



OPERATING POLICY

OP No.: HPTN011-07

Page 1 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

APPROVAL

Chairperson, HPTN Prevention Management Group

Date

PURPOSE

Define the guidelines and process by which the Network ensures that manuscripts resulting from research conducted within HPTN:

- Reflect accurate reporting of the design, conduct, and analysis of studies;
- Are developed in a collaborative fashion with the active participation of all investigators participating in the design and conduct of the study;
- Are published expeditiously and widely disseminated and;
- Protect the confidentiality of medical, personal and product information in accordance with the Privacy Act, the requirements for the protection of human subjects and any applicable clinical trials agreements.

SCOPE

This procedure applies to all activities associated with the authorship, review, and timeline of manuscripts.

RESPONSIBILITIES

Protocol Chair(s) and Protocol Biostatisticians are jointly responsible for developing or reviewing primary, secondary, and tertiary manuscript concepts, developing or reviewing manuscript timelines, identifying manuscript writing committees, prioritizing manuscript development, monitoring timelines, and adhering to manuscript review procedures outlined in this policy. In addition, the Protocol Biostatistician is responsible for providing analysis results for inclusion in the manuscript within the specified time.

Manuscript Writing Committee is responsible for drafting manuscripts within the specified manuscript timeline.

OPERATING POLICY

OP No.: HPTN011-07

Page 2 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

Lead Author or HPTN Point of Contact is responsible for ensuring adherence to manuscript timelines and submission for reviews as described below.

Protocol Team (PT) is responsible for reviewing draft manuscripts submitted by Writing Committees within the specified time.

Scientific Committee (SC) Chair is responsible for reviewing draft manuscripts submitted by Writing Committees within the specified time.

Manuscript Review Committee (MRC) is responsible for reviewing draft manuscripts and abstracts and ensuring a review by the HPTN Network Laboratory (NL) when appropriate within the specified time.

CORE Clinical Research Manager (CRM) is responsible for facilitating the planning and submission of manuscripts received from lead authors for each review and for ensuring that authors are aware of the HPTN Publication Policy.

CORE Manuscript Coordinator is responsible for receiving manuscripts from CORE CRMs, submitting them to the MRC for review, for following up on communications with the MRC as needed and for forwarding them to the CORE Information and Communications staff for inclusion in the HPTN bibliography.

DEFINITIONS

Primary Manuscript

Publications that are journal articles or meeting abstracts that report the findings of primary, secondary and tertiary study objectives as described in an HPTN study protocol.

Secondary Manuscript

Journal articles and meeting abstracts that address scientific questions not identified as study objectives in an HPTN study protocol, but rely on data collected or analyses performed by HPTN investigators

Tertiary Manuscript

Publications resulting from research conducted in support of HPTN activities, such as literature reviews, that do not rely on HPTN data.

Public Use Data Sets

OPERATING POLICY

OP No.: HPTN011-07

Page 3 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

Study data made available to the public in special data sets prepared by the SDMC for wide scale dissemination. In general, all identifying information is stripped out of Public Use data sets so that they may be used without consulting the relevant IRBs. Data released to HPTN investigators per HPTN Operating Policy HPTN017 does not constitute public use data.

PROCEDURES

1 PRIMARY MANUSCRIPTS

1.1 Concept Development

The PT Chair(s) (or designee) and lead statistician (or designee) develop a manuscript concept. If the PT Chair(s) and lead statistician are not involved in the preparation of the concept, the concept must be submitted to them for review and approval prior to proceeding with development.

Manuscript concepts should contain the following:

- Short (one or two paragraph) explanation of the rationale, hypothesis and objectives of the manuscript;
- Short (one paragraph or outline) summary of analysis plan, data presentation (including shell tables) and required HPTN NL support, if necessary;
- Identification and relevance to the HPTN mission; and
- Recommendation for writing team members.

1.2 Timeline

The PT Chair(s) (or designee) and lead statistician (or designee) develop a manuscript timeline prior to the initiation of manuscript development. If the PT Chair(s) and lead statistician are not involved in the preparation of the timeline, the timeline must be submitted to them for review and approval prior to proceeding with development.

A manuscript timeline should minimally contain the following information:

- HPTN protocol number;
- Expected date of last participant follow-up visit;
- Date data expected to be locked;
- Start date of manuscript preparation;
- Expected date of submission for PT review;

OPERATING POLICY

OP No.: HPTN011-07

Page 4 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

- Expected date of submission for SC Chair review;
- Expected submission date to MRC.

The Protocol Chair(s) and lead statistician are jointly responsible for monitoring timelines set forth in the manuscript concept and for reporting to the Manuscript Review Committee (MRC). Primary manuscripts should be submitted to the MRC for review within eight months following the last scheduled participant follow-up visit. This allows time for cleaning and locking the analysis data set, running analyses, describing findings, and review of the manuscript by the PT and relevant SC Chair.

1.3 Monitoring Timelines

In addition to the Protocol Chair(s) and Protocol Biostatistician, the Statistical and Data Management Center (SDMC) is responsible for tracking progress on manuscripts. Reports on the progress of manuscript development across protocols will be made to Network Leadership by the SDMC Principal Investigators (PIs) on a regular basis.

