Standard Operating Procedures for Data Access, Use, Transfer, Sharing and Archiving	**Version No:** 1
	Approved Date: 06 November 2020
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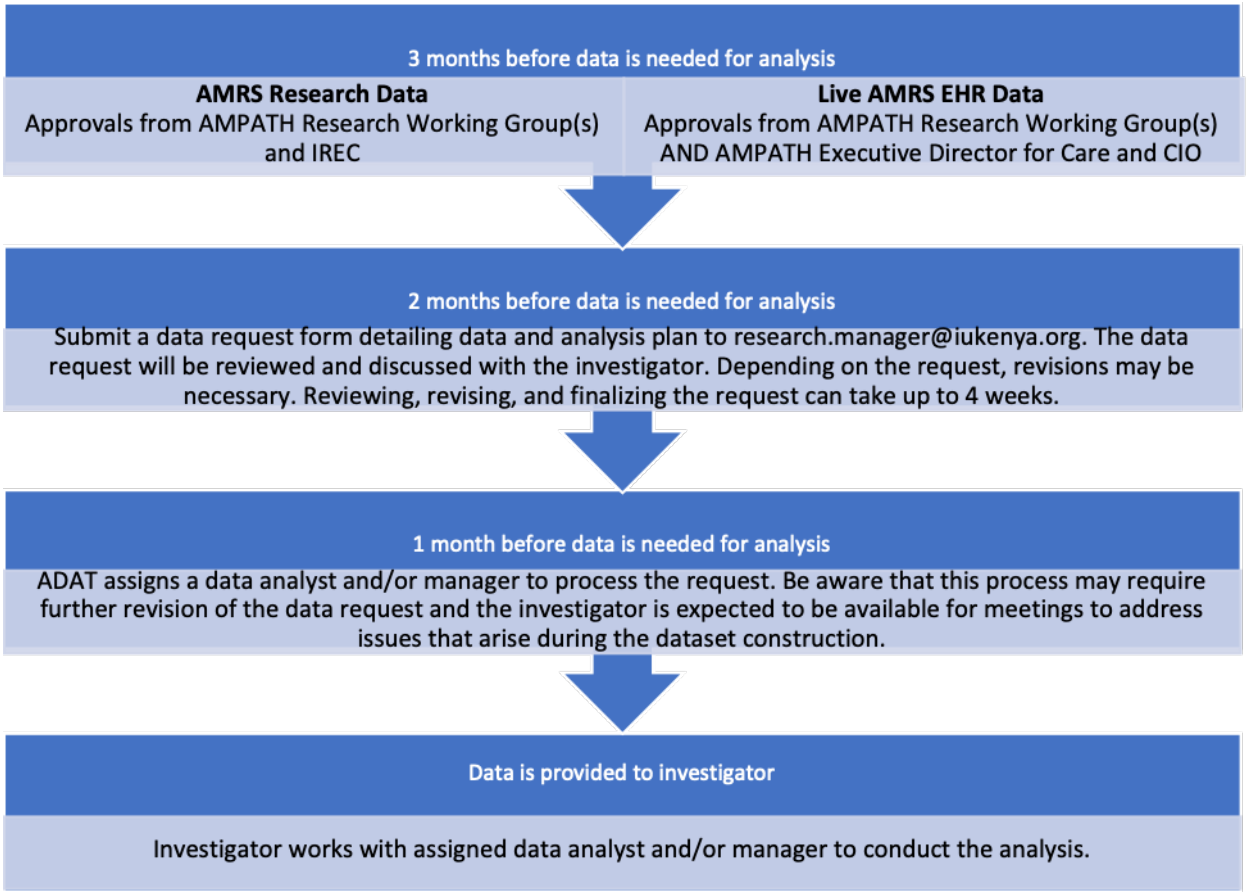
PROCESS OVERVIEW

The following process flow includes the average minimum times required to process a data access and/or sharing request. Only studies that have completed the new study review process and have all applicable AMPATH research working group and IREC approvals are eligible to submit Data Access and/or Sharing Requests. See the SOP for Research Project and Grant Proposal Development, www.ampathkenya.org/research-policies-and-procedures, for details on the required study reviews. Actual processing times vary from study to study.

