author needs to address and/or revise the document based on MRC reviewer comments and then resubmit the publication for an additional MRC review. For primary publications (manuscripts, abstracts, posters and oral presentations), if the MRC reviewer suggests major revisions, the revised publication should be shared and approved by PPC, before resubmission to MRC review.

Note: Only upon obtaining a final “APPROVED” recommendation (with or without minor comments/revisions) 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 (original submission and resubmission). The target timeline for the original review of abstracts, posters, and presentations is four working days for an original submission, and two working days for resubmission.

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

For publications that are not protocol-specific, 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 Product Developers who provided study product for analysis through an MTA. The Lead Author will forward the publication via email to the MTN LOC (Pitt) Manuscript Coordinator or MRC Chair. Then the MTN LOC (Pitt) Manuscript Coordinator or MRC Chair will assign an MRC reviewer 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 will refer it to the MTN Steering Committee 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 who will communicate with the Protocol Chair to resolve the conflict.

Third-Party Agreements: Third-party agreements with 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.

20.3.5 Publication Submission

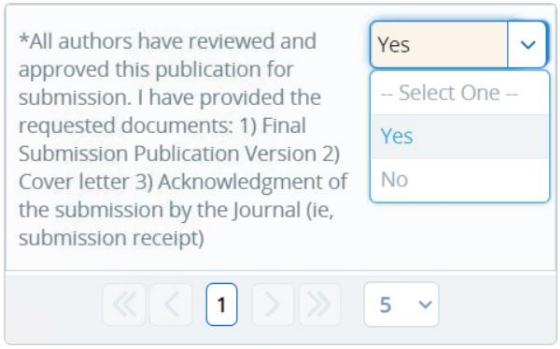
Abstracts or manuscripts may not be submitted to the target venue without review by the PPC, the MRC, and the Product Developer(s), as applicable and as described in Sections 20.3.1 – 20.3.4.

Typically, primary 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 a Lead Author requests an exception to this rule, it will be considered by the PPC and MRC.

The Lead Author revises the approved MRC-reviewed Publication, if applicable, as described above, and creates the Final Submission Publication. The MTN LOC (Pitt) Manuscript Coordinator ensures documentation from the MRC review step (i.e., draft version sent for MRC review, comments/recommendations) are archived in Datavision.

Following submission of an abstract or manuscript to a target venue, the Lead Author needs to provide a copy of the Final Submission Publication to the PPC and, via Datavision, to the MRC for tracking purposes. The Lead Author will receive a request via Datavision ("Upload submitted version") to upload copies of the following documents to Datavision: 1. The Final Submission Version Publication; 2. Acknowledgment of the submission by the conference or journal (i.e., submission receipt); 3. Cover letter (for journal submissions only). In addition, the Lead Author

is required to confirm that the publication was reviewed and approved by all authors, by responding to the statement provided in the Datavision “Upload submitted version” step.



The MTN LOC (Pitt) Manuscript Coordinator ensures submitted documentation (as described above) are archived in Datavision. Copies of the submitted publication may be provided to the Product Developer, via Datavision, by the MTN LOC (Pitt) Manuscript Coordinator, if requested or as per any agreements in place.

20.3.6 Publication Progression

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). A copy of communications with the key feedback/recommendations of journal reviewers should be provided to the MTN LOC (FHI 360) CRM and/or MTN LOC (Pitt) MRC Coordinator and archived (and updated) by the MTN LOC (Pitt) MRC Coordinator in Datavision.

For manuscript submissions, responses 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.

It is the responsibility of the Lead Author to determine if required edits are substantive enough to modify the essential components of the manuscript including key data analyses and/or key conclusions of the manuscript as previously endorsed by the PPC and MRC. Lead Author may consult with PPC chair to help determine if the revisions are substantive and require modification of essential components as defined above.

- If the requested changes to the manuscript are not substantive and do not modify the key analyses or conclusions, the Lead Author can revise the manuscript and resubmit without additional PPC or MRC reviews, but the Lead Author must inform the MTN LOC (FHI 360) CRM or PPC that this is being done.
- However, if journal review feedback requires major revisions, and indicates the need to revise the paper’s essential components, the Lead Author may not resubmit the revised manuscript to the journal until the PPC (and MRC, if applicable) have completed second reviews.

Following submission of the revised manuscript to the journal, a copy of the revised publication is emailed by the Lead Author to the MTN LOC (FHI 360) CRM and/or MTN LOC (Pitt) MRC Coordinator and archived by the MTN LOC (Pitt) MRC Coordinator in Datavision.

