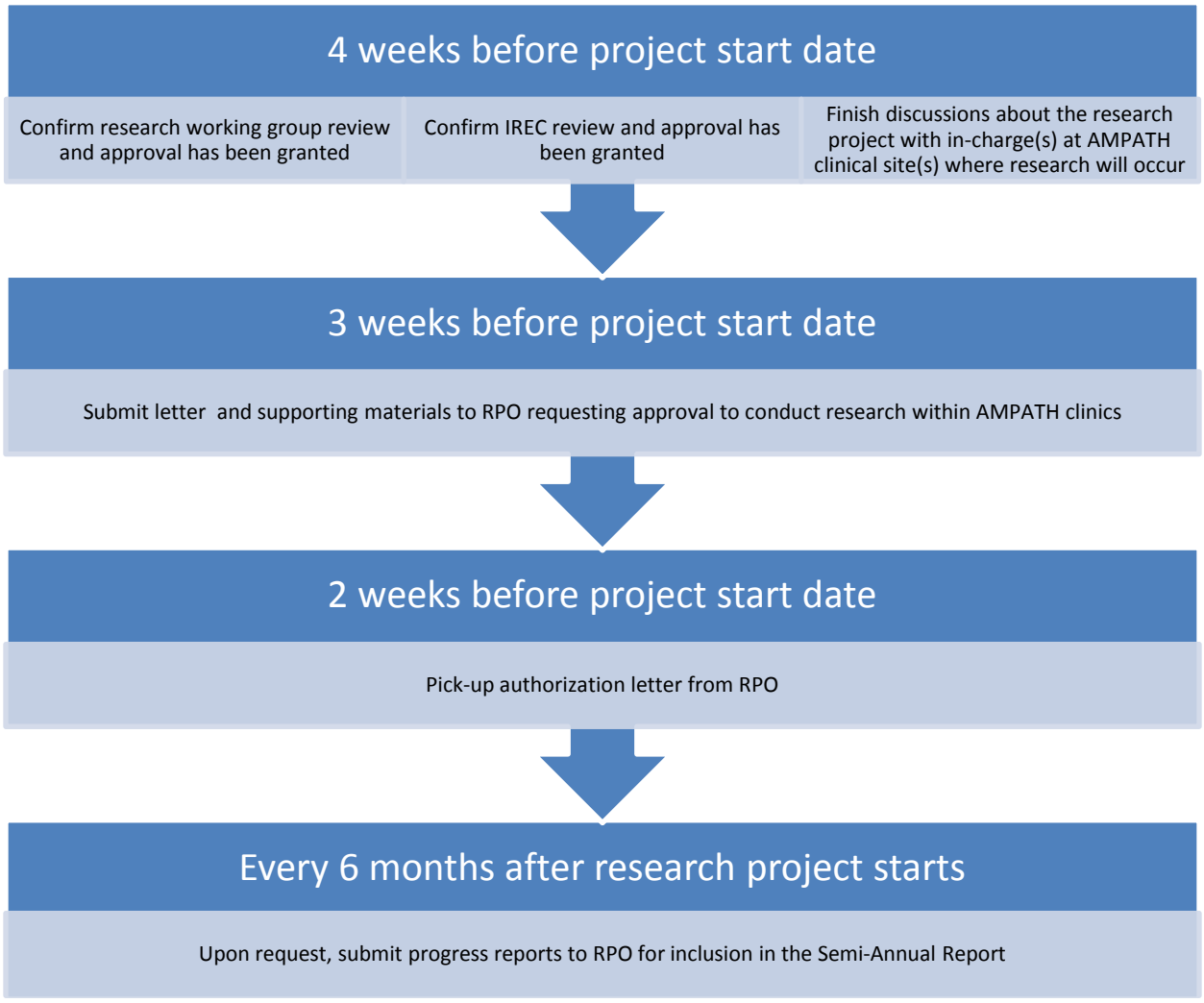
Standard Operating Procedures for Implementation of Research Projects at AMPATH Clinical Sites	**Version No:** 2
	Approved Date: 7 February 2014
	Effective Date: 1 March 2014

Process Overview

Please note project implementation is contingent on completing all required research working group and IREC/IRB reviews as well as meeting AMPATH's policy requirements for research. The following process represents minimum notification times and begins when all required approvals have been granted and a project is ready to begin approved research. Investigators are encouraged to begin this process as early as possible.