Data Access Request Process

Studies with AMPATH and IREC approvals may request access to AMRS datasets or, in some cases, live AMPATH EHR data. The process flow diagram below describes the process for requesting access to a prepared dataset from ADAT for your study. Additional processes for data sharing and archiving are not included in the diagram and described in other parts of the SOP. It is important for researchers to be aware that the process of converting data from AMRS to a research-grade dataset can be intensive and technically challenging, and usually requires several interactions with researchers. Key parameters that need to be decided in advance, and which may change once the data are accessed, include date ranges, inclusion/exclusion criteria, definition of variables and concepts, missing or incomplete data, etc. The actual content of the dataset may change during the process.



BACKGROUND

The Academic Model Providing Access to Healthcare (AMPATH), Moi University and Moi Teaching and Referral Hospital and a consortium of North American Medical Schools, is a pioneer in the development of electronic health records systems in East Africa. As the technology AMPATH uses to manage patient and program data has evolved and made it easier to store, analyze, and share health data, the AMPATH Medical Records System (AMRS) has created new and important opportunities for research to improve the health of the people in western Kenya and other resource limited settings. AMPATH is obligated to exercise prudent stewardship over the information with which it has been entrusted and recognizes the need to share data with research collaborators, sponsors, academic journals, and other research stakeholders under certain circumstancs to ensure our research is transparent, rigorous and reproducible. AMPATH also recognizes the need to share institutional information with partners to accomplish its research mission and that, when disclosing this information, AMPATH must exercise due care for data privacy and security. Furthermore, to ensure compliance with applicable laws, regulations, and institutional policies, it is vital to evaluate and approve the ability of third parties to appropriately handle and protect information before data is shared.

PURPOSE

The purpose of this SOP is to define:

1. Protected Health Information and its use for research conducted at AMPATH;
2. AMPATH Research Program policy on data access and transfer for AMPATH affiliated entities and partners and non-AMPATH affiliated entities and partners;
3. Guidelines for constituting data transfer and use agreements; and,
4. Approved procedures for data sharing, data transfer, and data archiving

SCOPE

This policy is applicable to all research involving human subjects and all other activities which, even in part, involve research conducted at AMPATH health facilities using patients, patient information, or other program data owned by AMPATH, Moi University, or Moi Teaching and Referral Hospital as well as data entrusted to AMPATH affiliated investigators.

PROTECTED HEALTH INFORMATION (PHI)

Protected Health Information (PHI) is any health information, including demographic information collected from an individual, that:

1. Is created, received, transmitted, or maintained by AMPATH Program or by a business associate on behalf of the AMPATH Program;
2. Identifies or can be used to identify an individual; and

3. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.
4. PHI can be oral or recorded in any form or medium.
5. Excluded from the definition of PHI are:
    a. Employment records held by AMPATH Program in its role as an employer.
    b. Records regarding a person who has been deceased for more than 50 years.

Permitted Uses and Disclosures of PHI for Research

The use or disclosure of protected health information will be permitted for research, regardless of the source of funding of the research, after it has received the following:

1. A valid authorization for the use or disclosure of the PHI requested from each individual participant in the research project obtained as part of an Institutional Review and Ethics Committee (IREC) approved informed consent process; or/unless
2. Approval of a waiver of authorization from IREC.

Reviews of PHI for the Preparation of Research

Prior to the use or disclosure of PHI needed to prepare a research activity, the researcher must provide a written documentation that:

1. The use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes needed to initiate a research activity including the identification of patients eligible for recruitment to the study;
2. No PHI will be removed from AMPATH facilities or data systems in the course of the review without prior authorization; and
3. The PHI for which use or access is sought is necessary for research purposes approved by IREC.

DATA ACCESS & TRANSFER REQUESTS

Types and definitions of data

AMRS Research Data – AMRS research data is pulled from the master research data set that has been cleaned, de-identified and prepared for use in research analyses by the AMPATH Data Analysis Team (ADAT).

Live AMRS EHR Data – Data from AMPATH's live EHR, also known as Point-of-Care or POC, is primarily used for clinical care operations and includes identifiable patient information from AMPATH clinics. Researchers may request limited access to live EHR data to assist in identification and recruitment of study subjects. Other uses of live EHR data may be considered on a case-by-case basis and must be approved by the AMPATH Executive Director for Care, Chief Information Officer, and IREC.

Prospectively Collected Study Data – Data collected prospectively by an AMPATH approved study that is not collected or maintained as part of AMRS may be shared and/or transferred at the discretion of the study's

Principal Investigator so long as the sharing and/or transfer of data complies with IREC approved protocol and informed consent requirements. Individual participant data must be de-identified prior to sharing or transfer.