If a manuscript is rejected, the Lead Author identifies a new target journal, in consultation with the writing team/Co-Authors. If minimal changes are required (i.e., mainly format-related changes (i.e., lengths, focus) to meet the new journal format), the Lead Author submits the publication to the new journal and notifies the PPC and MTN LOC (FHI 360) CRM who notifies the MTN LOC (Pitt) MRC Coordinator of the new submission.

Similar rules about the need to resubmit to PPC (and MRC review) apply as above: It is the responsibility of the Lead Author to determine if edits are substantive enough to modify the essential components of a manuscript including key analyses and/or conclusions of the manuscript previously endorsed by the PPC and MRC. If substantive revisions to the essential components are required (as described above), the Lead Author submits the publication to PPC review and approval (and MRC if determined as necessary by PPC) prior to submission to the new journal. Similarly, if an abstract is rejected, the Lead Author identifies a new target conference, and informs the PPC on new target venue.

A copy of the new publication version, submitted to the new target journal, as well as copies of the cover letter and acknowledgment of the submission by the journal should be provided to MTN LOC (FHI 360) CRM (via email) or MTN LOC (Pitt) MRC Coordinator (via email or via Datavision). All documents are archived in a new relevant Datavision file, to reflect the current manuscript version and the title of the new target journal.

The Lead Author informs the PPC and/or MTN LOC (FHI 360) CRM and/or MTN LOC (Pitt) MRC Coordinator as to the status of the publication – acceptance and/or declination. The Lead Author ensures the accepted publication (for journal submissions) meets the NIH Public Access Policy as described in Section 20.3.8.

Upon publication, the MTN LOC (Pitt) Manuscript Coordinator updates the Datavision files (status and citation information) and archives copies of published/presented publications. Copies of the published/presented publications may be provided to the Product Developer via Datavision.

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

20.3.7 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).

Materials pertaining to studies completed prior to November 30, 2021 (i.e., all studies except for MTN-042) should include the following statement:

> 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. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

The MTN LOC, LC and SDMC each had different award numbers: *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".

Materials pertaining to studies not completed by November 30, 2021 [including MTN-042 (DELIVER)], should explain that the study is being conducted by the MTN, which from 2006 until November 30, 2021, was an HIV/AIDS clinical trials network funded by NIAID, with co-funding from NICHD and NIMH – all components of the US NIH.

> The study was designed and implemented by the Microbicide Trials Network (MTN). From 2006 until November 30, 2021, the MTN was part of the HIV/AIDS clinical trial network and was 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. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

20.3.8 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.

20.3.9 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 BSWG, Community Working Group (CWG) and members of the study management team [i.e., MTN LOC (FHI 360), MTN SDMC, MTN LOC (Pitt), Behavioral Researchers 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.

20.3.10 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.

20.3.11 Publications of Data from an MTN-Approved Ancillary Study

Publications resulting from ancillary studies are prepared and reviewed in accordance with relevant DAIDS and MTN policies. Specifically, manuscripts and abstracts (and posters/oral presentations) developed using data obtained via an MTN-approved ancillary study must undergo the MTN publication process described in this section, with a few notes:

- No publication concept form is required for the primary manuscript/abstract.
- All ancillary study publications need to undergo Co-Author and MRC reviews. However, PPC review and approval and Product developer(s) (if applicable) review are not required if no data collected and/or analyzed from an MTN study is used in the publication.

20.3.12 Publications of Data from an SDMC-Released Public Use Data Set

Federal research funders 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, abstracts (and related posters/oral presentations) and manuscripts may be developed independent of MTN oversight and do not require a review by the PPC, BSWG, or MRC. The MTN is not responsible in any way for the content of manuscripts developed using these data.

20.3.13 Public Dissemination of Results Being Reported in a Publication

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 CTA(s). When MTN study results are being published in a journal or presented at a scientific conference, the NIAID Office of Communications and Government Relations and the MTN Communications and External Relations Director coordinate media outreach and public dissemination in accordance with embargo policies. They work with the study's Lead Author, the Protocol Chair, MTN Principal Investigator and others at the discretion of NIAID (see Section 8 of this Manual for further information about Public Information Policy and Press Releases/Public Statements).

20.3.14 Conflict of Interest Disclosure

Journals and conferences often require submission of conflicts of interest statements. See the ICMJE guidelines and sample forms at http://www.icmje.org/conflicts-of-interest. Based on the process used at each publisher/journal for collection of conflicts of interest disclosures, the forms or related information are collected from Co-Authors either by the Lead Author or by the journal.