Purpose

To ensure research projects meet IREC and IRB requirements for the conduct of research and follow guidelines for conducting research at AMPATH clinical sites and catchment areas.

Procedure

AMPATH clinical sites provide care to more than 3.5 million people in AMPATH's catchment area. To help ensure the operations of clinical sites are not disrupted by research activities, investigators are required to adhere to the following implementation procedures:

1. Prior to conducting any research at an AMPATH clinic, the research proposal must:
    a. Complete research working group review as described in the SOP for Research Grant and Project Budget Development. Contact AMPATH Research Program Office (RPO), research.manager@iukenya.org, for assistance with working group reviews;
    b. Complete Institutional Review and Ethics Committee (IREC) review and receive IREC approval to initiate a research study (Collaborating institutions must complete the IRB review and approval process at their home institutions in addition to IREC review); and
    c. Contact the AMPATH clinical site in-charge(s) at the AMPATH clinical site(s) where research will be conducted to discuss the proposed research study.
2. A letter must be written to RPO requesting approval to conduct of research within the AMPATH clinics. The letter should be accompanied by (1) a copy of the IREC/IRB approval(s) and (2) a copy of the protocol. The letter should contain the following:
    - Location of the AMPATH clinic(s)where the study will be conducted;
    - A list of the names, e-mail addresses, and phone numbers of study personnel and their site responsibilities;
    - A statement of study requirements including:
        - Project space needs
        - Transportation to and from project sites for personnel and materials
        - Any special requirements, e.g. chest x-rays, needed to conduct the study at AMPATH sites
    - Funding source and budget
    - Estimated duration of the research project
3. RPO issues research authorization letter(s) to the investigator to carry with them to the approved clinical sites;
4. Upon arrival at the approved clinical site(s), the investigator presents the research authorization letter(s) to the in-charge in order to initiate research at the site(s);
5. Due to space limitations within the MTRH-AMPATH modules 1-4, only one research assistant per study is allowed to work in a module at any given time. Investigators may contact RPO, research.manager@iukenya.org, to request an exception to this requirement.

6. The researcher shall keep a current list of the all patients recruited for the study. Patients enrolled in NIH studies will be identified and exempted from further study participation for a specified period of time according to the requirements of NIH or any other granting agency. This will assist the Research Office in protecting patients from study fatigue.
7. The study must not interfere with the daily running of the AMPATH clinics.
8. In the case of a serious adverse event, studies are required to submit a Prompt Reporting Form, http://medicine.iu.edu/ampathresearch/index.php/forms/irec-forms/, to the Research Manager and the IREC secretariat within 72 hours of the event's occurrence. Studies should also review and comply with the adverse event reporting policies and procedures of any partner institutions or sponsors involved in the study.
9. All studies must submit a semi-annual (June and December) report to the Research Office. In addition, all studies must submit a one page summary of the study findings to the Research Office when the study is completed.
10. All publications resulting from research at AMPATH sites or using AMPATH data, must receive approval from the Publications Committee prior to submission to an external audience or publisher. Please route draft publications to RPO, research.manager@iukenya.org, following the procedures in the *SOP for Authorship and Pre-Publication Review*.

SOP Version Log

Version	*Date*	*Authors*	*Summary of Changes*
2	7 February 2014	J. Kiplagat-Kirui D. Plater	• Added a process flow chart and timeline • Clarified process for implementing research projects at AMPATH clinical sites • Updated content of project initiation request letter to RPO • Updated policy to emphasize pre-publication review responsibilities