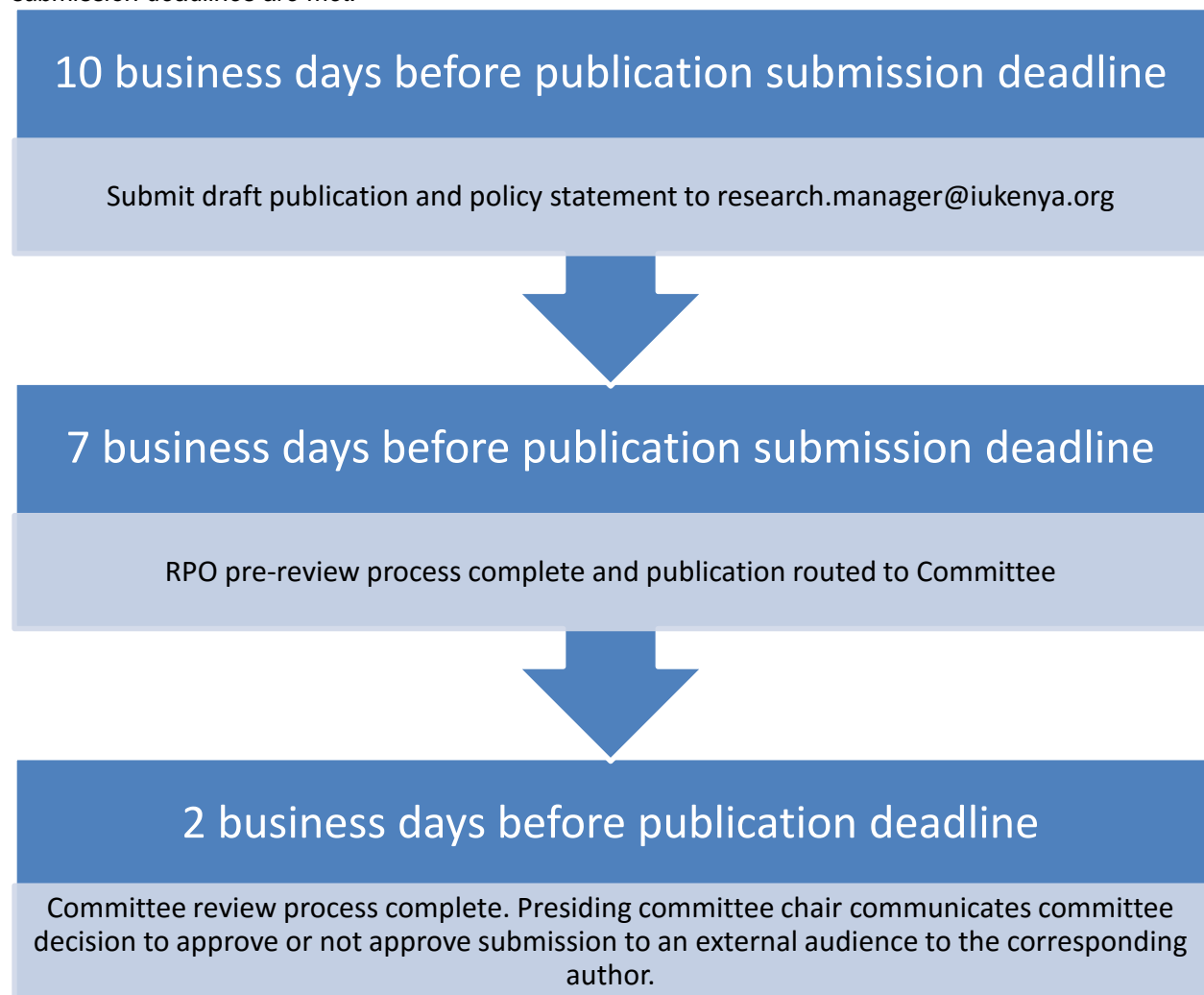


Standard Operating Procedures for Authorship and Pre-Publication Review	Version No: 4
	Approved Date: 28 January 2019
	Effective Date: 28 January 2019

Process Overview

Please note this process flow includes the minimum times required by the Research Program Office (RPO) and the Publications Committee to process and review a publication for submission to an external publisher. Investigators are strongly encouraged to begin this process as early as possible to ensure submission deadlines are met.



