Standard Operating Procedures for International Trainees Engaging in Research Activities at AMPATH	**Version No:** 5.0
	Approved Date: March 4, 2019
	Effective Date: March 4, 2019

Process Overview

Conducting a research project from the concept stage to completion is a time intensive process. The following process timeline provides the estimated time trainees and mentors will need to complete the pre-departure requirements for research. Trainees who will be unable to complete the new study review process prior to arrival in Kenya are strongly encouraged to work on an approved pre-existing project.

16 weeks before trainee travel to Kenya

Contact RPO, research.manager@iukenya.org, to discuss proposed research activities and requirements for trainee research.

Contact AMPATH Consortium office to review trainee travel requirements, e.g. visa, housing, medical licensure, insurance, etc.

14 weeks before trainee travel to Kenya

Submit a New Study Information Form, proposed budget, and study protocol to research.manager@iukenya.org for review by research working groups, ADAT, and Lab as needed.*

8-10 weeks before trainee travel to Kenya

Submit IREC and IRB applications and/or amendments.‡

Submit trainee research activity approval request and documentation.

2-4 weeks before trainee travel to Kenya

Confirm with RPO that SOP requirements have been met.

Confirm itinerary and other travel arrangements with AMPATH Consortium office.

Only applies to trainees who plan to initiate a new research project/study as part of their visit.

‡IREC applications for new research should be submitted after review by the AMPATH Research Working Groups has been completed. Mentors may also need to submit study amendments to existing IRB and IREC approvals for any trainees who will be participating in previously approved research activities.

<div style="background-color:red; color:white; text-align:center; font-weight:bold;">
TRAINEE RESEARCH ACTIVITIES THAT FAIL TO COMPLY WITH AMPATH RESEARCH POLICIES WILL NOT BE ALLOWED TO PROCEED AND MAY RESULT IN THE TERMINATION OF TRAINEE TRAVEL.
</div>

Purpose

To ensure that international trainees engaging in AMPATH related research activities (1) are able to participate in safe and collaborative research that provides mutual benefit to the trainees and the people of Kenya; (2) have appropriate faculty oversight and support for proposed research activities; (3) adhere to AMPATH's requirements for the conduct of research.

Applicability

The policies and procedures described in this Standard Operating Procedure (SOP) apply to non-Kenyan international undergraduate, graduate, and postgraduate scholars, residents and fellows who (1) are engaged in a temporary and defined period of formalized training to enhance their professional skills and research independence; (2) does not hold a permanent faculty appointment at their home institution; (3) are not considered eligible to serve as a Principal Investigator or Project Director on a research project by their home institution and/or the sponsoring agency for a project; and (4) plans to engage in any research activities at AMPATH.

Pre-Departure Procedure

At least 16 weeks before international trainees plan to travel to Kenya and participate in research activities at AMPATH, the trainee must complete the AMPATH Visitor Information From, www.ampathkenya.org/visitor-registration, to ensure the following requirements have been met:

1. **International Research Mentor/Supervisor** – Before travelling to Kenya, all trainees must identify a Faculty member from the trainee's home institution willing to serve as the international research mentor/supervisor. The international research mentor must be an active participant in the AMPATH research program and the mentor's home institution must be a current member of the AMPATH research collaboration. The international research mentor is responsible for:
   a. Helping guide trainees in the development and execution of appropriate research activities in Kenya;
   b. Serving as a co-investigator and/or co-author as needed;
   c. Assisting trainees in identifying Kenyan Research Co-mentor(s);
   d. Coordinating with Kenyan Research Co-mentor(s)/supervisor(s) to oversee and guide the development and implementation of trainee research activities;

e. Communicating regularly, either in person when in country, or via email/phone when not in Kenya, with the Kenyan Research Co-mentor/supervisor and with the trainee regarding the research activities throughout the course of the trainee's project;

f. Identifying an onsite Administrative Coordinator (See section 3 on Administrative Coordinator responsibilities) to oversee trainees when the international research mentor is not onsite in Kenya;

g. Checking in with trainees on a regular schedule (best practice recommendation is every two weeks for most trainees), either in person when in country, or via phone and/or video conference when not in Kenya;

h. Notifying the AMPATH Research Program Office of trainee research activities as described in this SOP; and

i. Ensuring trainees comply with all applicable AMPATH policies and procedures for research and trainee engagement in Kenya.