Data Access & Transfer Requests for AMPATH affiliated entities and investigators

AMPATH affiliated entities and investigators may access and use AMRS Research Data and, under certain circumstances, live AMRS EHR data. The process for requesting access and transfer for these data are outlined in the first page under "Process Overview." Only studies that have completed the new study review process and have all applicable AMPATH research working group and IREC approvals are eligible to submit Data Access and Transfer Requests. As part of AMPATH's Research Project and Grant Proposal Development process, investigators work with ADAT to: 1) determine if the proposed analyses can be conducted using existing AMRS data or if prospective data collection will be needed; 2) determine the budget support that will be needed to access AMRS data and conduct proposed analyses; and 3) prepare a plan for conducting the required study analyses (refer to SOP on Research Project and Grant Proposal Development here: www.ampathkenya.org/research-policies-and-procedures .) Actual processing times vary from study to study. It is important for researchers to be aware that the process of converting data from AMRS to a research-grade dataset can be intensive and technically challenging, and usually requires several interactions with the researchers. Key parameters that need to be decided in advance, and which may change once the data are accessed, include date range for datasets, inclusion/exclusion criteria, definition of specific variables and concepts, how to handle missing or incomplete data, etc. The actual content of the dataset may change during the process.

Data Access & Transfer Requests for Non-AMPATH affiliated entities and investigators

AMPATH is strongly committed to safeguarding the data entrusted to us by the patients and communities we serve. Transfer of AMPATH data from AMRS to an external data repository is generally not permitted unless the transfer is part of a defined research purpose that has been reviewed and approved by the AMPATH research working groups, IREC, and the Director of Research. AMPATH will not allow access to or transfer of AMPATH data from AMRS to a non-AMPATH entity or research partner except in the following limited cases:

AMPATH Approved Study Protocol Involving a Non-AMPATH Consortium Research Partner.

In general, AMPATH does not permit research activities by an external entity or researcher who is not affiliated with an AMPATH Consortium Institution. Exceptions include those who have received special permission to engage in a limited program of research or are participating in an AMPATH Consortium Institution-led study to provide expertise or services essential to the research study and not otherwise available through the Consortium. AMPATH research working group and IREC approved studies involving a non-AMPATH entity or research partner may request approval to access, transfer, and/or use of AMPATH data for the limited and approved research activities defined in the study protocol and/or data management plan. Only the minimum dataset needed for the research activities defined in the study protocol and/or data management plan will be allowed to be shared or

transferred to an external entity or research partner and a valid data use and transfer agreement is required before data may be shared or transferred. The transferred data may only be used for the purpose of the AMPATH project that the non-AMPATH partner is collaborating on, and may not be used for any other purpose.

Sponsor Data Requests.

In certain circumstances, sponsors may require research data produced with sponsor funds to be made available to verify and reproduce study analyses, for use in public health surveillance, or to meet public access requirements. In cases where a data management plan has been approved and a subcontract agreement governing the use, sharing, and transfer of data to a sponsor is in place, data will be made available to the sponsor in accordance with the terms set out in the subcontract agreement. In general, AMPATH does not allow the transfer of individual-level data not directly produced as part of the funded research. This includes transfer of the AMRS Research Dataset, in whole or in part, to publicly available data repositories. If AMRS or other AMPATH data are needed to verify or reproduce results, limited access may be provided to de-identified data with approval from the AMPATH Co-Directors of Research in consultation with ADAT.

Academic Journal Requests.

Academic journals for clinical research may require authors to include a data availability statement. The following provides guidance on describing the availability of AMPATH research data.

Prospectively Collected Study Data – For studies that prospectively collect data, the data is owned by the study's Principal Investigator(s). AMPATH does not have any specific data sharing requirements for prospectively collected data that does not involve AMRS data. PIs should determine data availability consistent with IRB and IREC approvals and establish a data availability statement for their prospective data. Prospective studies are encouraged to follow the International Committee of Medical Journal Editors (ICMJE) standards for data availability statements and include the following basic information in their data availability statement: 1) when individual participant data will be available (including data dictionaries); 2) what data will be shared; 3) what other documents will be shared; 4) when data will be available (availability start and end dates); 5) with whom the data will be shared; 6) for what types of analyses; and 7) by what mechanisms will data be made available.

