INTRODUCTION

COVID-19 spread is emotionally challenging for many people, changing day-to-day life in unprecedented ways. We, therefore, should all play a role to protect ourselves and each other and help prevent further spread of the disease. The Kenyan Government has put in place multiple measures to limit the spread of the virus including containment of the population in the areas with confirmed cases, stay at home, social distancing, cough etiquette, handwashing and sanitizing, use of masks while in public, night curfew, and enforced quarantine for travelers and their contacts among others.

World Health Organization alongside the Government of Kenya is continuing to provide advice and updated information on COVID-19. Once the preventive measures are achieved and a reduction in COVID-19 transmission rates, the Kenyan government is recommending a gradual resumption of work activities. This is being done stepwise, with work that is considered essential for health protection and the economy recommended to resume first and work that can be done effectively while working from home last. However, regardless of how and to what extent normal work activities resume, it is highly likely that some measures will remain in place for some time to avoid a steep increase in infection rate. In line with these, the AMPATH research Program is considering re-opening of its research activities, upon meeting the outlined criteria provided in this policy.

Purpose of the policy

The purpose of this policy is to guide the research projects as they begin re-opening of their non-essential research activities following suspension at the beginning of COVID-19 pandemic.

Decision to Reopen

The following plan to reopen AMPATH research activities is dependent on local and national guidance in Kenya on reopening approaches. The guidance included in this document is meant to be in line with government guidelines or requirements and may be changed without warning as new guidelines emerge. Studies may be required to suspend operations at any time to ensure the safety of our participants, staff, faculty, and communities.

Guidelines

Starting July 1, 2020, non-essential research activities that meet the restart guidelines defined in this policy and approved by respective PI’s can resume research activities. Studies that can continue to operate remotely should maintain social distancing and remote working arrangements. Non-essential research studies that resume enrolling study participants at MTRH and AMPATH/MOH clinic sites or in community based settings will be required to enact measures to protect study participants and research personnel, and comply with public health directives to limit community spread of COVID-19. Studies should use the following guide to determine when study activities are allowed to resume.
# Return to Work Policy for AMPATH Research Program Staff

## Essential Research Activities

- Work that directly relates to preventing, containing, or treating the COVID-19 pandemic
- Clinical trials and other research activities that if discontinued would have a significant negative impact on human health or patient care
- Work that directly relates to national security
- Activity that if discontinued would pose a safety hazard
- Laboratory or field work where discontinuation would result in loss of significant data and samples
- Longitudinal or seasonal work where discontinuation would result in loss of significant data or samples
- Work to maintain critical equipment, whether in stand-by mode or operational
- Research administration, compliance, and other support functions required by law

## Clinic-Based & In-Patient Research

- All non-essential research activities that occur in MTRH and MOH clinics and in-patient facilities including in-person recruitment of study participants

## Community-Based Research

- All non-essential research activities occurring at community-based partner sites including in-person recruitment of study participants

## Office & Laboratory-Based Research

- All non-essential research activities that occur in AMPATH offices or laboratory facilities
- Personnel and activities that can continue remotely are encouraged to continue remotely
# Return to Work Policy for AMPATH Research Program Staff

<table>
<thead>
<tr>
<th>Essential Research Activities</th>
<th>Clinic-Based &amp; In-Patient Research</th>
<th>Community-Based Research</th>
<th>Office &amp; Laboratory-Based Research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When are these activities allowed to resume?</strong></td>
<td>Currently allowed if restart criteria has been met</td>
<td>Allowed on or after July 1, 2020, once restart criteria are met</td>
<td>Allowed on or after July 1, 2020, once restart criteria are met</td>
</tr>
</tbody>
</table>
| **What criteria must be met for activities to resume?** | - Defined safety protocol in-place to ensure appropriate social distancing, PPE, and handwashing and hand sanitizing measures are followed by study personnel and study participants  
- IREC approval obtained for any modified study procedures needed to protect research personnel and study participants | - No active travel ban and/or quarantine orders limiting travel in or out of a clinic site location  
- Approval from the in-charge of clinic reopening and resumption of research activities is allowed  
- Research restart checklist complete with any modifications to minimum safety guidelines documented in a written safety protocol approved by the Principal Investigator  
- 30 day supply of PPE and supplies needed to implement safety protocols are procured and available to study personnel  
- IREC approval obtained for any modified study procedures needed to protect research personnel and study participants | - No active travel ban and/or quarantine orders limiting travel to/from office/lab facility  
- Research restart checklist complete with any modifications to minimum safety guidelines documented in a written safety protocol approved by the Principal Investigator  
- 30 day supply of PPE and supplies needed to implement safety protocols are procured and available to study personnel  
- IREC approval obtained for any modified study procedures needed to protect research personnel and study participants |
|                                |                                |                          |                                  |
Considerations before re-opening

