MTN-020/025 Publication Plan

1.0 MTN-020/025 Protocol Team Publication Goals

It is the goal of the MTN-020/025 Protocol Teams to ensure trial data are cleaned, analyzed, and completed for publication as soon as possible; publications utilizing MTN-020/025 data are published in a timely fashion; and all site leadership and management team members are provided an opportunity to develop or participate in the development of MTN-020/025 manuscripts.

2.0 MTN-020/025 Publication Committees

MTN-020:
The MTN-020 Protocol Publications Committee (PPC) will oversee the MTN-020 publication process. The Publications Committee will include the following individuals: Jared Baeten (Protocol Chair), Thesla Palanee-Phillips (Protocol Co-chair), Elizabeth Brown (SDMC Statistician), Lydia Soto-Torres (DAIDS Medical Officer), and Katie Schwartz (FHI 360 Clinical Research Manager). Other members from the protocol team will be consulted and asked to review concepts (to ensure feasibility as well as scientific merit), abstracts, and manuscripts as needed, based on expertise.

MTN-025:
The MTN-025 Protocol Publication Committee (PPC) will oversee the MTN-025 publication process. The MTN-025 Publications Committee will include the following individuals: Jared Baeten (Protocol Chair), Thesla Palanee-Phillips (Protocol Co-chair), Nyaradzo Mgodi (Protocol Co-chair) Elizabeth Brown (SDMC Statistician), Lydia Soto-Torres (DAIDS Medical Officer), and Ashley Mayo (FHI 360 Clinical Research Manager).

For both trials all qualitative concepts received by the PPC will first be forwarded and reviewed by the qualitative publications subcommittee, who will make a recommendation to the relevant ASPIRE/HOPE PPC.

2.1 Publication Committee Responsibilities

The responsibilities of the MTN-020/025 PPC include:

1. Setting priorities for MTN-020/025 data analyses (it is expected that analysis priorities will continuously be prioritized and reprioritized with SCHARP);
2. Developing an abstract template for team members to use, ensuring consistency in approach and language;
3. Triaging manuscript development and proposals from study investigators for use of data collected from MTN-020/025;
4. Ensuring the appropriate composition of MTN-020/025 analysis and writing teams;
5. Recommending a mentor for the lead author, if requested;

6. Confirming and finalizing the appropriate author list with the lead author for each MTN-020/025 publication;
7. Reviewing and providing feedback to authors on draft publications;
8. Adhering to the publication review procedures that are outlined in Section 20 of the MTN MOP;
9. Approving abstracts, manuscripts, oral presentations and posters prior to sponsor approval and MTN MRC submission;
10. Coordinating and verifying consistency and accuracy between multiple publications from the study;
11. Managing required sponsor approvals of all abstracts, manuscripts, posters and oral presentations (as required per Clinical Trials Agreement with IPM);
12. Establishing and monitoring timelines for publication development and review and routinely updating the MRC on publication status;
13. Disseminating and publishing as much information as is possible from the data collected during the course of MTN-020/025.

The responsibilities of the qualitative subcommittee include:

1. Review all qualitative concepts that come to the MTN-020/025 PPC and provide a recommendation to the PPC as to whether these concepts should move forward
2. Recommend qualitative mentors as needed

These objectives will be accomplished using the guidance of the MTN Publications Policy which is located in Section 20 of the MTN Manual of Operational Procedures:
http://www.mtnstopshiv.org/node/187

3.0 MTN-020/025 Concept Development Guidelines

Proposals for publications (abstracts or manuscripts) and presentations should be submitted to the MTN-020/025 PPC, utilizing the MTN Publication Concept Proposal Form available on the MTN website. These include concepts for both multi-site and single-site analyses. If a site-initiated concept is developed, the proposal should not be submitted to the MTN-020/025 PPC without prior approval from the site IoR. The site IoR should be cc'd on any site concept submission to the PPC. When any type of concept is proposed, the lead investigator (person submitting the concept) should identify a mentor to help guide the process. If the lead author does not have significant publication experience, it is recommended that a mentor be identified. The mentor does not need to have worked on ASPIRE/HOPE, but be very experienced in analysis/manuscript writing. The MTN-020/025 PPC can assist with this as needed. The mentor should be engaged during concept development and help lead a small writing team through all stages until publication. A mentor is also required when submitting conference abstracts.