1.4 Review

The lead author submits the manuscript to the CORE CRM who coordinates the manuscript review processes.

1.4.1 Protocol Team Review

Prior to submission for SC and MRC review, the CORE CRM will distribute the draft manuscript to the PT, sponsor(s) and product manufacturer (if applicable) for review and comment. Once all comments have been received and incorporated into the manuscript draft by the lead author, the CORE CRM will submit the manuscript to the Chair of the SC or designee.

1.4.2 Scientific Committee Chair Review

The SC Chair (or designee if SC Chair is an author or not available) reviews manuscripts submitted by the CORE CRM within 10 working days. Following completion of this review, once all comments have been received and incorporated into the manuscript draft by the lead author, the CORE CRM submits the manuscript to the Manuscript Review Committee (MRC) through the CORE Manuscript Review Coordinator.

OPERATING POLICY

OP No.: HPTN011-07

Page 5 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

1.4.3 Manuscript Review Committee (MRC) Review

The composition of the MRC is described in the HPTN Manual of Procedures. The MRC Chair designates a primary and secondary reviewer to provide comments, one of whom is from the SDMC. The MRC Chair will designate a reviewer from the HPTN NL, if applicable. The MRC reviews the manuscripts within 10 working days of receipt via conference call. Comments designated by the MRC as “Major” must be addressed by the manuscript author. Those designated as “Minor” are for consideration only and do not need to be addressed by the author. Following review, the MRC sends the comments and outcome back to lead author with a copy to the CORE Manuscript Coordinator. The possible MRC review outcomes are:

1. Endorse for publication or,
2. Endorse with requested modifications to be reviewed by the MRC Chair or,
3. Require a second MRC review to obtain HPTN support.

1.5 Publication

Prior to submission of manuscripts for publication, a final copy is provided by the lead author to the CORE CRM for tracking purposes.

If a manuscript is not accepted for publication and reviewer feedback indicates a need to reformulate the essential components before it can be resubmitted or submitted to another journal, it must be reviewed again by the MRC.

1.6 Authorship

The HPTN criteria for authorship are defined in the International Committee of Medical Journal Editors’ “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications” Section II.A “Authorship and Contributorship” attached in Appendix A. Typically the second author listed in primary HPTN publications is the study statistician.

When US government (e.g., NIH, CDC) staff are co-authors, manuscripts must be approved by their institute/agency. The US government staff person is responsible for obtaining the necessary approvals.

If a primary manuscript is accepted provisionally with required or recommended

OPERATING POLICY

OP No.: HPTN011-07

Page 6 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

changes/additions, if a journal invites a revised draft of the same article, or if an article is being submitted to another journal with minimal changes, the lead author in consultation with the writing committee may respond to the editor without MRC review. It is the responsibility of the writing committee to differentiate between alterations that reflect mere editorial changes and those which essentially modify the analyses and/or conclusion of the study previously endorsed by the MRC.

1.7 Acknowledgments

All publications and presentations will include a statement acknowledging the HPTN and NIH's support for the work and listing the applicable cooperative agreement numbers, unless the journal's policy precludes such an acknowledgment. A copy of this statement is attached in Appendix B.

1.8 Disputes

Disputes with respect to the manuscript development and preparation process will be resolved by the MRC. If the dispute cannot be resolved by the MRC, the MRC Chair will refer it to the HPTN Prevention Management Group (PMG) for final resolution.

1.9 Third Party Agreements

Third party agreements with product sponsors will include an agreement on publications policy and authorship in accordance with the guidelines set forth in the study's Clinical Trials Agreement (CTA).

1.10 Publicity

Refer to HPTN MOP section 7.10.

2 SECONDARY MANUSCRIPTS

2.1 Concept Development

Any investigator affiliated with the study may originate secondary manuscript concepts. These concepts should be submitted to the PT Chair(s) and lead statistician for review and approval. The PT Chair(s) will respond to the authors of the concept within 10 working days after receipt of the concept.

If study data has been released by the SDMC as a Public Use data set (see Section 5), concepts and manuscripts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

OPERATING POLICY

OP No.: HPTN011-07

Page 7 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

2.1.1 Single-Site Study Data

Concepts using single site data may be developed into manuscripts following receipt of approval from the PT Chair and Protocol Statistician. Manuscripts require PT, SC, and MRC review prior to submission to a journal as per Section 2.3 below.

2.1.2 Multi Study Concepts

Concepts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of manuscript development. Manuscripts require PT, SC, and MRC review prior to submission to a journal as per Section 2.3.

2.2 Timeline

There is no requirement for preparation of a timeline and no deadline to submit for MRC within eight months of last participant visit.

2.3 Review

All secondary manuscripts require PT, SC and MRC review. Refer to Section 1.4 above.

2.4 Publication

Refer to Section 1.5 above.

2.5 Authorship

Refer to Section 1.6 above. Note that the lead statistician may or may not serve in the role of the second author on secondary publications.

2.6 Acknowledgements

Refer to Section 1.7 above.

2.7 Disputes

Refer to Section 1.8 above.