AMRS Data – AMRS data, either the reaserch dataset or the live EHR, is accessed as part of the procedures set forth under the AMPATH Consortium. The AMPATH Consortium restricts the sharing of individual-level data to outside entities. Investigators or entities requesting verification of the analyses reported in the manuscript should contact the study PI who can request permission from the Directors of Research and ADAT to make these data available. Authors should use the following data availability statement for publications relying on AMRS data:

> *Study data were accessed from the Academic Model for Providing Access to Healthcare (AMPATH) electronic medical records (www.ampathkenya.org) system under the procedures setforth by the*

AMPATH Consortium . The AMPATH consortium restricts the sharing of Individual-level data with outside entities. The data set used for this study can be made available, on a case by cases bases, upon request and with approval from the AMPATH Consortium, in accordance with AMPATH policies and procedures. Requests related to data sharing should be email to the corresponding author who will be responsible for contacting the AMPATH Research Program (research.manager@iukenya.org) to request the approval.

Request for Special Exceptions

All requests for special exceptions to allow the transfer of data to an external entity or research partner will be considered by the AMPATH Co-Directors of Research, on a case-by-case basis, in consultation with ADAT. In cases involving live EHR data (POC), approve for transfer will need to be granted by the CIO, and the AMPATH Executive Director of Care.

DATA TRANSFER AND USE AGREEMENTS

AMPATH has adopted the Federal Demonstration Partnership's (FDP) standards for Data Stewardship and Data Transfer and Use Agreements, www.thefdp.org/default/committees/research-compliance/data-stewardship. These standards provide a low-burden method for sharing data in compliance with generally accepted data stewardship practices to protect study subjects, their PHI, or other sensitive or proprietary information owned by the AMPATH program.

When is a Data Transfer and Use Agreement needed?

A valid Data Use and Transfer Agreement must be executed by the project PI before data can be transferred for use by individuals or entities outside of one of AMPATH's member institutions in the following cases:

1. **Human Subjects Data (Required)**: When human subjects data that includes at least one of the following 18 Health Insurance Portability and Accountability Act (HIPAA) identifiers and no other agreement or regulation governs the transfer and use of data:
    a. Name
    b. Address (all geographic subdivisions smaller than a county, including: the box number, street name, and town code
    c. All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
    d. Telephone numbers
    e. Fax number
    f. E-mail address
    g. Personal Identification Number
    h. Medical record number
    i. Health plan beneficiary number

j. Account number
k. Certificate or license number
l. Any vehicle or other device serial number
m. Web URL
n. Internet Protocol (IP) Address
o. Finger or voice print
p. Photographic image - Photographic images are not limited to images of the face
q. Any other characteristic that could uniquely identify the individual

This includes data sets with PHI, Personally Identifiable Information (PII), and Limited Data Sets.

2. **Non-Human Subjects Data (May be Required):** The transfer of non-Human Subjects data (including de-identified data) requires a Data Transfer and Use Agreement if no other agreement governs the transfer and use of the data.

When is a Data Transfer and Use Agreement not needed?

A separate Data Transfer and Use Agreement is not required if specific data transfer and use terms are defined in a valid sub-award agreement, material transfer agreement, confidentiality agreement, collaboration agreement (including unfunded MOUs), clinical trial agreement, or sponsor notice of award. The terms included in these agreements should adhere to generally accepted data stewardship practices and include specific terms for the retention of data, its destruction, or other uses not covered by applicable law.

Data Transfer and Use Agreement Templates.

In cases where a Data Transfer and Use Agreement is required, AMPATH recommends PIs use the FDP standard Data Use and Transfer Agreement templates adapted as necessary to meet any applicable partner contractual and/or regulatory requirements. An equivalent standard agreement can be used if needed to comply with local regulatory standards. The FDP templates include the following elements:

1. **Data Transfer and Use Agreement Face Page with Attachments 1 & 3** – http://thefdp.org/default/assets/File/Documents/dtua_feb_2019.pdf

Attachments (Select by Data Transfer Type):

