

Standard Operating Procedure for Research Project and Grant Proposal Development

Version No: 8

Approved Date: 23 May 2019

Effective Date: 23 May 2019

Process Overview

The following process flow includes the average minimum times required to process a new study submission. Actual processing times vary from study to study. Investigators are strongly encouraged to begin the review process as early as possible to ensure submission deadlines are met.

7-8 weeks before lead institution proposal routing deadline

Contact Research Program Office, research.manager@iukenya.org, to discuss proposal and policy requirements

Consult RSPO to begin development of project budget

6 weeks before lead institution proposal routing deadline

Submit New Study Information Form, draft project budget, and proposal to research.manager@iukenya.org. Research Program Office reviewes proposal and budget. Assigns proposal to working group(s), ADAT, and/or Lab for review within 3 business days of proposal submission

Working group chair(s) provide preliminary comments and feedback and schedule discussion of the proposal within 10 business days

Full working group(s) discuss proposal within 1 month of review assignment

4 weeks before lead institution proposal routing deadline:

Research Program Office routes approved budget and proposal to RSPO for final review and processing RSPO reviews project budget, budget Justification, and works with PI(s) to revise budget as needed within 10 business days of routing from RPO



2 week before lead institution proposal routing deadline:

RSPO approves final budget

RSPO sends final budget, budget justification, & proposal to the Dean of SOM, Principal of CHS, and Director of MTRH for approval within 3 business days of routing

RSPO submits approved proposal by grant submission deadline



Development Checklist: Is your proposal ready?

Check your proposal to make sure it's met all the following requirements before submitting to a sponsor and/or IREC.

- Proposal submitted to AMPATH Research Program Office (ARPO) via the <u>New Study</u> Information Form
- Proposal assigned & routed by ARPO to research working group(s) and core(s)
- Proposal presented and discussed at assigned working group and core meetings
- Proposal approved by all assigned working group(s) and core(s)
- Budget submitted to RSPO for review and processing
- Budget includes all of the following required items:
 - North American Research Facility Fee (or waiver)
 - o Indirects at maximum amount allowed by sponsor (or waiver)
 - o IREC fee (or waiver)
 - 5% FTE for Moi Research Program Manager (or waiver)
 - Medical Health Insurance for Kenyan project personnel
 - o Biostats & Data Management costs as approved by ADAT (if applicable)
 - Laboratory support as approved by Lab Core (if applicable)
 - o Informatics support as approved by Informatics Core (if applicable)
- Final budget reviewed and approved by ARPO
- Submit & celebrate!

Next steps . . .

Once your application is submitted don't forget to:

- □ Send a final copy of the application package to ARPO, <u>research.manager@iukenya.org</u>
- Submit proposal for IREC review
- Notify ARPO of sponsor funding decision



PROPOSALS FAILING TO COMPLY WITH THESE GUIDELINES WILL NOT BE ALLOWED TO SUBMIT TO SPONSORS AND/OR IMPLEMENT PROJECT ACTIVITIES AND BUDGET AS WRITTEN UNTIL ALL POLICY REQUIREMENTS ARE MET. NON-COMPLIANT PROPOSALS ALREADY SUBMITTED TO SPONSORS MAY BE FORCED TO WITHDRAW FUNDING APPLICATIONS FROM CONSIDERATION UNTIL ALL REQUIREMENTS ARE MET.

Purpose

To ensure that all AMPATH research projects: (1) are feasible, scientifically sound, not in competition with one another for scarce resources (patients, staff time, specimens, etc.), and in harmony with AMPATH's mission, values, and strategic priorities; (2) include an appropriate share of the costs needed to support research infrastructure and related activities at AMPATH; and (3) set faculty investigators compensation at a level consistent with proposed percent effort.

Applicability

This SOP applies to any collaborative research activity, including student or trainee research projects and practicums, that (1) will involve one or more AMPATH consortium partners from outside Moi University and/or Moi Teaching and Referral Hospital; (2) will use AMPATH infrastructure and/or research resources (including delivery system, information systems, data, and intellectual resources; <u>OR</u> (3) will use retrospective clinical or patient data included in the AMPATH Medical Records System and/or other associated data systems; and/or (4) will prospectively collect data from AMPATH patients.