OPERATING POLICY

OP No.: HPTN011-07

Page 8 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

2.8 Third Party Agreements

Refer to Section 1.9 above.

2.9 Publicity

Refer to Section 1.10 above.

3 TERTIARY MANUSCRIPTS

3.1 Concept Development

Any investigator affiliated with the study may originate tertiary manuscript concepts. These concepts should be submitted to the PT Chair(s) and lead statistician for review and approval. The PT Chair(s) will respond to the authors of the concept within 10 working days of receipt of the concept.

If study data has been released by the SDMC as a Public Use data set (see Section 5), concepts and manuscripts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

3.1.1 Single-Site Study Data

Concepts using single site data may be developed into manuscripts following receipt of approval from the PT Chair and Protocol Statistician. Manuscripts require PT, SC, and MRC review prior to submission to a journal as per Section 2.3.

3.1.2 Multi Study Concepts

Concepts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of manuscript development. Manuscripts require PT, SC, and MRC review prior to submission to a journal as per Section 2.3.

3.1.3 Timeline

There is no requirement for preparation of a timeline and no deadline to submit

OPERATING POLICY

OP No.: HPTN011-07

Page 9 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

for MRC within eight months of last participant visit.

3.2 Review

All tertiary manuscripts require PT, SC and MRC review.

3.3 Publication

Refer to Section 1.5 above.

3.4 Authorship

Refer to Section 1.6 above. Note that the lead statistician may or may not serve in the role of the second author on tertiary publications.

3.5 Acknowledgements

Refer to Section 1.7 above.

3.6 Disputes

Refer to Section 1.8 above.

3.7 Third Party Agreements

Refer to Section 1.9 above.

3.8 Publicity

Refer to Section 1.10 above.

4 ABSTRACTS

4.1 Concept Development

Concepts are not required for abstracts.

4.2 Review Requirements

The lead author submits the abstract to the CORE CRM who coordinates the abstract review processes.

All abstracts require an expedited MRC review; except for those developed from Public

OPERATING POLICY

OP No.: HPTN011-07

Page 10 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

Use data sets (see Section 5). Prior to MRC review, the abstract should be reviewed by the Protocol Chair (or designee), Protocol Statisticians (or designee), and/or other PT members designated by the Protocol Chair. The MRC Chair will triage abstracts as necessary to the SDMC, to the HPTN NL, or to the SMC for review to determine that the analyses are appropriate and the data reported accurately. All abstracts will be reviewed by the MRC chair and a designated member statistician within three working days.

If study data has been released by the SDMC as a Public Use data set (see Section 5), abstracts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

4.2.1 Single-Site Study Data

The completed abstract using single site data is sent to the CORE CRM who coordinates the MRC review.

4.2.2 Multi-Site Study Data

Abstracts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of abstract development.

5 PUBLIC USE DATA

Federal research sponsors often require that data be made available to the public in the form of “Public Use” data sets, which have been prepared by the SDMC for wide scale dissemination. If study data is released by the HPTN SDMC as a public use data set, the HPTN is not responsible in any way for the content of abstracts or manuscripts developed using these data, and such manuscripts will not be reviewed by the PT, SC or MRC.

APPENDICES

Appendix A – International Committee of Medical Journal Editors’ “Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications” Section II.A “Authorship and Contributorship”

OPERATING POLICY

OP No.: HPTN011-07

Page 11 of 11

Title: HPTN Publication Policy

Effective Date: 31 Jul 2008

Appendix B – Guidance on acknowledgement of support for manuscripts resulting from HPTN funded studies.

Appendix C – HPTN Prevention Management Group Notification of Testing Form for HPTN Stored Specimens

Appendix D – List of HPTN-related Cooperative Agreement numbers

REFERENCES

HPTN Manual of Operations Sections 4.2.4, 7.7

REVISION HISTORY

Version	Effective Date	Supersedes	Review Date	Change
HPTN011-00				<i>Initial Release</i>
HPTN011-01	<i>01 Jan 2007</i>	<i>HPTN011-00</i>	<i>01 Jan 2008</i>	<i>Clarified procedure; administrative changes</i>
HPTN011-02	<i>07 Feb 2007</i>	<i>HPTN011-01</i>	<i>07 Feb 2008</i>	<i>Administrative change</i>
HPTN011-03	<i>05 Mar 2007</i>	<i>HPTN011-02</i>	<i>05 Mar 2008</i>	<i>Administrative change</i>
HPTN11-04	<i>01 Apr 2008</i>	<i>HPTN011-03</i>	<i>01 Apr 2009</i>	<i>Annual review; no changes made</i>
HPTN11-05	<i>31 Jul 2008</i>	<i>HPTN011-04</i>	<i>30 Jul 2009</i>	<i>Administrative change</i>
HPTN11-06	<i>31 Jul 2008</i>	<i>HPTN 011-05</i>	<i>30 Jul 2009</i>	<i>Add correct version #; Administrative change</i>
HPTN11-07	<i>31 Jul 2008</i>	<i>HPTN 011-06</i>	<i>30 Jul 2009</i>	<i>Remove track changes; administrative change</i>