**FAILURE TO FOLLOW THE GUIDELINES IN THIS SOP CAN RESULT IN A
REQUIREMENT TO NOT SUBMIT OR EVEN WITHDRAW A MANUSCRIPT OR
ABSTRACT ALREADY SUBMITTED**

Purpose

To ensure that all investigators and students involved in AMPATH research, clinical, and administrative programs (1) obtain formal approval and clearance from co-authors, program directors and other stakeholders to submit publications to external publishers and audiences; (2) adhere to international standards for publication in peer reviewed medical and scientific publications; and (3) comply with AMPATH SOPs for research.

Publications Committee Overview

The Publications Committee ensures that publications resulting from AMPATH collaborations do not misrepresent the program or author affiliations. The Publications Committee reviews are friendly peer reviews from knowledgeable colleagues designed to help strengthen publications originating from AMPATH.

Members of the Committee include, but are not limited to:

- Co-Directors of AMPATH Research (Kenya and North America)
- AMPATH Program CEO
- Dean, School of Medicine
- Co-Field Directors of Research
- Research Program Lead Biostatistician
- AMPATH Research Program Managers (Kenya and North America)
- Other appropriate subject matter experts

Publications Committee reviews the following:

- **Clinical Program**
 - Does the publication reflect what is actually being done on site?
 - Are individuals who make a substantive contribution to this program named as co-authors?
 - Has the director of the program being described been named as a co-author?
 - Was the director of the program notified of the potential publication and allowed to review it?

- **Research Program**
 - Does the research project have IREC/IRB approval?
 - Is the PI of the project named as a co-author?
 - Was the PI of the project notified of the potential publication and allowed to review it?
 - Are the conclusions supported by the presented data?
- **Personal Observations or letters to the editor**
 - Does the potential program maintain patient and staff confidentiality?
 - Does the publication reflect what is actually being done on site?

Required Pre-Review Approvals

Before publications are submitted for review by the Publications Committee, authors should ensure the following approvals have been granted.

1. **Research Project Approval** – Approval must be sought from the Project PI whose data are being used for the publication.
2. **Co-author Approval** – All co-authors must be notified of their co-authorship and given the chance to review the potential publication prior to submission.

Publication Committee Review Procedure

Prior to submission to a publisher, conference, or external audience, all publications must complete the publications pre-review process by the Publications Committee. Before submitting a publication for review by the Publications Committee, all authors should review and approve the publication for submission. Publications should be submitted at least 10 business days before the publication submission deadline using the following procedure:

1. At least 10 business days before the publication submission deadline, the corresponding author submits the following items to the AMPATH Research Program Office (RPO) (research.manager@iukenya.org):
 - 1.1. A copy of the publication; and
 - 1.2. A one paragraph summary describing what the author(s) believe the leadership should know/learn about the research described in the publication that might contribute to AMPATH program policy.
2. RPO conducts a pre-review within 3 business days of submission to (1) confirm submission completeness and (2) confirm correct affiliations, AMPATH acknowledgement statements, and standard AMPATH templates and style are used.
3. After the RPO pre-review process is complete, publications are routed by RPO to the Publications Committee.
4. Publications Committee members review submitted proposals and copy the corresponding author on their comments within 5 business days of submission.

5. Authors may be required to submit revisions to the publications committee prior to final approval.
6. If a committee member believes a publication should not be published, the entire committee will review the publication and make a determination.
7. Final approval for external submission is granted by the co-director of research who is presiding chair of the Publications Committee for the month and a statistician (when applicable) within 5 business days of submission to the committee.

After 5 business days unless otherwise notified the submitting author can consider their work to be approved for submission.

After a publication has been approved by the Publications Committee, all co-authors must sign the journal’s co-authorship clearance form when applicable. Lead authors should retain copies of the journal’s co-authorship clearance form when applicable.

Standard Publication Elements

All publications should include the following standard elements.

1. **Author Identification** – All individuals who have had substantive input into the program or the project will be considered for co-authorship. Authors should include the leadership of the clinical program and/or the Principal Investigator (PI) of a project must be considered for co-authorship on any publication (manuscript or abstract) resulting from the project. Authorship is determined using the guidelines published by the [International Committee of Medical Journal Editors \(ICMJE\)](http://www.icmje.org) (www.icmje.org).

