

Standard Operating Procedures for Research Data Requests	Version No: 1.0
	Approved Date: 28 April 2010
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Objectives

To ensure that:

- New research can be reviewed and prioritized by appropriate AMPATH investigators so that program goals are being met.
- Data elements needed to address the research question are within the scope of the AMRS.
- Appropriate design and analysis methods are being used to address the research question
- Ample time is available to meet deadlines for abstracts, grant submissions, etc.
- Appropriate resources are available to respond to the data request

What this SOP Covers

This SOP pertains to requests for data from the AMPATH Medical Records System, support for which is extremely limited at present. Associated analytic support may also be requested. Requests that utilize other databases, such as nutrition, PMTCT, etc. may sometimes be considered but must be approved by the individual holder(s) of those data. The Research Managers can provide contact information for the appropriate program(s).

Funding

Those requesting data for funded research will be expected to cover the expenses associated with data management support needed to fulfill the request. A separate SOP, containing a schedule of fees, is currently under development. In the interim, PI's must contact the DMC and ADAT Chairs to discuss fee structures.

Those anticipating use of AMRS and associated databases for a funded research project must include specific line items for personnel time needed for project support. An SOP is under development for this purpose as well. In the interim, PI's developing grant proposals must contact both the ADAT and DMC Chairs to ensure that proper resources will be allocated to data management and analysis.

Expected timelines

ADAT is currently supporting nearly 50 projects with a very limited staff of data managers and statisticians. *For those requesting data for unfunded research, the time from initial request to receipt of a working dataset can take up to six months.*

Contact the Chairs of the appropriate Research Working Group.

Prior to embarking on the data request, investigators are required to discuss their proposal with the Chair(s) of the appropriate Research Working Group (RWG). The investigator should be prepared to give a short description of the research concept. The RWG Chair will advise on RWG-specific requirements for formal review, ongoing AMPATH research that may be relevant, and potential collaborators for the project. The RWG Chair can also advise on an approximate timeline for review by the RWG once the formal concept and data request have been submitted.

The Research Managers, Co-Field Directors of Research, or Co-Directors of Research can advise the investigator on the appropriate RWG(s) to contact in advance of formal data request submission. Contact information is given below.

Where it is not clear which Research Working Group is the most appropriate, the Program Managers will discuss this with the requestor and one or more chair and arrive at a mutually agreeable Research Working Group to review the request.

Preparation of Concept Sheet and Data Request.

The data request has two components: a concept sheet and the formal specifications of the data request. The concept sheet and data requests should be designed to convince the RWG members that the proposed investigation is methodologically sound, hypothesis-driven, logistically feasible, addressing a new and relevant question, and inclusive of relevant collaborators.

The **concept sheet** includes a paragraph describing the scope of the proposed research, references to relevant published research, and connections to ongoing projects in the AMPATH Consortium. The concept sheet should also contain information about whether or not this is a prospective trial (if this is a prospective trial then a *new project form* must be additionally submitted to the RWG).

The **data request form** specifies hypotheses being investigated, plans for analysis, key personnel, and specific variables needed from AMRS. All fields in the data request form must be completed. Moreover, *investigators must familiarize themselves with AMPATH data collection forms in advance of submitting the request, and specify variables needed in terms of AMPATH data fields.* For data items requested from the AMRS the requestor must provide the name of the AMPATH data collection form (i.e. AMPATH Adult enrollment Form) and the questions number (s). It is available on the website <http://wiki.ampath.org.ke>, or the Research Managers can provide instructions on obtaining a copy.

Investigators must also differentiate those variables being requested from AMRS and those being collected prospectively by the project.

Submission of Concept Sheet and Data Request to Research Manager. Completed concept sheets and data requests will be formally submitted to the Research Manager using the email address data.requests@iukenya.org. The Research Manager will log the request and forward it to the appropriate RWG Chairs and inform co-Directors of research of all new requests. Investigators should check with the Research Manager or RWG Chair about meeting schedules, and submit the formal request at least one week prior to the next RWG meeting.

For RWG that meet infrequently, a timeline for conducting the review and reporting back to the investigator will be established by the RWG Chair(s) and communicated to the investigator. The review should not exceed 4 weeks.

Review by appropriate research working group (2-4 weeks).

The RWG will either request revisions – which must be resubmitted for approval – or will grant approval for submission to the AMPATH Data Analysis Team (ADAT).

The RWG Chair will communicate the RWG decision to the Research Manager. If approval is granted, the Research Manager will forward the data request to ADAT. If revisions are needed, the investigator will be notified and a revised data request must be resubmitted to the Research Manager. Once approval has been given by the RWG Chair(s), the data request will be forwarded to ADAT.

RWG have the discretion to review and approve requests via electronic discussion, particularly when meetings are infrequent.

Review by ADAT (1-2 weeks). ADAT meets every Wednesday. Approved data requests will generally be forwarded to ADAT each Friday afternoon. The proposal will be reviewed for feasibility in terms of data extraction, for appropriate use of statistical methods, and for feasibility of meeting the request in the stated timeframe.

If at all possible, the Kenyan and North American Principal Investigators should participate in the ADAT call on which their proposal is discussed. If schedules do not allow this, one or more of the other study investigators should participate in order to answer questions that arise during the ADAT discussion.

Processing the Data Request (1-4 months). In consultation with RWG Chairs, Co-Field Directors and the co-Directors of Research, ADAT will prioritize and begin processing the data request. *Data requests will not necessarily be handled on a first-come first-served basis.* Projects will be

prioritized according to several factors, including availability of personnel and potential benefit to the AMPATH Program, broadly construed.

Specific factors that will be taken into account include the following:

- Purpose (grant / manuscript / etc) – with preference given to those activities that will ultimately have greatest benefit for the AMPATH program
- Whether the requestor has funding to support AMPATH data management and/or biostatistical support
- Affiliation of requestor to AMPATH (Moi, AMPATH Consortium, Students, Staff, funded researchers, etc)
- Number of data requests already in progress for a single investigator
- Project deadlines

Once the data request has been reviewed and prioritized, the Research Manager and ADAT Chair will communicate with the investigator about timeline and needed revisions.

Other considerations

IRB/IREC Approval. Those planning to submit data requests for research will first have to show approval of their proposed participation by the necessary ethical review boards. At a minimum this will require Moi University IREC approval, and depending on the individual's affiliations, other universities or organizations as well. In addition, the investigator must provide certification of having passed the Human Subjects Protection test IN ADVANCE of the data request being considered. More details on these processes can be obtained from the Research Manager. *Unless specifically stated in the IREC and IRB approvals, all data analyzed will be de-identified.*

Student Research. Generally speaking, AMPATH does not have the necessary resources to respond to data requests submitted for student research. Students working with AMPATH faculty may use data that already have been released for a specific project, but must submit a request to use the data to the appropriate RWG. Students must get IREC/IRB approval for secondary use of pre-existing datasets.

Research Manager Contact Information

Jepchirchir Kipligat-Kirui, Moi University
April Bell, Indiana University
Email: data.requests@iukenya.org

SOP Version Log			
Version Number	Date	Authors	Summary of Changes
Version 1	28/04/2010	J. Kiplagat-Kirui A. Bell	<ul style="list-style-type: none">• First version of SOP published
			<ul style="list-style-type: none">•
			<ul style="list-style-type: none">•
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