Note that the ASPIRE PPC will meet monthly to discuss submitted concepts. Time permitting, MTN-025 concepts will be discussed during these scheduled calls. Should the volume of MTN-025 concepts warrant a separate meeting, ad hoc MTN-025 concept review calls will be scheduled. The

schedule for these calls for 2018 is below. Concepts must be received before this date to be reviewed, and authors will get feedback following the call (within the week). If concepts are submitted after this date, they will be reviewed at the next PPC review call, unless urgent review is needed (rare circumstances only). When concepts are approved, the lead author will be notified and asked to follow up with the protocol statistician directly for next steps on analysis support and timelines (as appropriate).

Concept Review Dates:
January 5, 2018
February 2, 2018
March 2, 2018
April 6, 2018
May 4, 2018
June 1, 2018
July 6, 2018
August 3, 2018
September 7, 2018
October 5, 2018
November 2, 2018
December 7, 2018

Qualitative concepts will be submitted to the ASPIRE/HOPE PPC per the usual process. The PPC will first ask the qualitative subcommittee to review these concepts, and then provide a recommendation to the PPC. If the lead author is requesting a mentor, or the qualitative subcommittee notes that a mentor is needed, FHI 360 will reach out to the lead author and request a mentorship application, which consists of a current CV, completion of the mentorship application form (see Appendix II), and a writing sample from the lead author. This process will ensure that an appropriate mentor can be identified and the timeline/prioritization of the concept can be assigned. In some cases, proposals requiring significant mentorship may not be able to be prioritized right away due to workload and other priorities.

Concepts for conference abstracts should be submitted *well in advance* of the conference deadline. When data analysis from SCHARP is needed and not already underway, a 6 week notice prior to the first internal review is preferred; less time is needed if the analysis is already underway (for a manuscript or other reason). The process for developing an abstract to submit to a conference is below, and timing should be considered prior to the submission of a concept. Current concept submission deadlines can be accessed on the MTN website—should an author want to submit to a conference that is not listed, contact the PPC for help with developing a submission timeline.

While the trial is ongoing, no post-randomization data may be used. This includes data at SCHARP, as well as on-site data from laboratory logs, chart notes, or site-specific worksheets or tools. Outside the baseline paper, no manuscript will be published prior to the primary manuscript without prior approval from the PPC.

At the end of the trial, priority will be given to analyses addressing primary and secondary study objectives of MTN-020/025; however, other analysis proposals will be considered based on their merits. In general, study data will be made available according to a plan that allows access in the following sequence:

1. MTN-020/025 Protocol Chairs and Protocol Statistician
2. ASPIRE/HOPE Site Investigators of Record
3. All other members of the protocol team and/or staff at the participating MTN-020/025 institutions
4. All other staff at non-participating MTN-020/025 institutions but member MTN institutions

At the end of the trial, the ASPIRE/HOPE Publications Committees will develop a priority publications list. Individuals interested in leading a manuscript will be asked to submit concept ideas so that master lists for MTN-020 and MTN-025 can be created, abstracts triaged and prioritized, and appropriate authors identified to ensure fair representation and participation across the protocol team. Submission of an idea or concept does not necessarily mean the submitting team member will be leading the concept, as multiple team members could have similar or overlapping ideas. It is the role of the PPC to ensure fair representation and participation across the protocol team.

Prior to the monthly publications calls (site IoRs and protocol team representatives), newly approved concepts will be circulated in pdf to the group so that people may express interest in joining the writing team. Once interest is expressed, the PPC will work with the lead investigator to develop a writing team for the manuscript/abstract.

