

Standard Operating Procedure for Research Project and Grant Proposal Development

Version No: 9

Approved Date: October 9, 2023

Effective Date: October 9, 2023

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> <u>Information Form</u>
- 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:
- AMPATH Research Facility Fee (or waiver)
- Indirects at maximum amount allowed by sponsor (or waiver)
- IREC fee (or waiver)
- Medical Health Insurance for Kenyan project personnel
- Biostats & Data Management costs as approved by ADAT (if applicable)
- Laboratory support as approved by Lab Core (if applicable)
- Informatics support as approved by Informatics Core (if applicable)
- Qualitative data management and analysis support approved by Qualitative Research
 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, research.manager@iukenya.org
- Submit proposal for IREC review



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 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:

1. Submit (1) a New Study Information Form, (2) proposed study protocol, and (3) budget to ARPO,



<u>research.manager@iukenya.org</u>, 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, Basic Science, Behavioural and Social Science, Cardiovascular & Metabolic Disease, Mental Health, Oncology, Pediatrics, Public Health/Primary Care, Pharmaceutical Care, and Reproductive Health) and (2) any relevant research cores (Operations, Data Management & Biostatistics, Clinical Informatics, Laboratory, Qualitative Research, and Bioethics) for review and approval. Assigned working group and core co-chairs 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 should notify ARPO and the investigator within 3 business days when a proposal is approved.
- 5. 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 the 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, Informatics, and Qualitative 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.

Table 1. Budget Elements at a Glance

Required Elements		
Facility Fee	The AMPATH Research Facility (ARF) Fee varies by project. Please consult the ARF Fee Rates table in the next section for more information.	
IREC Fee	See IREC schedule below	
Salaries and Fringe Benefits	Check RSPO for rates	
Indirects	Maximum allowable rate	
Recommended Elements (Vary by Project Needs)		
Biostats & Data Management	Determined by ADAT review	
Laboratory Support	Determined by Laboratory Review	
Informatics Support	Determined by Informatics Core Review	
Qualitative Data Support	Determined by Qualitative Core Review	
Publication and Dissemination Fees	\$500-2,500	
Project Space	\$16.58 per square foot per year	
Travel	\$5,000 per international trip	
Local Transportation	Check ARPO for rates	
Telecommunications Costs	\$4 per hour call	

Required Budget Elements

The following budget elements may be required for all AMPATH Research Projects with total direct



budgets of US\$20,000 or more (Table 1). Brief descriptions of these elements are provided below. Projects with direct budgets under USD \$19,999 may be eligible for reduced fees or waivers. Please see the Fee Exceptions & Waivers section below for details. All of these budget elements should be included on the Moi/MTRH institution main or subcontract budget.

AMPATH Research Facility Fee — The ARF Fee will be administered by the AMPATH Research Program Office and Research and Sponsored Projects Office (RSPO) at Moi University and MTRH on behalf of the AMPATH Consortium. This fee will be considered a specialized service fee and established in compliance with OMB's Part 200 - Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (specifically, see § 200.468 Specialized service facilities), which superseded OMB Circular A-21 Cost Principles for Universities on December 26, 2013. The revised ARF Fee will support specialized research service facilities outside of what is supported by indirect costs for general operations and grants management (i.e. services provided by RSPO). Please refer to the AMPATH Research Facility Fee SOP_linked here for a complete description of the fee structure.

The ARF Fee will be applied to any grant or contract conducted at AMPATH that utilizes AMPATH research infrastructure – including projects led by Consortium and non-Consortium member institutions. The ARF Fee rate will be established for individual research projects in consultation with the research program office and RSPO during the proposal grant review process. The ARF Fee will be calculated annually by multiplying the total direct costs of the Moi/MTRH portion of the award with a percentage determined by the size of the project budget in each of the project years as defined in Table 2. There will be a higher rate charged for projects led by institutions that are not part of the AMPATH Consortium*.

Table 2. ARF Fee Rates

Total Direct Costs on Moi/MTRH Budget	ARF Fee Rate **
Moi/MTRH may be the prime awardee or operate as a sub-awardee. If Moi/MTRH is a sub-awardee, then the rate is determined by whether the prime institution of the award is an AMPATH Consortium member or not.	·
AMPATH Consortium Member Fees	
\$50,000 and above	5%
\$20,000 to \$49,999	3%



Unfunded to \$19,999	Fee waiver	
AMPATH Non-Consortium Member Fees		
\$50,000 and above	7%	
\$20,000 to \$49,999	5%	
Unfunded to \$19,999	Fee waiver	

*The AMPATH Consortium is an international network of universities and academic health centers led by Indiana University. Under this SOP, an institution is considered an AMPATH Consortium member if they have an active AMPATH Consortium MOU with Indiana University and are a dues-paying member at the time of the award. If an institution's Consortium status changes during the course of an award, the institution's status at the time of the award will be used to calculate the ARF Fee Rate for the duration of the award. For the purposes of this SOP, Moi University and Moi Teaching and Referral Hospital fall under rates established for AMPATH Consortium Member Fees.