2. **Standard Author Affiliations**– AMPATH related publications should include a list of author affiliations. Unless an affiliation format is specified by a publisher, authors should list author affiliations using the following standard format:

*¹University/Institution
Name, College, School,
Department/Division, City,
State, Country*

Authors affiliated with the Moi University College of Health Sciences should use the following format:

²Moi University, College of Health Sciences, School of <INSERT NAME>, Department of <INSERT NAME>, Eldoret, Kenya

Example Author Affiliation List

Jane A. Doe, MD, MS^{1,2,3}; John A. Doe, MBChB, MMED, MPH^{2,4}; Jane B. Doe, PhD⁵; John B. Doe, PhD⁵; Jane C. Doe, BA^{1,2}; John C. Doe, MS⁵; Jane D. Doe, MBChB, MMED^{2,4}; John D. Doe, ScM, MD^{2,3,6}

¹Indiana University, School of Medicine, Department of Pediatrics, Children’s Health Services Research Indianapolis, IN, United States

²Academic Model Providing Access to Healthcare (AMPATH), Eldoret, Kenya

³Regenstrief Institute, Inc., Indianapolis, IN, United States

⁴Moi University, College of Health Sciences, School of Medicine, Department of Child Health and Paediatrics, Eldoret, Kenya

⁵Indiana University, School of Medicine, Department of Biostatistics, Indianapolis, IN, United States

⁶Indiana University, School of Medicine, Department of General Internal Medicine, Indianapolis, IN, United States

Authors affiliated with the AMPATH care program should use the following format:

³*Academic Model Providing Access to Healthcare (AMPATH)*

3. USAID Acknowledgement Statement

Publications using AMPATH data and recruiting participants supported by USAID funds must include the following acknowledgement statement for USAID in the publication.

This research has been supported by the President's Emergency Plan for AIDS Relief (PEPFAR) through USAID under the terms of Cooperative Agreement No. AID-623-A-12-0001 It is made possible through joint support of the United States Agency for International Development (USAID). The contents of this <SPECIFY TYPE OF PUBLICATION> are the sole responsibility of AMPATH and do not necessarily reflect the views of USAID or the United States Government.

4. Poster and Presentation Templates

The AMPATH Research Program provides standard templates for poster and PowerPoint presentations. Please contact RPO, research.manager@iukenya.org, to request online access to the current presentation templates.

Alternative Publication Review

Publications originating from multicenter research studies may be exempted from the AMPATH publications review process if an alternative publications review process has been established for the study. In order to receive exemption from the review process, the AMPATH site PI must submit a formal request to RPO, research.manager@iukenya.org, before the study commences. The request should include a detailed description of the proposed review process and a justification explaining why the study should be exempted from the normal AMPATH publications review process. Exemption requests are reviewed by the AMPATH co-directors for research. If approved, exempted studies will not be required to follow the normal AMPATH publications review process but are expected to:

1. Circulate copies of reviewed publications to the AMPATH Publications Committee for their information;
2. Submit a one paragraph summary to research.manager@iukenya.org describing what the author(s) of each reviewed publication believe the clinical leadership should know/learn about the research described in their publication that might contribute to AMPATH program policy;
3. Submit final copies of any manuscripts published in peer reviewed journals to research.manager@iukenya.org; and
4. Comply with any additional requirements mandated by the AMPATH co-directors of research.

Monitoring of Publications

Publication approval and submission is tracked by RPO. Published manuscripts are included in the AMPATH Research Publications Bibliography updated quarterly by RPO. Copies of the final publications must be submitted to the RPO, research.manager@iukenya.org, for inclusion in the bibliography and

RPO records. A compendium of publications describing what AMPATH should learn from the publications submitted to the committee is produced quarterly by RPO and circulated to AMPATH leadership.

SOP Version Log			
Version	Date	Authors	Summary of Changes
2	10 May 2013	J. Kiplagat-Kirui A. Bell	<ul style="list-style-type: none"> • Clarified policy for withdrawing publications that have not complied with AMPATH SOPs for research
3	7 February 2014	J. Kiplagat-Kirui D. Plater	<ul style="list-style-type: none"> • Added a process flow chart and timeline • Clarified pre-publication review process flow and times for critical processes • Updated committee structure to reflect current membership and changes in AMPATH role titles • Added standard publication elements including formats for author identification, affiliations, and AMPATH-Plus acknowledgements • Updated policy for monitoring of publications and inclusion of policy statements in publications compendium • Added a section on alternative publication review mechanisms
4	15 January 2019	D. Plater J. Wagner E. Walumbe	<ul style="list-style-type: none"> • Clarified what the Publications Committee reviews