MTN-020/025 PPC will ask each site IoR and all lead authors (with pending manuscripts) to participate in a regularly scheduled publications call. This will ensure that publication timelines are adhered to, and each site is actively involved and aware of the publications in process and can represent site interests in authorship participation. Although the IoR will officially represent the site on ASPIRE publication calls, other staff are welcome to listen in on publications calls, and an alternate may be delegated if/when the IoR is unavailable to join.

4.0 MTN-020/025 Publication Authorship/Sponsorship Guidelines

Authorship should be reflective of the multi-site nature of ASPIRE and HOPE, MTN publication policies, and generally accepted International Committee of Medical Journal Editors (ICMJE) suggested authorship guidelines. Authorship should be based on the collaborative contributions of all investigators; from conception and design, or acquisition of data, or analysis and interpretation

of data; drafting the abstract or revising it critically for important intellectual content; and final approval of the version to be presented/published.

Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Everyone who is listed as an author should have made a substantial, direct, intellectual contribution to the work to take public responsibility for appropriate portions of the content. The authorship guidelines set forth by the International Committee of Medical Journal Editors (ICMJE) will be followed. The ICMJE recommends that authorship be based on the following 4 criteria:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement 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.

The following approach for operationalizing these guidelines will be implemented:

- The person leading the scientific inquiry, data interpretation, and writing of the abstract/manuscript should be the first author. It is the responsibility of the first author to ensure and document that all co-authors reviewed and approved the submitted manuscript/abstract and to maintain documentation of any forms that 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 first author or co-author on abstracts/manuscripts related to that aspect of the study (e.g., safety measures, behavioral measures).
- The SCHARP statistician who works with the first author to analyze the data for the abstract/manuscript should be included as a co-author (and is usually 2nd or 3rd). The Protocol Statisticians are responsible for designating the most appropriate SCHARP member to the authorship team.
- Representatives from the MTN BRWG, BSWG, ASPIRE/HOPE CWG, and members of the study management team (from FHI 360, SCHARP, LOC-PITT, the LC, and MTN Pharmacy) should be considered for authorship on relevant abstracts/manuscripts.
- Protocol Chairs should be given the option of being included as co-authors on all abstracts/manuscripts but it is not expected that the Chairs will necessarily be authors on all manuscripts from ASPIRE/HOPE.

Specific to multi-site abstracts/manuscripts:

- For any abstracts/manuscripts that are cross-cutting in nature, the Protocol Chairs, DAIDS Medical Officer and Lead CRM (FHI 360) should be invited to participate as authors. Authorship inclusion will only take place if ICMJE authorship requirements are met, and this group does not expect to be included as authors on every ASPIRE/HOPE manuscript.

- A representative from each site should be included as a co-author whenever possible, assuming ICMJE requirements are also fulfilled. When abstract submission guidelines limit the number of co-authors, the PPC will facilitate decision-making on site representation in the authorship team, making every effort to ensure fairness across sites over time.
- As appropriate, all authorship lists for abstracts/manuscripts that include data from more than one site should include "for the MTN-020/ASPIRE Study Team" or "for the MTN-025/HOPE Study Team" at the end of the authorship list. A standard template listing of protocol team members will be developed by the Publications Committees. This listing should be included at the end of all multi-site ASPIRE and HOPE manuscripts (after the acknowledgement section), as allowable by the journal formatting and other requirements.

Once analysis has begun, lead authors must show quarterly progress toward manuscript development. If the ASPIRE/HOPE Publications Committee does not see progress being made, the committee will talk with the lead author about possibly reassigning this responsibility. Specific timelines will be developed for each manuscript to ensure development stays on track.