Proposal Development and Review

Before a research proposal can be submitted to a potential sponsor, IRB or IREC, Investigators are required to submit a New Study Information Form, AMPATH Research Program Office (ARPO), research.manager@iukenya.org, for review and routing to the appropriate research working groups and cores. Final approval of new research proposals is granted by the Kenyan Co-Director of Research for the AMPATH Consortium (Winstone Nyandiko) and the Interim North American Co-Director of Research for the AMPATH Consortium (Kara Wools-Kaloustian) once the requirements described in this SOP are met. The procedure for routing proposals for review and approval is as follows:

 Submit (1) a New Study Information Form, (2) proposed study protocol, and (3) budget to ARPO, research.manager@iukenya.org, at least 6 weeks before the lead institution's deadline for routing and submission of new grant proposals and/or the planned submission date to IREC.



- 2. ARPO reviews and assigns submitted proposal to (1) one or more of AMPATH's 10 research working groups (Adult Medicine, Cardiovascular & Metabolic Disease, Basic Science, Behavioural and Social Science, Paediatrics, Public Health/Primary Care, Oncology, Pharmacy, Reproductive Health, and Tuberculosis) as well as any relevant research cores (Operations, Data Management & Biostatistics, Clinical Informatics, Laboratory, and Bioethics) for review and approval; (2) ADAT for review of biostatistics and data management requirements; and (3) AMPATH Reference Lab for review of laboratory needs if required by the project.; (4) Clinical Informatics if AMPATH informatics resources will be used. Assigned working group and core cochairs or their designees review submitted proposal, schedule discussion of the proposal by the full working group, and send preliminary feedback to corresponding investigators within 10 days of review assignment.
- 3. Full working group reviews proposal and provides feedback and approval decision within one month of proposal assignment.
- 4. Working group and core co-chairs or their designees notify ARPO and the investigator within 3 business days when a proposal is approved.
- If required, ADAT, Laboratory, and Informatics completes proposal review and sends approval and feedback to the corresponding investigator within 10 days of proposal routing and notifies ARPO of review decisions.
- 6. Studies not seeking funding can proceed to IREC review after working group and ARPO reviews are complete.
- 7. Studies seeking funding will be reviewed by ARPO for compliance with AMPATH SOPs. After ARPO compliance review is complete, the corresponding investigator completes an RSPO routing request form and the proposal is routed to RSPO for final review and submission to sponsor.

Expedited Review Requests

Investigators may request an expedited review process in instances where a sponsor has mandated an application deadline that is less than 6 weeks from the time a funding opportunity is announced. Investigators must submit a copy of the funding opportunity announcement with its release date and application deadline for ARPO to verify it meets the above criteria. Proposals that are granted an expedited review are required to submit all required materials including 1) a New Study Information Form, (2) proposed study protocol, and (3) budget to ARPO, research.manager@iukenya.org. Proposals will be assigned for rapid review by an appropriate working group, ARPO, ADAT, Laboratory, and Informatics Cores, if required. All review groups assigned an expedited proposal will provide written feedback and provisional approval within 5 business days to facilitate proposal submission. Following provisional written approval, working groups may reserve the right to discuss expedited proposals in regularly scheduled meetings. However, the proposal will be allowed to submit if provisional approval is granted through the



expedited review process.

Students/Trainees engaged in a formal training program may also request an expedited review process when dictated by program deadlines. Students/Trainees should submit a request for an expedited review following the above procedure and include documentation of the required deadline.

Standard Budget Elements

Discussions on project budgets should be initiated early, 4-6 weeks prior to a grant submission deadline. Please contact ARPO, research.manager@iukenya.org, to discuss SOP requirements and the budget development and review process as early as possible.