2. **Kenyan Mentor** – In addition to an international research mentor, all trainees must also identify a research mentor from the Moi University faculty or MTRH staff. The Kenyan Mentor is responsible for:

a. Serving as a co-investigator and/or co-author on the trainee's project(s) and a co-author on all papers emanating from this research, unless the mentor declines authorship.

b. Coordinating with international research co-mentor(s) to oversee and guide the development and implementation of trainee research activities;

c. Meeting with mentored trainee(s) on a regular basis to obtain updates on their research and discuss any issues arising;

d. Communicating regularly with the international research mentor about trainee research activities; and

e. Ensuring trainees comply with all applicable AMPATH policies and procedures for research and trainee engagement in Kenya.

3. **Onsite Administrative Coordinator** – All trainees must have an onsite Administrative Coordinator while on-the-ground in Kenya. The onsite Administrative Coordinator is responsible for responding to trainee safety, security, and personal conduct concerns while a trainee is on-the-ground in Kenya. The international research mentor may serve as the trainee's onsite Administrative Coordinator as long as the international research mentor will be present in Kenya for the duration of the trainee's stay. ***If the international research mentor is not able to be onsite in Kenya for any portion of the trainee's stay, the mentor must identify a qualified onsite faculty or staff member from an AMPATH consortium member institution to serve as the trainee's onsite Administrative Coordinator.*** The onsite Administrative Coordinator is responsible for:

a. Responding to safety and security concerns raised by or pertaining to the research trainee(s);

b. Serving as an emergency contact for research trainees while in Kenya;

c. Ensuring research trainee(s) comply with all AMPATH policies and procedures and safety, security, and personal conduct guidelines; and

d. Checking in with trainee(s) on a regular basis to address any issues of concern in order to elevate serious issues to home institution leadership.

The following required information will be collected when the trainee completes AMPATH's Visitor Information Form. The Research Program Office will confirm and share this information with the executive field director, clinical team leaders, and operations staff within 3 business days. Notification should include the following information:

a. Administrative Coordinator name;

b. Administrative Coordinator home institution;

c. Administrative Coordinator contact information including e-mail address and Kenya phone number;

d. Name of trainee(s) the Administrative Coordinator will be responsible for;

e. Explicit start and end dates for which the Administrative Coordinator will be responsible for responding to trainee safety, security, and personal conduct concerns while a trainee is on-the-ground in Kenya; and

f. Written confirmation from the onsite Administrative Coordinator acknowledging their responsibilities.

Please note that Clinical Team Leaders are primarily responsible for clinical trainees on the ground in Kenya and have limited capacity to take on additional oversite responsibilities for research trainees. Clinical Team Leaders will consider requests to serve as onsite administrative coordinators for research trainees on a case by case basis in consultation with the Research Program Office and AMPATH Executive Field Director. Along with the Research Program Office and AMPATH Executive Field Director, the Clinical Team Leaders will advise onsite administrative coordinators on safety, security, and personal conduct concerns of research trainees and serve as emergency back-ups for onsite administrative coordinators.

4. **Research Activity Approval** – Before trainee research activities can commence, proposed trainee research activities must be reviewed and approved by the Kenyan and North American co-directors of research. All proposed trainee research activities are reviewed to confirm proposed activities are aligned with AMPATH research program mission, values, and strategic priorities and ensure compliance with AMPATH policies and procedures for research. In keeping with the afore mentioned pre-departure timelines, at least 16 weeks before departure, the

following items should be included in the [AMPATH Visitor Information Form](). The Research Program Office shall review and approve:

- a. **Research Activity Description** – A short 1-2 paragraph description of the research activities the trainee will engage in while in Kenya including the title(s) of the project(s) the trainee will work on during their stay;
- b. **Activity Dates** – the trainee's proposed arrival and departure dates;
- c. **Location(s) of Research**– Location(s) where trainee will engage in research;
- d. **Planned Housing** – Verification of housing arrangements while in Kenya;
- e. **Local Transportation Arrangements** – Please provide a description of travel arrangements for the trainee to and from the primary project site including a description of the mode of transportation (e.g. walking, taxi, project vehicle, etc.;
- f. **Mentors & Onsite Administrative Coordinator** – Names and contact information of trainee research mentors and onsite administrative coordinator;
    - g. **New Research Review and Approval** – If the trainee plans to initiate a new research project, the project must be reviewed and approved following the standard procedures outlined in *AMPATH's Research Project and Grant Proposal Development Policy* (See website for applicable policies, ampathkenya.org/research-policies-and-procedures). This includes review and approval by the appropriate research working group(s) and, if applicable, the AMPATH Data Analysis Team (ADAT) and Reference Laboratory Director. Trainees and mentors are advised to begin this process at least 16 weeks before travelling to Kenya.
- h. **IRB & IREC Approval** – After review and approval by the research working group(s), ADAT, and Reference Laboratory, new project proposals must be reviewed and approved by the Moi University Institutional Research Ethics Committee (IREC) and the trainee and mentor's Institutional Review Boards (IRBs). It is recommended that a minimum of 8-10 weeks be allowed to complete the IREC review process. Details for submitting a proposal to IREC are available on the IREC website, www.irec.or.ke. *No research activities can commence until all regulatory approvals have been received. Trainees who plan to participate in existing research studies that have already obtained IRB and IREC approval should be added to the list of project personnel.*
- i. **Online Orientation** – All research trainees are required to complete the consortium's online orientation for first time visitors and provide a completion report.

If the above requirements are met, AMPATH is willing to host the trainee's research. Please note, AMPATH cannot support unfunded research either financially or with infrastructure support (e.g., data management and analysis, project oversight). This must be provided by the trainee and/or

the trainee's mentor(s). Information on fees required to support AMPATH research infrastructure can be found at *AMPATH's Research Project and Grant Development SOP*, ampathkenya.org/research-policies-and-procedures.

5. **Consortium Policies & Procedures** – Trainees conducting research must comply with all AMPATH consortium policies and procedures. Prior to departure, trainees and mentors should review the AMPATH Consortium policies for trainees travelling to Kenya to ensure all pre-departure requirements have been met.

Arrival Procedures

On arrival in Kenya, the trainee is responsible for reporting to the Research Program Office and confirming their previously approved research plans. Trainees are also responsible for contacting their research mentors and onsite administrative coordinators upon arrival.

Trainees Already in Kenya

Trainees who are already on the ground in Kenya for a clinical rotation or other approved activity should follow the approval process outlined in this SOP. Any trainee interested in research who has not received prior approval should contact the Research Program Office to discuss the approval requirements and process. Trainees are not permitted to initiate any research activity without first obtaining the approvals described in this SOP.

Waiver of Requirements

The Research Program Office will consider requests to waive requirements described in this SOP on a case by case basis. Waiver requests must be submitted in writing to research.manager@iukenya.org at least 4 weeks before travel to Kenya. The Research Program Office along with the Co-Directors of Research will review waiver requests and provide written notification of a decision to the requesting mentor and/or trainee within 10 business days. Trainee travel cannot commence until written notification from the Research Program Office to waive SOP requirements has been received or all of the requirements outlined in this SOP have been met.

SOP Version Log			
Version Number	*Date*	*Authors*	*Summary of Changes*
Version 1	3/1/2011	J. Kiplagat-Kirui A. Bell	• First version of SOP published
Version 2	3/7/2013	D. Plater	• Updated names and contact information for co-directors of research
Version 3	12/8/2015	D. Plater R. Pettigrew J. Kiplagat-Kirui	• Updated pre-departure requirements and approval process for trainee research; • Added requirements for onsite administrative coordinator;

			• Detailed required documentation to be submitted to Research Program Office by trainees; • Refined timeline for approval; and • Updated SOP applicability statement.
Version 4	5/30/2018	J. Kiplagat-Kirui D. Plater J. Wagner	• Removed Consortium policy link. • Updated AMPATH's Research Project and Grant Development SOP links
Version 5	3/4/2019	D. Plater J. Wagner E. Walumbe	• Includes link to AMPATH Visitor Information Form • Added overview of AMPATH Visitor Information Form process