2. **De-Identified Data about Human Subjects** – http://thefdp.org/default/assets/File/Documents/dtua_attachment_2_deidentified_data.pdf
3. **Limited Data Set** – http://thefdp.org/default/assets/File/Documents/dtua_attachment_2_limited_data.pdf
4. **Personally Identifiable Information – Common Rule Only (Not covered under HIPAA, FERPA, or similar laws or regulations governing personal information) –** http://thefdp.org/default/assets/File/Documents/Att2_Identifiable_Common_Rule_Feb_2019.pdf
5. **Personally Identifiable Information – HIPAA (Data is Protected Health Information ("PHI") as that term is defined in the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), at 45 C.F.R. §160.103 (and not a Limited Data Set))** – http://thefdp.org/default/assets/File/Documents/Att2_Identifiable_HIPAA_Feb_2019.pdf

6. **Other (Use when a specific attachment for a specific data type does not exist)** – http://thefdp.org/default/assets/File/Documents/dtua_attachment_2_other.pdf

Agreement templates should incorporate appropriate language as described in each part of the agreement template and adapted to meet applicable regulatory standards for data transfer. In cases, where regulatory requirements conflict, the higher standard of protection should be applied.

Limited Data Sets for Research Purposes

Following review and approval by the AMPATH Data Analysis Team (ADAT), the Research Program Office may authorize the use or disclosure of a limited data set of health information for research purposes. A valid Data Use Agreement must be executed prior to any disclosure of a limited data set for research.

PROCEDURES FOR DATA SHARING

Studies approved to share data with a research partner shall use the following minimum procedures for data sharing:

1. Submit a summary of the dataset to be shared including a description of the data and the purpose for use and transfer to research.manager@iukenya.org. RPO will confirm the studies are approved by both research working group(s) and IREC and have valid Data Transfer and Use Agreements in place.
2. PIs can request an optional review by ADAT to ensure that:
    - All data is de-identified.
    - Data transfer process meets minimum security and encryption standards.
    - A backup of the transmitted data is archived.

    RPO will assist PIs in routing datasets to ADAT when review is requested by the PI.
3. Use of AMPATH data is limited to the terms defined in the project's data transfer and use agreement. Any additional use not defined in the original agreement will require separate approval.

PROCEDURES FOR DATA TRANSFER

Studies approved to transfer data to a research partner should follow good practice standards for data transfer and adhere to the following minimum standards.

1. For security purposes, data files should be transferred using standard encryption methods and generally accepted data stewardship standards to ensure all personally identifiable information is securely protected.
2. Each dataset will be stripped of all personal identifiers and will undergo a de-identification process below and is compliant with HIPPA or equivalent standard;
    - Delete subject ID numbers and assign a random number to each subject
    - Delete site ID numbers and assign a random number to each
    - Delete investigators or clinician names/IDs
3. No patient identifying information (e.g. names, patient identification numbers, etc.) should ever be

transmitted in an unencrypted format by e-mail or other online transfer protocol.

4. Usernames and passwords should be distributed directly to the intended user(s).

PROCEDURES FOR DATA ARCHIVING

Upon study completion and publication of study results, AMPATH approved studies are required to maintain study data for use in verifying and/or reproducing published study analyses for a minimum of 36 months after publication of the final manuscript. After this period, study data will be archived as required by applicable sponsor and regulatory guidelines, usually for 7 years.

1. Aside from the original analysis, datasets generated and distributed by ADAT, all datasets used for analysis should be transferred to the ADAT server for archival.
2. In addition, all program code (written, for example, in SAS, STATA, R etc.) used to manipulate the original analysis datasets and generate the results should be transferred to ADAT along with the associated log and output files. The log files should provide an electronic record of exactly what code was executed to generate the results in the output files.
3. Written documentation of how the original datasets were manipulated such as exclusion of specific patients or encounters, derivation of new variables, etc. should also be provided to ADAT.

In general, ADAT must have all information necessary to recreate all published results generated from AMPATH data.

Abbreviations

ADAT - AMPATH Data Analysis Team
AMPATH - Academic Model Providing Access to Healthcare
AMRS - AMPATH Medical Records System
CIO - Chief Information Officer
COP - Chief of Party
FDP - Federal Demonstration Partnership
HIPAA - Health Insurance Portability and Accountability Act
IP - Internet Protocol
IREC - Institutional Review and Ethics Committee
POC - Point of Care
PHI - Protected Health Information

SOP Version Log			
Version Number	***Date***	***Authors***	***Summary of Changes***
Version 1	2020-11-06	S. Grinter J. Hogan J. Kiplagat-Kirui A. Mwangi W. Nyandiko D. Plater M. Scanlon J. Wagner E. Walumbe K. Wools-Kaloustian	• First version of SOP developed