**The AMPATH Research Program Office and Research Sponsored Projects Office in Kenya reserve the right to determine fee reductions and waivers on a per-project basis based on factors including but not limited to size and scope of project and prior institutional and/or investigator engagement at AMPATH.

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

Institutional Review and Ethics Committee (IREC) Review Fee – IREC charges a standard fee to cover the cost of required human subject reviews. 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.

Salaries and fringe benefits for personnel – Projects are required to include medical cover costs/Fringe benefits for each staff employed in their projects. Please check with Senior Director, Finance and Administration at RSPO, Robert Rono (ampathcontracts@ampath.or.ke), for standard salary and fringe benefit rates.

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.

<u>Fee Reductions & Exceptions.</u> Required budget amounts may be reduced in exceptional cases. ARPO, in consultation with RSPO and research cores, will review requests to alter budget requirements if eligibility requirements are met:

- 1. Total direct budget is equal to or under US\$ 19,999;
- 2. Proposed project is funded through a career development award;
- 3. Project is funded by an exploratory or pilot award (of less than \$100,000 total costs) and its primary purpose is to produce pilot data for future funding, and/or its primary purpose is to establish research teams and collaborations for future research projects;
- 4. Project is focused on institutional training or infrastructure building with less than \$100,000 total costs in funding, and its primary purpose is to establish and enhance research training, and/or establish and enhance research infrastructure; or
- 5. Project is funded through an intramural award.

Recommended Budget Elements



The following budget elements are strongly recommended for successful research collaborations but are not explicitly required.

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.

Laboratory Support – Projects requiring AMPATH Reference Laboratory support are required to complete the laboratory section of the *New Study Information Form*. Proposals are routed by ARPO to the AMPATH 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.

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 programming 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.

Qualitative data management and analysis – The AMPATH Qualitative Research Core (AQRC) complements and enhances existing AMPATH research infrastructure by providing services such as transcription and translation, qualitative data collection, data management and analysis; and training on qualitative research and methodologies. The AQRC routinely offers the following services: translation, transcription, data coding, training of research teams for qualitative research tasks, and equipment hire (e.g. audio recorders). The appropriate level of support is determined through review by the AQRC team when a new study proposal is submitted to the ARPO for review.

Investigators should complete the Qualitative Data Management & Analysis section of the *New Study Information Form* when submitting their proposal to the ARPO for review. Proposals are routed to AQRC by ARPO for review within 3 business days of submission. AQRC reviews are completed within 10 business days of proposal routing and approval along with the recommended ARQC budget is sent to the corresponding investigator and ARPO prior to the budget's routing to RSPO.



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.

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.

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 Senior Director, Finance and Administration at RSPO, Robert Rono (robertrono@iukenya.org), for estimates on local and regional travel in East Africa.

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 Please consult the *SOP for Use of Research Vehicles* and contact ARPO, research.manager@iukenya.org, for both vehicle availability and the latest rental rate. Please check with Senior Director, Finance and Administration at 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 Chief Executive Officer, 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).

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 pro-rating

of required program fees; and



		 Adds process for reviewing informatics needs of 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
Version 9.0	J. Kiplagat-Kirui O. Limo M. Scanlon W. Turientine	 Updated AMPATH Research Facility (ARF) Fee section to reflect revised fee structure; Added a link to the ARF Fee SOP to the "Standard Budget Elements" sub-section "AMPATH Research Facility Fee"; Removed mention of Moi Research Program Manager from the Required "Budget Elements" section; Updated budget fee reduction considerations to mirror updated ARF Fee SOP; Updated ARF Fee from "prime/international" budget element to a "Moi/MTRH budget element"; Removed "Interim" from North American Co-Director of Research title throughout; Added mention of Qualitative Research core (AQRC) to all sections referencing working groups and cores; Added Mental Health Working Group to list of workings throughout document; Added AQRC budget line item to "Standard Budget Elements"; Removed mention of vehicle fee rate from "Recommended Budget Elements" section; Updated ink to New Study Information form in REDCap throughout document; Updated "Moi Reference Laboratory" to "AMPATH Reference Laboratory"; Moved ADAT and Lab budget descriptions from "Standard Budget Elements" section to the "Recommended Budget Elements" section; Received approval of changes by the AMPATH Directors of Research



 Updated the RSPO contact to Senior Director, Finance and Administration and the position Director, MTRH to CEO, MTRH