Budget Elements at a Glance				
Required Elements				
Facility Fee	US\$ 218.00 per 1% North American Faculty FTE			
Indirects	Maximum allowable rate			
IREC Fee	See IREC schedule below			
Moi Research Program Manager	5% FTE			
Medical Health Insurance Costs	Check RSPO for rates			
Biostats & Data Management	Determined by ADAT review			
Laboratory Support	Determined by Laboratory Review			
Informatics Support	Determined by Informatics Core Review			
Recommended Elements (Vary by Project Needs)				
Publication and Dissemination Fees	\$500-2,500			
Project Space	\$16.58 per square foot per year			
Travel	\$5,000 per international trip			
Local Transportation	\$1.06 per kilometer			
Telecommunications Costs	\$4 per hour call			

Required Budget Elements

The following budget elements are required for all AMPATH Research Projects with total direct budgets of US\$50,000 or more. Projects with direct budgets under US\$50,000 may be eligible for reduced fees or waivers. Please see the Fee Exceptions & Waivers section below for details.

International Partner Budgets

The following items should be included on the international (non-Kenyan partner) prime institution's budget.

AMPATH Research Network Facility Fee – Research projects that include funding for
investigators at academic institutions or other research organizations based outside of Kenya
should include the AMPATH Research Network Facility Fee in their direct costs. The facility fee
helps provide members of the AMPATH Research Network with access to critical research
support services and infrastructureneeded for the development and implementation of successful



collaborative research ventures at AMPATH. This included, but is not limited to, ensuring the availability of high quality research data management and analysis infrastructure, the provision of high quality communications resources to facilitate international collaboration, training of research support personnel, and administrative support for the network of institutions engaged in AMPATH related research.

The fee is calculated based on the total amount of supported international faculty investigator effort on a project and a specified fee rate. The rate is calculated by multiplying the fee rate by the total number of FTE percentage points in the first project year. The fee amount for each subsequent project year is inflated at a rate of 2%.

The fee rate is reviewed at the end of

Sample Facility Fee Calculation

At the 2019-20 rate, the AMPATH Research Network Facility Fee is calculated as US\$ 218.00 per 1% North American investigator FTE for 12 Calendar Months in Project Year 1 and is inflated on an annual basis at 2% inflation. For example, if a grant budget includes support for 3 North American faculty investigators from 3 different institutions at 10% FTE (1.2 calendar months) per investigator, the budget must include a direct line item of US\$ 6,540 in the first year (US\$ 218 x 30% total North American FTE x 100 = \$6,540), \$6,670 in year two, and \$6,804 in year three. The fee totals should appear on the prime North American institution's budget for all partners.

each fiscal year and adjusted for the new fiscal year. Rate adjustments are usually published one month before the start of the new fiscal year and go into effect on July 1, of each year. Please note that the AMPATH Research Network Facility Fee should only be included on the prime international partner institution's budget.

All AMPATH Research Facility Fee calculations must be reviewed and confirmed by ARPO prior to submission to a sponsor. Please contact ARPO, research.manager@iukenya.org, for assistance in calculating the facility fee requirements for your project.

Moi Budgets

The following items should be included on the Moi University budget.

- 1. Indirects Indirects or Facilities and Administrative costs should be included at the maximum rate allowed by a sponsor. The NIH currently limits indirects paid to foreign entities to 8%. However, other US Federal Agencies and sponsors may apply different rates and investigators should check with potential sponsors to confirm the maximum allowable rate. On grants whose sponsors do not allow indirect support, additional direct line item budgeting of administrative supports may be required and projects should consult with RSPO to determine the appropriate levels of administrative support that should be budgeted.
- Institutional Review and Ethics Committee (IREC) Review Fee Moi charges a standard fee
 to cover the cost of required human subject reviews by IREC. The reviews covered by these fees

are not otherwise supported by indirects or other fee mechanisms and should be included as a direct line item on research project budgets. The IREC fee is determined using a sliding fee schedule as follows:

Total Project Directs Budget (USD)	IREC Fee (USD)
Unfunded Student/Trainee Project	\$10
Unfunded Masters Project	\$20
Unfunded PhD Candidate Project	\$30
Unfunded Faculty Project	\$50
\$0 - 50000	\$500
\$50 000 - 100 000	\$1,000
\$100 000+	\$1,500

In cases where IRB/IREC fees are not allowed by a sponsor, please contact RSPO to discuss specific budget requirements. For assistance or questions with IREC fees, please contact the IREC administrator, irecoffice@gmail.com.