5.0 MTN-020/025 Publication Review Process

Once a concept has been approved by the MTN-020/025 PPC (specifically for manuscript development, or an abstract for conference submission), the review process will include:

1. All members of the writing team must review and approve the manuscript/abstract prior to submission to the appropriate PPC. If an abstract is accepted by the conference for oral or poster presentation, the oral presentation or poster must also be approved by the MTN-020/025 PPC.
2. The lead author will submit the manuscript/abstract to the appropriate PPC by e-mail **(**mtn020pubcommittee@mtnstopshiv.org or mtn025pubcommittee@mtnstopshiv.org), and indicate the target journal or venue (for abstracts and presentations). The publication must be formatted/written in line with target journal or conference requirements.
3. The PPC aims to complete the review and provide comments for the author according to the following timelines: a) manuscripts: within approximately 14 days; b) meeting abstracts, posters and oral presentations within approximately 7 days.
4. Once the lead author receives comments and feedback, she/he will address these in a timely manner and resubmit to the MTN-020/025 PPC for review.
5. Once the PPC has approved the abstract/manuscript, the FHI 360 CRM will distribute the abstract/manuscript to the sponsor for review and approval.
6. The PPC will compile final comments from all reviewers and submit to the lead author.
7. Once final comments have been received and incorporated, the lead author will submit the revised abstract/manuscript/poster to the FHI 360 CRM. The FHI 360 CRM will submit the manuscript/abstract to the MTN MRC using DataVision. Abstracts (and posters/oral presentations) must be submitted to the MRC at least 2 weeks prior to conference deadlines.
8. The MTN MRC will review manuscripts within 10 working days (4 working days for abstracts, posters and oral presentations) and send the MRC recommendations and comments (if

provided) directly to the lead author via the Datavision system. The MRC coordinator will provide each author with a Datavision User ID. The MRC recommendations are either "APPROVED" or "NOT APPROVED- Revisions required"). If the MRC recommendation is "NOT APPROVED- Revisions required", then the author needs to address the comments and then resubmit for an additional MRC review cycle via the Datavision system.

9. It is the responsibility of the lead author to: a) submit the abstract/manuscript to the target meeting/journal, b) send the MTN MRC a copy of the submitted (or presented/published) version of the abstract/manuscript/presentation using the Datavision system, and c) provide updates to the PPC regarding the publication status as well as the full details of the journal's response/comments (i.e., provide a copy of the disposition letter to the FHI360 CRM). The FHI 360 CRM then informs the MRC of these updates.
10. If upon submission to the originally selected target journal, peer-review comments provided by the journal require substantive changes to the manuscript (such as additional results added, major modifications to the conclusions section etc.), the revised manuscript (in tracked changes) must be circulated to the PPC for the review and approval, followed by final MTN MRC review and approval.
    NOTE: For primary papers, **any** revisions to journal comments should be reviewed by the PPC; if changes are substantive, the revised manuscript should be submitted to MRC review. If lead author decides to resubmit the manuscript to a new target journal changes, he/she needs to inform the PPC.
11. If the abstract is accepted by the conference organizers, the development and approval of the oral or poster presentation requires following again steps 1-8 above for abstract/manuscripts.
12. The lead author must also ensure the PPC and MRC has final versions of all manuscripts and conference oral and poster presentations.

6.0 Publication Acknowledgments

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

The acknowledgement section for publications (i.e., manuscripts, posters, oral presentations) should include the following statement of support:

"The study was designed and implemented by the Microbicide Trials Network (MTN) and funded by the National Institute of Allergy and Infectious Diseases (UM1AI068633, UM1AI068615, UM1AI106707), with co-funding from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health (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 following language must also be added to posters, oral presentations and manuscripts (in the acknowledgement section or other appropriate location):

"The vaginal rings used in this study were developed and supplied by the International Partnership for Microbicides (IPM)."

