

REF: AMREF - ESRC P1201/2022

July 13, 2022

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Dear Dr. Orlando,

RESEARCH PROTOCOL: PREVALENCE AND SHORT TERM OUTCOMES OF COMORBIDITIES AMONG HIV POSITIVE ADULTS ON HIV CARE AND TREATMENT IN MERU COUNTY, KENYA (CHAO STUDY)

Thank you for submitting your protocol to the Amref Ethics and Scientific Review Committee (ESRC).

This is to inform you that the ESRC has reviewed and approved your protocol. Your application approval number is ESRC P1201-2022. The approval period is from July 13, 2022, to July 12, 2023, and is subject to compliance with the following requirements:

- a) Only approved documents (including informed consents, study instruments, advertising materials, material transfer agreements, etc.) will be used.
- b) All changes including (amendments, deviations, violations, etc.) are submitted for review and approval by Amref ESRC before implementation.
- c) Death and life-threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the Amref ESRC within 72 hours of notification.
- d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to Amref ESRC within 72 hours.
- e) Clearance for export of biological specimen must be obtained from the relevant government authorities for each batch of shipment/export.
- f) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
- g) In case of late renewal, the Amref ESRC shall not be held responsible for any severe adverse events (SAEs) that may occur as a result of research activities that were carried out after the expiry of approval.
- h) Submission of an executive summary report within 90 days upon completion of the study to the Amref ESRC.
- All government regulations for prevention and control of the spread of COVID-19 including social distancing, provision of personal protective equipment for participants and research assistants should be adhered to during data collection. All research assistants should be monitored for COVID 19 symptoms and referred for testing in case they present with symptoms.



Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) <a href="https://research-portal.nacosti.go.ke">https://research-portal.nacosti.go.ke</a> and also obtain other clearances needed.

Please do not hesitate to contact the ESRC Secretariat (<u>esrc.kenya@amref.org</u>) for any clarification or query.

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CC: Samuel Muhula, Monitoring & Evaluation and Research Manager, Amref Health Africa in Kenya.