IREC does not waive its fees for students or trainees. However, unfunded student/trainee projects may be eligible to receive IREC's student rate of KSH 1,000 (US \$10) for unfunded projects. Please contact the IREC administrator, irec@mtrh.or.ke or irecoffice@gmail.com, for instructions to request the student/trainee project rate.

- Moi Research Program Manager Explicit support for the Moi Research Program Manager should be included in the Moi budget, established by negotiation with the ARPO. The minimum required support is 5% FTE (a total of US\$ 2,467 at 2019-20 rates). Please contact the ARPO, research.manager@iukenya.org, to confirm current rates.
- Medical Health Insurance Costs Projects are required to include medical cover costs/Fringe benefits for each staff employed in their projects. Please check with RSPO, Robert Rono (<u>robertrono@iukenya.org</u>), for Fringe benefit rates.
- 5. Biostatistics & Data Management Support— Projects requiring access to data from AMPATH Medical Record System (AMRS) and other associated AMPATH data systems, lists of potential eligible AMPATH study participants, sample size calculations, data analysis services, and/or other AMPATH biostatistics and data management services are required to include sufficient budget support for these services. The appropriate level of support is determined through review by the AMPATH Data Analysis Team (ADAT) when a new study proposal is submitted to the ARPO for review.

Investigators should complete the Biostatistics and Data Management section of the *New Study Information Form* when submitting their proposal to the ARPO for review. Proposals are routed to ADAT_by ARPO for review within 3 business days of submission. ADAT reviews are completed within 10 business days of proposal routing and approval along with the recommended ADAT budget is sent to the corresponding investigator and ARPO prior to the budget's routing to RSPO. In general, required support for biostatistics and data management falls into the following tiers.



Tier 1: Consultation Only

Projects that primarily require advice and consultation from ADAT on interpreting and working with clinical care data in the AMPATH environment along with occasional statistical or data management consultation will be required to include Tier 1 Biostatistics & Data Management support in their project budgets. This support typically includes 5% FTE support for a faculty statistician and 5-10% support for a data manager or analyst.

Tier 2: Consultation Plus

Research projects that require use of AMRS data and will require intensive support from ADAT on issues related to identifying and extracting data from the AMRS Master Dataset along with the delivery of an analysis ready dataset and the participation of ADAT staff in research project meetings and work are classified as Tier 2 projects. In most cases, these projects require data management support but do not require faculty level input regarding statistical design and analysis. Tier 2 projects are normally required to provide 5-10% FTE support for a faculty data management supervisor and 25-100% FTE support for a data manager depending on specific project needs.

Tier 3: Full Scale Collaboration

Tier 3 projects require intensive engagement by faculty level biostatisticians who will work on the project proposal, develop project design and sample size, write an analysis plan, participate in research as an integral member of the project team, attend project meetings, oversee data management and analysis, extract and manage data from AMPATH's data systems, assist in writing publications, and/or work with a project team to construct and manage a database for primary data collection. Support at this level typically includes 10-25 % FTE support for a PhD level statistician, 20-50% FTE support for a Master's level statistician, and 25-100% FTE support for one or more data managers.

- 6. Laboratory Support— Projects requiring Moi Reference Laboratory support are required to complete the laboratory section of the New Study Information Form. Proposals are routed by ARPO to the Moi Reference Laboratory Manager for review within 3 business days of submission. Laboratory reviews are completed within 10 business days of proposal routing and approval along with the recommended laboratory budget is sent to the corresponding investigator and ARPO prior to the budget's routing to RSPO.
- 7. Informatics Support—Projects requiring information technology support and business consulting are required to complete the informatics section of the New Study Information Form. Informatics supports include technical support for project personnel, website and database programing and development, software and app development, online survey programming, installation and administration of back office systems including servers and network administration. Proposals are routed by ARPO to the AMPATH Informatics Core for review within 3 business days of



submission. Informatics reviews are completed within 10 business days of proposal routing and approval along with the recommended informatics budget is sent to the corresponding investigator and ARPO prior to the budget's routing to RSPO.

