### 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.

<table>
<thead>
<tr>
<th>Timeframe Before Deadline</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>7-8 weeks before lead institution proposal routing deadline</td>
<td>Contact Research Program Office, <a href="mailto:research.manager@iukenya.org">research.manager@iukenya.org</a>, to discuss proposal and policy requirements; Consult RSPO to begin development of project budget</td>
</tr>
<tr>
<td>6 weeks before lead institution proposal routing deadline</td>
<td>Submit New Study Information Form, draft project budget, and proposal to <a href="mailto:research.manager@iukenya.org">research.manager@iukenya.org</a>.</td>
</tr>
<tr>
<td>4 weeks before lead institution proposal routing deadline</td>
<td>Research Program Office routes approved budget and proposal to RSPO for final review and processing</td>
</tr>
<tr>
<td>2 week before lead institution proposal routing deadline</td>
<td>RSPO approves final budget</td>
</tr>
</tbody>
</table>
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), research.manager@iukeny.org, including:
  o New Study Information Form
  o Study protocol or concept note
  o Budget
  o Funding Opportunity Announcement (if seeking funding)

☐ 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:
  o North American Research Facility Fee (or waiver)
  o Indirects at maximum amount allowed by sponsor (or waiver)
  o IREC fee (or waiver)
  o 5% FTE for Moi Research Program Manager (or waiver)
  o Medical Health Insurance for Kenyan project personnel
  o Biostats & Data Management costs as approved by ADAT (if applicable)
  o 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, research.manager@iukeny.org

☐ Submit proposal for IREC review

☐ Notify ARPO of sponsor funding decision
**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; OR (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, a copy of their research protocol, and budgets to the 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 (Rachel Vreeman) 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, 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; (3) AMPATH Reference Lab for review of laboratory needs if required by the project; (4) Clinical Informatics if AMPATH informatics resources will be used; and (4) consortium discipline leader for.

3. 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.

4. Full working group reviews proposal and provides feedback and approval decision within one month of proposal assignment.

5. Working group and core co-chairs or their designees notify ARPO and the investigator within 3 business days when a proposal is approved.

6. 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.

7. Studies not seeking funding can proceed to IREC review after working group and ARPO reviews are complete.

8. 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@iukeny.org. Proposals will be assigned for rapid review by an appropriate working group, ARPO, and the 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@iukeny.org, to discuss SOP requirements and the budget development and review process as early as possible.

<table>
<thead>
<tr>
<th><strong>Budget Elements at a Glance</strong></th>
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<tbody>
<tr>
<td><strong>Required Elements</strong></td>
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<tr>
<td>Facility Fee</td>
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<tr>
<td>Indirects</td>
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<tr>
<td>IREC Fee</td>
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<tr>
<td>Moi Research Program Manager</td>
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<tr>
<td>Medical Health Insurance Costs</td>
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<tr>
<td>Biostats &amp; Data Management</td>
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<tr>
<td>Laboratory Support</td>
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<tr>
<td>Informatics Support</td>
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<tr>
<td><strong>Recommended Elements (Vary by Project Needs)</strong></td>
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<tr>
<td>Publication and Dissemination Fees</td>
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<tr>
<td>Project Space</td>
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<tr>
<td>Travel</td>
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<tr>
<td>Local Transportation</td>
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<tr>
<td>Telecommunications Costs</td>
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</tbody>
</table>

**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.

1. **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 infrastructure needed 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 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@iufenya.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.

2. **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:

<table>
<thead>
<tr>
<th>Total Project Directs Budget (USD)</th>
<th>IREC Fee (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unfunded Student/Trainee Project</td>
<td>$10</td>
</tr>
<tr>
<td>Unfunded Faculty Project</td>
<td>$20</td>
</tr>
<tr>
<td>$0 – 50,000</td>
<td>$500</td>
</tr>
<tr>
<td>$50,000 – 100,000</td>
<td>$1,000</td>
</tr>
<tr>
<td>$100,000+</td>
<td>$1,500</td>
</tr>
</tbody>
</table>

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.

3. **Moi Research Program Manager** – Explicit support for the Moi Research Program Manager should be included in the Moi budget, established by negotiation with the RPO. The minimum required support is 5% FTE (a total of US$ 1,883 at 2015-16 rates). Please contact the RPO, research.manager@iukenya.org, to confirm current rates.

4. **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, Christine Tonui (cchuani@iukenya.org) and Robert Rono (robertrono@iukenya.org), 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 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.

**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;
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.

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
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 RPO to ensure that sufficient funds are available to support the dissemination activities and active participation of Kenyan faculty investigators.

2. **Project Space** – The RPO manages two research compounds outside of the main AMPATH centre and charges a standard 2015-16 rate of US$ 19 per square foot for project space. 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 RPO 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, Christine Tonui (cchuani@iukenya.org) and Robert Rono (robertrono@iukenya.org), for estimates on local and regional travel in East Africa.

4. **Local Transportation** – Local transportation costs in Kenyan 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, Christine Tonui (cchuani@iukenya.org) and Robert Rono (robertrono@iukenya.org), for estimates on local transportation.

5. **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-PIs (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.

<table>
<thead>
<tr>
<th>Version 5.0</th>
<th>1 July 2016</th>
<th>J. Kiplagat-Kirui D. Plater</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Clarifies process for expedited review of new study proposals;</td>
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<tr>
<td></td>
<td></td>
<td>Revises applicability statement to more clearly define projects covered by this SOP;</td>
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<td>Clarifies applicable routing deadlines;</td>
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<td>Adds a summary table of required and recommended budget elements;</td>
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<tr>
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<td>Makes medical insurance a required budget element;</td>
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<td>Clarifies indirect requirements;</td>
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<tr>
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<td></td>
<td>Adds explanation of IREC rates for student/trainee projects;</td>
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<tr>
<td></td>
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<td>Simplifies process for budget review</td>
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<td>Includes summary checklist</td>
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<td>Revises timeline for proposal submission to reflect current minimum processing deadlines for RSPO;</td>
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<tr>
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<td>Adds an applicability statement describing who is covered by this SOP;</td>
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<td>Updates new study proposal process to clarify the review process and better reflect actual practice;</td>
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<td>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;</td>
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<tr>
<td></td>
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<td>Updates description of AMPATH Research Facility Fee;</td>
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<td>Establishes new tiered fee structure for biostatistics and data management;</td>
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<td></td>
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<td>Describes process for fee waivers and pro-</td>
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</table>
• Adds process for reviewing informatics needs of research projects and ensuring proper budgeting for informatics.