HIV Prevention Trials Network (HPTN) 084-01 Publication Guidance

All manuscripts, abstracts, and presentations generated from HPTN research are subject to the HPTN Publication Policy*,* which is included as Section 21 of the HPTN Manual of Operations (<https://www.hptn.org/resources/manual-of-operations>). The purpose of this document is to outline additional procedures that have been developed specifically for abstracts, publications and presentations that arise from data generated from HPTN 084-01.

**Collaboration**

HPTN 084-01 is a collaborative study involving a number of entities:

* The HPTN, including the Statistical and Data Management Center (SDMC), the Laboratory Center (LC), the Leadership and Operations Center (LOC), and clinical research sites, is sponsored by the Division of AIDS (DAIDS), which is part of the National Institute of Allergy and Infectious Disease (NIAID) at NIH, with some funding provided by the Bill & Melinda Gates Foundation and study drug provided by ViiV Healthcare.

**Plans for Data Analyses, Presentation, Abstract and Manuscript Development**

It is the intention of the HPTN 084-01 Study Team that all the various entities involved in the study be engaged in the dissemination of findings through abstracts, presentations and publications. This effort involves the following principles:

* Abstracts, presentations and publications utilizing HPTN 084-01 data are presented and published in an expeditious manner.
* Writing assignments are clearly defined and agreed upon among HPTN 084-01 chairs and may include team members and collaborators.
* All HPTN 084-01 team members and collaborators are encouraged to propose concepts for development into abstracts, presentations and publications. The Protocol Chairs will approve or reject concept proposals.
* The process of selecting and prioritizing concepts for abstract, manuscript and presentation development will be transparent.

**Publication Committee Members**

The Chair and Co-chair of the study, in collaboration with the study’s statisticians, will have the overall responsibility for spearheading and streamlining all abstracts, publications and presentations from HPTN 084-01. They will be assisted by an HPTN 084-01 Publications and Presentations (P&P) Group (084-01PubsCommittee@HPTN.org) that will help in the review of concepts, abstracts, presentations and manuscripts, as well as the prioritization process. The HPTN 084-01 P&P Group will also assist in the selection of manuscript writing groups, taking into account individual contributions to the work and allowing for opportunities for individuals involved in HPTN 084-01 to participate in this effort.

The HPTN 084-01 P&P Group will consist of the following individuals:

* HPTN 084-01 Protocol Chair: Sybil Hosek
* HPTN 084-01 Protocol Co-Chair: Lynda Stranix-Chibanda
* HPTN Statistical and Data Management Center (SDMC) Representatives:
	+ Protocol Statistician: Jim Hughes
	+ Data Managers: Julie Ngo
* HPTN Laboratory Center (LC) Representatives:
	+ HPTN LC Co-Director, HPTN Pharm Core Lead: Mark Marzinke
	+ Senior QA/QC Coordinator: Estelle Piwowar-Manning
	+ QA/QC Coordinator: Yaw Agyei
* HPTN 084-01 Medical Officer: Adeola Adeyeye
* HPTN 084-01 study team members ensuring one representative per country:
	+ Sinead Delany-Moretlwe
	+ Pamela Tshandu (community team member)\*
	+ Carrie Matthew (observer/early-career investigator)\*
	+ Bekezela Siziba
	+ Tarisai Murefu(community team member)\*
	+ Miria Chitukuta (observer/early-career investigator)\*
	+ Brenda Gati
	+ Doreen Kemigisha (community team member)\*
	+ Dick Luyimbazi (observer/early-career investigator)\*
* Representatives from Bill & Melinda Gates Foundation (Lut Van Damme) and ViiV Healthcare (Cindy McCoig)
* Other individuals who may be called upon in an *ad hoc* manner to participate in the process as needed (i.e., other experts)
* HPTN Leadership and Operations Center (LOC)/Group Facilitators:
	+ Senior Clinical Research Manager: erica hamilton
	+ Senior Clinical Project Manager: Scott Rose
	+ Prevention Research Specialist: Amber Babinec

*\*Note: Community team members on the P&P Team will comment on community-oriented products: for non-community papers, observers will comment.*

**Manuscript Writing Group**

After Protocol Chair approval of a concept, each Manuscript Writing Group will be established by the lead author. The Writing Group will be chaired by the designated lead author. The lead author will be responsible for establishment of a timeline (see Appendix 1) for the manuscript development process, ensuring adherence to the timeline, obtaining concurrence from all coauthors, and facilitating appropriate reviews and approvals by the HPTN 084-01 P&P and the HPTN manuscript review committee. A representative from the SDMC will be included as part of each manuscript writing team that involves study data. At least one member of the HPTN LC will also be included as part of the manuscript writing team for all manuscripts that include laboratory data. If the lead author or any other member of the writing team is unable to deliver on their responsibilities, they will be replaced after discussion with the HPTN 084-01 P&P.

Lead authors are invited to attend HPTN 084-01 Publications Committee calls to provide progress updates and to seek input and discussion from the Committee. If a lead author cannot join a call, s/he/they should ask a co-author to attend to provide an update. If neither the lead author nor a co-author can attend, the lead author is asked to provide a written update to the committee.