Pro-Rating, Exceptions & Waivers

Required budget amounts may be pro-rated or waived for student or trainee projects and practicums, projects with the primary aim of producing pilot data for future funding opportunities, and/or projects with the primary aim of demonstrating program capabilities for future funding opportunities. Investigators must complete the Budget Waiver section of the *New Study Information Form* when submitting a new study proposal for review. ARPO will review waiver requests and approve the following exceptions to the budget requirements if eligibility requirements are met.

Pro-Rated Budget requirements

ARPO may approve pro-rated amounts for the Research Program Manager, Biostatistics and Data Management, Laboratory, and Informatics requirements described in this SOP if the following eligibility requirements are met:

- 1. Total direct budget is between US\$ 20,000 and 50,000;
- 2. Proposed project period does not exceed 24 months;
- Project is part of a student/trainee practicum, its primary purpose is to produce pilot data for future funding, and/or its primary purpose is to demonstrate program capabilities for future funding opportunities; and
- 4. Project PIs have not received a fee waiver or exception 12 months prior to the date of proposal submission.

ARPO in consultation with RSPO, ADAT, the Laboratory, and Informatics Core, will determine appropriate pro-rated amounts on a case by case basis for eligible projects.

Budget Waivers

ARPO may waive any or all support requirements for the Research Program Manager, Biostatistics and Data Management, Laboratory, and Informatics requirements described in this SOP if the following eligibility requirements are met:

- 1. Total direct budget is under US\$ 20,000;
- 2. Proposed project period does not exceed 24 months;
- 3. Project is part of a student/trainee practicum, its primary purpose is to produce pilot data for future funding, and/or its primary purpose is to demonstrate program capabilities for future funding opportunities; and
- 4. Project PIs have not received a fee waiver or exception 12 months prior to the date of proposal submission.

Recommended Budget Elements

The following budget elements are strongly recommended for successful research collaborations but are



not explicitly required.

- 1. Publication and Dissemination Fees Projects are required to provide a plan to disseminate the results of their study. AMPATH Research urges dissemination of research findings to the wider research community, but also to policy-makers and the local communities that were engaged in research processes. Any planned publication and dissemination costs should be included as a line item in project budgets and will be reviewed by the ARPO to ensure that sufficient funds are available to support the dissemination activities and active participation of Kenyan faculty investigators.
- 2. Project Space The ARPO manages research project space in the Chandaria Cancer and Chronic Disease Centre on the MTRH campus. Project space is available at a standard rental rate of US\$ 16.58 per square foot. This rate includes rental fees, cleaning, general maintenance, and shared equipment and infrastructure. Please note that the standard rate for space is reviewed annually and adjusted to current market rates. Updated standard rates will be circulated by ARPO prior to the start of the fiscal year. Please check with the ARPO, research.manager@iukenya.org, to determine space availability and the total current rate for project rental space.
- 3. **Travel** If travel to disseminate research findings is planned, support should be budgeted for both Kenyan and non-Kenyan investigators when feasible. Optimally, both the North American and the Moi budgets should include line items supporting local and international travel for Kenyan and non-Kenyan co-investigators to present research findings. The default estimate is US\$ 5,000 per person for international travel, accommodation, and conference fees. Please check with RSPO, Robert Rono (robertrono@iukenya.org), for estimates on local and regional travel in East Africa.
- 4. Local Transportation Local transportation costs in Kenya should be considered and included in the budget when appropriate. If staff will be hired to work at sites outside of Eldoret, investigators should include transportation and lodging costs for Human Resources staff to travel to the site to conduct interviews. Vehicles may be rented through the ARPO at US\$ 1.06 per kilometre. Please consult the SOP for Use of Research Vehicles and contact ARPO, research.manager@iukenya.org, for vehicle availability. Please check with RSPO, Robert Rono (robertrono@iukenya.org), for estimates on local transportation.
- Telecommunications Costs Projects are responsible for covering telecommunication costs for in-country and international conference calls as well as internet access fees.