7.0 ASPIRE-specific Standards

To ensure consistency across abstracts and manuscripts, it is recommended that the following conventions be followed:

1. The first reference of the trial (in the title, as well as in the text body) should be MTN-020/ASPIRE. Either MTN-020 or ASPIRE may then be used later in the manuscript.
2. ASPIRE should always be described for the benefit of readers unfamiliar with the protocol. A one-line explanation is often sufficient. For example: MTN-020/ASPIRE was a randomized, double-blind, placebo-controlled trial of the dapivirine vaginal ring for the prevention of HIV-1 acquisition in healthy sexually active HIV-1 uninfected women (ClinicalTrials.gov number NCT01617096).
3. It is suggested that the locations (city, country) of the ASPIRE sites be provided in the abstract.
4. The ASPIRE study team (for authorship purposes or otherwise) should be referenced as "MTN-020/ASPIRE Study Team".
5. For multi-site manuscripts, the study team (see Appendix III) must be provided at the end of the manuscript (as the journal allows).

8.0 HOPE-specific Standards

To ensure consistency across abstracts and manuscripts, it is recommended that the following conventions be followed:

1. The first reference of the trial (in the title, as well as in the text body) should be MTN-025/HOPE. Either MTN-025 or HOPE may then be used later in the manuscript.
2. HOPE should always be described for the benefit of readers unfamiliar with the protocol. A one-line explanation is often sufficient. For example: MTN-025/HOPE was an open label extension to the MTN-020/ASPIRE trial, which assessed the continued safety of and adherence to the dapivirine vaginal ring for the prevention of HIV-1 acquisition in former MTN-020 participants (ClinicalTrials.gov number NCT01617096 and NCT02858037).
3. It is suggested that the locations (city, country) of the HOPE sites be provided in the abstract.
4. The HOPE study team (for authorship purposes or otherwise) should be referenced as "MTN-025/HOPE Study Team".
5. For multi-site manuscripts, the MTN-025 study team (see Appendix IV) must be provided at the end of the manuscript (as the journal allows).

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

It is the responsibility of the lead author to ensure that a journal article meets the NIH Public access policy and is posted on **PubMed Central (**PMC). Many journals/publishers automatically post the final published version of all NIH-funded articles directly to PMC on behalf of the author. However, some journals require that authors make special arrangements to post directly to PMC, while others require that the author submit the publication to the NIH Manuscript Submission (NIHMS) system. More information is provided at:

http://www.mtnstopshiv.org/sites/default/files/attachments/NIHMS%20submission%20guidelines%20link%20updated%20Mar%201%202016.pdf.

10.0 References

All lead authors should be familiar with and follow:

- Section 20 of the MTN MOP: MTN Publication Policy
- ICMJE manuscript guidelines (http://www.icmje.org/recommendations/browse/manuscript-preparation/)
- For reporting of randomized controlled study, follow the Consolidated Standards of Reporting Trials (CONSORT) 2010 guidelines and check list (http://www.consort-statement.org/consort-2010)

Appendix I: MTN-020/025 Qualitative Concept Mentorship Application

Date:
Investigator/Team Member Name:
Investigator/Team Member Institution:
Investigator/Team Member Email Address:
Concept Title:
Suggested Mentor (*OK to leave blank if you do not have one in mind*):

1. Please provide a brief explanation of your desire to write this paper.

2. Career goals

    a. What are your short and long term career goals?

    b. How does writing this paper fit into those plans?

3. What do you hope to learn/ gain from this experience (i.e. writing a paper, getting mentored)?

Submit this application to the MTN-020/025 Publications Committee (mtn020pubcommittee@mtnstopshiv.org or mtn025pubcommittee@mtnstopshiv.org)

Appendix II: MTN-020/ASPIRE Study Team

Study Team Leadership: Jared Baeten, University of Washington (Protocol Chair); Thesla Palanee-Phillips, Wits Reproductive Health and HIV Institute (Protocol Co-chair); Elizabeth Brown, Fred Hutchinson Cancer Research Center (Protocol Statistician); Lydia Soto-Torres, US National Institute of Allergy and Infectious Diseases (Medical Officer); Katie Schwartz, FHI 360 (Clinical Research Manager)