**Guidance for Authorship**

The following is suggested guidance on authorship for HPTN 084-01 abstracts, publications and presentations:

* Authorship should be reflective of the key role of individuals in various aspects of the study, of the multi-site nature of HPTN 084-01 and the publication policies of the HPTN.
* Active involvement of early-stage investigators at every stage of development of all abstracts, publications and presentations is expected.
* Authorship should be reflective of the generally accepted authorship guidelines for peer‑reviewed journals. As such, authorship should be based on substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; drafting the manuscript or revising it critically for important intellectual content; and final approval of the version to be presented/published.
* The designated lead author should be the first author of the manuscript. Other authors should reflect the writing team and acknowledge key contributions in the design and implementation of the study, analysis, and interpretation. A representative from the HPTN LOC and DAIDS should be considered as authors on appropriate abstracts/manuscripts.
* For manuscripts that involve data from multiple sites, the Manuscript Writing Group should include some representation from the participating sites. All efforts will be made to ensure parity over time. All authorship lists for manuscripts that include data from more than one site should include “on behalf of the HPTN 084-01 Study Team” at the end of the authorship list. The acknowledgement section or supplementary appendix of the manuscript should include the name of at least one individual from each participating site. The site IoR is responsible for designating the most appropriate site representative to be listed as a member of the HPTN 084-01 Study Team.
* HPTN 084-01 is a multicenter study, thus, no data from a single site that involves components of the study may be presented or submitted for publication prior to presentation and/or publication of the overall study component results (Primary Manuscript). Once the overall results are made public through presentations/publications, proposals may be submitted for presentation or publication of single site data analyses by following the Concept Submission procedure.

**Submission of Abstracts and Concepts for Publications**

Draft abstracts and concepts for publications regarding HPTN 084-01 should be submitted for consideration utilizing the concept submission form below when applicable (Appendix 2). These include proposals for both multi-site and single-site analyses. As previously stated, the HPTN 084-01 Chairs will review and prioritize such requests based on scientific merit and feasibility.

**Review and Approval (Appendix 1)**

All HPTN 084-01 abstracts and manuscripts must be reviewed by the HPTN 084-01 P&P prior to submission. In addition, abstracts and manuscripts must be reviewed by the HPTN manuscript review committee (MRC) according to the HPTN Publication Policy. As such, all abstracts and manuscripts must be reviewed by the HPTN Manuscript Review Committee (MRC) prior to submission. The MRC reviews manuscripts within 5 working days of receipt with the following possible outcomes:

1. Endorse for publication
2. Endorse with recommended modifications to be reviewed by the MRC Chair
3. Recommend a second MRC review after modifications are made to obtain HPTN support

All abstracts will be reviewed by the MRC chair and a designated member statistician within three working days.

Additionally, all abstracts, presentations and manuscripts should be reviewed by the relevant pharmaceutical companies and funders, ViiV and the Bill and Melinda Gates Foundation. Medical Officer review during the P&P review process will serve as review by DAIDS.

**Appendix 1**

Review Process for HPTN 084-01

Manuscripts

Primary Author(s) Drafts Abstract

Co-authors Review

HPTN 084-01 Publications and Presentations (P&P) Committee Review (to include pharmaceutical companies and funders)

(10 working days)

**Abstract Submission**

Primary Author(s) Drafts Manuscript

**Manuscript Submission**

HPTN MRC Review

(5 working days)

Co-authors Review

Concept Proposal Reviewed and Approved by Chair and Co-Chair

ViiV and BMGF Review

(15 working days; sent 10 working days prior to sending to P&P Committee)

Abstracts

HPTN MRC Review

(5 working days)

HPTN 084-01 P&P Committee Review (5 working days)

Review Process for HPTN 084-01 Conference Presentations

(Posters and Slide Sets)

Primary Author(s) Drafts Presentation

**Final Presentation**

HPTN 084-01 P&P Committee Review (to include pharmaceutical companies, funders, as necessary)

(10 working days)

Co-authors Review

**Appendix 2**

**Appendix 2**

**HPTN 084-01 Publications Concept Proposal Form**

**Date: \_\_\_\_\_\_\_\_\_\_\_\_**

Submitter name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Submitter institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Submitter** **email address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

This proposal should be brief (1-3 pages) and include the following:

1. Proposed presentation/abstract/manuscript title and names of the lead author as well as potential participating authors (if known).
2. Specify the meeting for presentation or abstract submission, or target journal for publication.
3. Briefly describe the rationale for the proposed concept.
4. Describe major goals of your proposal.
5. Provide details of the proposed outcome(s) and independent variables of primary interest (e.g. risk factors) that support the analysis for the major goals,
6. List study sites from which data will be used for the proposed analysis.
7. Proposed timeline for completion of analysis.
8. OPTIONAL: Most analyses will be performed by the HPTN Statistical and Data Management Center (SDMC). Exceptions should indicate the statistical methods/approaches anticipated for the manuscript and reasons why the analysis should be performed without the SDMC’s involvement. (This includes all qualitative work.)

Submit this Proposal Form to erica hamilton (ehamilton@fhi360.org) and Amber Babinec (ababinec@fhi360.org), cc’ing Sybil Hosek (sybilhosek@gmail.com) and Lynda Stranix-Chibanda (lstranix@uz-ctrc.org).