Budget Review

All grant budgets must be reviewed by both ARPO and RSPO prior to submission to a sponsor. Budgets and budget justifications should be submitted to RSPO at least 10 business days before the grant submission deadline or the prime institution's internal application routing deadline. RSPO routes the final budget to ARPO for final compliance review and sign-off at least 2 business days before submission deadline. ARPO reviews budget proposals for compliance with AMPATH SOPs. RSPO reviews budget proposals to ensure that project budgets meet the minimum institutional requirements described above before routing to the Principal of the College of Health Sciences and Director of MTRH for final approval.

Faculty/Investigator compensation and budget management

Moi faculty member time commitments and compensation levels must be discussed in detail with the Moi PI and RSPO before submission of a grant. Adjustments in funds awarded may be made at any time by the funding agency, at the agency's sole discretion, even after an award has been made and at any time in the course of a project. Additionally, project needs and participant's time availability may change as a project matures, affecting both time contributions and compensation. If adjustments must be made in percent time commitments and/or compensation of a faculty investigator, these changes should be made in consultation with the affected persons and RSPO in advance of their implementation.

Budgets should be co-managed by both local and international Principal Investigators. To this end, full budget information from the prime institution and from subcontracts should be made available to the co-Pls (international and Kenyan).

SOP Version Log				
Version	Date	Authors	Summary of Changes	
Version 3	31 January 2012	A. Bell J. Kiplagat-Kirui	 Updated IREC contact information. Clarified the grants development process. Added new website URL. 	
Version 3.1	18 February 2013	J. Kiplagat-Kirui D. Plater	 Updated contact information; Clarified AMPATH Research Facility Fee requirements; and Removed requirement for %FTE support for North American Research Program Manager. 	
Version 3.2	1 July 2013	D. Plater	 Updated AMPATH Facility Fee Rate from the 2012-13 rate of US\$166.13 to the 2013-14 rate of US\$ 192.30. 	
Version 4.0	7 February 2014	J. Kiplagat-Kirui D. Plater	 Added a process flow chart and timeline; Clarified research grant and project development process flow and times for critical processes; Streamlined proposal routing process and forms required for new study proposal routings; 	



			 Clarified responsibilities for publication and dissemination of research results and associated costs; Changed standard budget element for biostatistics and data management to a single fee from % FTE support for a data manager and biostatistician; Revised project space costs; Updated and clarified standard budget elements for travel and local transportation; and Update budget review process.
Version 5.0	1 July 2016	J. Kiplagat-Kirui D. Plater	 Clarifies process for expedited review of new study proposals; Revises applicability statement to more clearly define projects covered by this SOP; Clarifies applicable routing deadlines; Adds a summary table of required and recommended budget elements; Makes medical insurance a required budget element; Clarifies indirect requirements; Adds explanation of IREC rates for student/trainee projects; Simplifies process for budget review Includes summary checklist Revises timeline for proposal submission to reflect current minimum processing deadlines for RSPO; Adds an applicability statement describing who is covered by this SOP; Updates new study proposal process to clarify the review process and better reflect actual practice; Reorganizes and updates standard budget elements into two categories – required elements and recommended elements – to better delineate supports all projects are required to include from those that are recommended for most but not all projects and organizes these into elements required for North American project budgets and Moi project budgets; Updates description of AMPATH Research Facility Fee; Establishes new tiered fee structure for biostatistics and data management; Describes process for fee waivers and prorating of required program fees; and Adds process for reviewing informatics needs o research projects and ensuring proper

budgeting for informatics.



Version 6.0	J. Kiplagat-Kirui M. Kidney D. Plater J. Wagner E. Walumbe	 Updates AMPATH Facility Fee Rate from the 2016-17 rate of US\$ 215.00 to the 2017-18 rate of US\$ 218.00 Revises Sample Fee Calculation Updates Project Space rate from \$19 to \$16.58 Updates IREC fee schedule
Version 7.0	D. Plater J. Wagner E. Walumbe	 Updates link to New Study Information Form Updates AMPATH Research Co-director
Version 8.0	J. Kiplagat-Kirui M. Kidney D. Plater J. Wagner	Updates Research Manager FTE fee to \$2,467