As the AMPATH Research Program, we are recommending making considerations in your plan for re-opening including:

- Assessing the risk of your study staff as well as that of your participants.
- Carrying out adaptations to the layout of the offices and the organization of work that will reduce COVID-19 transmission before resuming work fully and before all study staff return to work. Consider resuming work in stages to allow adaptations to be carried out. Be sure to inform research staff about the changes and provide them with new procedures and training, if necessary, before they resume work.
- Paying special attention to workers who are at high risk and be prepared to protect the most vulnerable, including older people and those with chronic conditions including hypertension, lung or heart problems, diabetes, or who are undergoing cancer treatment or some other immunosuppressed and pregnant staff. Pay special attention to staff with close family members who are at high risk.
- Considering putting in place support for staff who may be suffering from anxiety or stress.
- Staff might be worried about an increased chance of infection at the workplace and may not want to return. It is important to understand their concerns, provide information about the measures taken and the support available to them.

Minimum Safety Guidelines

In preparing to reopen, all studies are asked to ensure the following minimum safety measures are in place to protect study teams and participants. PIs should review the following minimum safety guidelines with study personnel and, where needed, develop additional study specific safety measures and trainings to ensure staff and participant safety. Modifications are allowable as long as minimum safety guidelines are met and the modifications provide greater protection than the minimum guidelines. PIs are responsible for documenting any additional safety measures specific to their studies in a written safety protocol that is shared with study personnel and updated regularly to comply with current public health guidance:

Staff Symptom Screenings

Studies are asked to ensure a process is in place to screen staff for COVID-19 symptoms before engaging in in-person research activities at clinic, community, and/or office work sites. Studies should follow the Ministry of Health’s recommendations to screen staff for the following symptoms in advance of any activities involving in-person contact. Staff with the following symptoms should be asked to stay at home and follow MOH guidance for reporting and self-quarantine:

- Low grade fever (37.3 ° C)
- Respiratory or flu like symptoms, i.e. shortness of breath, mild persistent cough, sneezing, running nose
- Tiredness, muscle pains
- Loss of taste and/or smell
Individual studies are responsible for managing the screening process for their study staff and communicating this requirement with study staff.

**Stay-at-Home & Sick Leave**

Staff exhibiting symptoms should stay at home and follow MOH guidelines for self-quarantine and notification of public health officials. Staff should use sick leave and will be allowed to return to work when they are symptom free for at least 10 days or have a confirmed negative COVID-19 test result.

**Remote Work**

Studies should review their study work requirements with study staff and identify activities that can be completed remotely. PIs should work with study staff to determine work from home ability and develop schedules to allow staff to work remotely when possible and to allow greater social distancing in offices and other work sites. Remote work arrangements are at the discretion of the study PI in consultation with study staff.

**Physical & Social Distancing**

Studies should adhere to the MOH’s social distancing guidelines at all work sites. These guidelines include, but are not limited to, the following measures:

- Ask staff to work remotely whenever possible
- Ask staff to avoid handshakes or other physical contact
- Arranging workstations to allow a minimum of 1 meter of space between work stations
- Staggering work schedules to minimize staff contact and allow physical distancing in workspaces
- Adding physical dividers/barriers between work spaces
- Limiting public access to office spaces
- Staggering break times

PIs are responsible for reviewing MOH guidelines and ensuring study activities comply with MOH recommendations.

**Travel to/from Project Work Sites**

Prior to resuming study activities, PIs should review travel restrictions that apply to any project site locations and confirm that the resumption of project work will comply with all curfew, quarantine, and/or travel bans currently in place for project sites.