Study sites and site Investigators of Record:
Malawi, Blantyre site (Johns Hopkins University, Queen Elizabeth Hospital): Bonus Makanani
Malawi, Lilongwe site (University of North Carolina, Chapel Hill): Francis Martinson
South Africa, Cape Town site (University of Cape Town): Linda-Gail Bekker
South Africa, Durban – Botha's Hill, Chatsworth, Isipingo, Tongaat, Umkomaas, Verulam sites (South African Medical Research Council): Vaneshree Govender, Samantha Siva, Zakir Gaffoor, Logashvari Naidoo, Arendevi Pather, and Nitesha Jeenarain
South Africa, Durban, eThekwini site (Center for the AIDS Programme for Research in South Africa): Gonasagrie Nair
South Africa, Johannesburg site (Wits RHI): Thesla Palanee-Phillips
Uganda, Kampala site (John Hopkins University, Makerere University): Flavia Matovu
Zimbabwe, Chitungwiza, Seke South and Zengeza sites (University of Zimbabwe College of Health Sciences Clinical Trials Unit): Nyaradzo Mgodi
Zimbabwe, Harare, Spilhaus site (University of Zimbabwe College of Health Sciences Clinical Trials Unit):): Felix Mhlanga

Data management was provided by The Statistical Center for HIV/AIDS Research & Prevention (Fred Hutchinson Cancer Research Center, Seattle, WA) and site laboratory oversight was provided by the Microbicide Trials Network Laboratory Center (Pittsburgh, PA). For qualitative data, management was provided by the Women's Global Health Imperative Program (RTI International, San Francisco, CA). *[Include appropriate data management reference as needed]*

Appendix III: MTN-025/HOPE Study Team*

Study Team Leadership: Jared Baeten, University of Washington (Protocol Chair); Thesla Palanee-Phillips, Wits Reproductive Health and HIV Institute (Protocol Co-chair); Nyaradzo Mgodi, University of Zimbabwe College of Health Sciences Clinical Trials Unit (Protocol Co-chair); Elizabeth Brown, Fred Hutchinson Cancer Research Center (Protocol Statistician); Lydia Soto-Torres, US National Institute of Allergy and Infectious Diseases (Medical Officer); Ashley Mayo, FHI 360 (Clinical Research Manager)

Study sites and site Investigators of Record:
Malawi, Blantyre site (Johns Hopkins University, Queen Elizabeth Hospital): Bonus Makanani
Malawi, Lilongwe site (University of North Carolina, Chapel Hill): Lameck Chinula
South Africa, Cape Town site (University of Cape Town): Gonasagrie Nair
South Africa, Durban – Botha's Hill, Chatsworth, Isipingo, Tongaat, Verulam sites (South African Medical Research Council): Gita Ramjee, Logashvari Naidoo, Simone Hendricks, Vaneshree Govender, and Vimla Naicker
South Africa, Durban, eThekwini site (Center for the AIDS Programme for Research in South Africa): Leila Mansoor
South Africa, Johannesburg site (Wits RHI): Thesla Palanee-Phillips
Uganda, Kampala site (John Hopkins University, Makerere University): Brenda Gati
Zimbabwe, Chitungwiza and Harare—Zengeza, Seke South and Splihaus sites (University of Zimbabwe College of Health Sciences Clinical Trials Unit): Nyaradzo Mgodi, Portia Hunidzarira, and Felix Mhlanga

Data management was provided by The Statistical Center for HIV/AIDS Research & Prevention (Fred Hutchinson Cancer Research Center, Seattle, WA) and site laboratory oversight was provided by the Microbicide Trials Network Laboratory Center (Pittsburgh, PA).

Note that the HOPE study team list will continue to be updated while the study is ongoing. The HOPE PPC will review reference to the study team to ensure it is accurate during final review of presentations/manuscripts.