Studies should review study procedures and identify areas where travel can be reduced or eliminated. When travel is required, studies should adhere to the following guidelines:

- Complete symptom screening prior to travel
- Use private transportation whenever possible
- Limit the number of personnel travelling in a single vehicle to promote social distancing
- Require staff travelling to wear face masks at all times
- Provide hand sanitizer for travelers and practice MOH hygiene recommendations
Face Masks & Personal Protective Equipment

Study personnel are required to wear face masks at all times at work site locations. Studies should ensure study personnel have access to required face masks. Clinic based studies should follow the clinical guidelines for face coverings and PPE at study sites. In cases where no clinical guidelines are in place and/or community based studies should follow the MOH’s guidelines for face masks and PPE.

Studies should review the PPE requirements for sites where study work activities will occur to identify the specific PPE supplies that will be needed to complete study activities. A 30 day supply of PPE to adequately support project activities should be procured and available to project personnel before work can resume. It is recommended studies implement a system to track and manage PPE supplies to ensure personnel have access to the required PPE needed to conduct study activities.

PIs are responsible for ensuring the appropriate use of PPE by their study teams at all worksite locations. PIs should review PPE requirements with study personnel and conduct trainings to ensure study personnel adhere to correct fitting, use, removal, cleaning, storing and disposal of PPE. Where appropriate, studies should develop arrangements for the cleaning, inspection, maintenance and disposal of PPE and provide training to study personnel on these arrangements.

Access to Handwashing Facilities and/or Hand Sanitizer

Studies should review MOH and MTRH guidelines for handwashing and sanitation with all study personnel. Studies are responsible for ensuring personnel have ready access to hand washing facilities with soap and/or hand sanitizer at all work site locations. Studies should review access to these facilities and ensure any handwashing supplies, e.g. soap, sanitizer, etc., are procured and available to study personnel at all study sites prior to the resumption of study activities.

Cleaning and Sanitation of Equipment and Work Spaces

Studies should review MOH guidelines for regular cleaning and sanitation of equipment and workspaces and identify any cleaning supplies and/or equipment that will be needed to ensure compliance with recommended sanitation procedures. PIs should review the requirements with study personnel and put in place a process to ensure personnel adhere to cleaning recommendations. Adequate cleaning supplies should be procured and made available to project personnel at all work sites prior to the resumption of study activities.

Sharing COVID-19 Prevention messages with study participants

Study staff should endeavor to educate and share COVID-19 prevention messages with their study participants. These should include

- Washing hands regularly with soap and running water for at least 20 seconds
- When coughing or sneezing, cover mouth & nose with flexed elbow and immediately wash your hands
• Wearing mask when in public places; markets, supermarkets, when walking or travelling by vehicle, motorbike, etc.
• Avoiding direct contact with anyone that has flu like symptoms; coughing, sneezing
• Avoiding touching mouth, eyes or nose
• Avoiding crowded places and observing a social distance of 2-3 steps from one person to another
• Staying at home, observing social distance and avoiding crowds at all times.

Supportive Supervision
More frequent supportive supervision will be needed, given how rapidly the pandemic evolves and how quickly protocols, procedures, and problems evolve with it. It is therefore, advised that research/study coordinators and investigators should work closely with their research staff recruiting or collecting data to ensure that they are well protected, including conducting a wellness assessment.

AMPATH Research Support Services
Research Sponsored Projects Office (RSPO), the Research Program Office (RPO), and Institutional Research Ethics Committee (IREC) staff are working remotely when possible to comply with public health directives and guidance. While we believe most services will continue with limited interruption during this period, please be aware that in-person service are limited and virtual meetings are encouraged. For questions regarding service availability, please contact the unit leads:

<table>
<thead>
<tr>
<th>Support Office</th>
<th>Status (as of 4/15/2020)</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>RSPO</td>
<td>Working remotely with in-person contact only for essential services</td>
<td>Robert Rono&lt;br&gt;<a href="mailto:robertrono@iukenya.org">robertrono@iukenya.org</a></td>
</tr>
<tr>
<td>RPO</td>
<td>Working remotely with in-person contact only for essential services</td>
<td>Chiri Kiplagat-Kirui &amp; David Plater&lt;br&gt;<a href="mailto:research.manager@iukenya.org">research.manager@iukenya.org</a></td>
</tr>
<tr>
<td>IREC</td>
<td>Working remotely with in-person contact only for essential services</td>
<td>Catherine Okwiri&lt;br&gt;<a href="mailto:irecoffice@gmail.com">irecoffice@gmail.com</a></td>
</tr>
</tbody>
</table>