

Proposed Project Title: Understanding Health Care Worker and Community Knowledge and Attitudes Towards Analytical Treatment Interruption (ATI) Research in Malawi.

Preferred Scholar On-Site Project Dates: Short-term project, on-site for 8 weeks between June and August 2024

Project Site: Blantyre, Malawi (Blantyre CRS)

Project Overview: The Blantyre clinical research site (CRS 30301), based in the Southern Region of Malawi, is a biomedical research institution affiliated to the Kamuzu University of Health Sciences in Malawi and the Johns Hopkins University in the USA. We conduct medical research through Phase I to IV clinical trials, observational cohort studies, as well as socio-behavioral studies including the one proposed in this RAMP project. The main focus of our research is the prevention, treatment and cure of HIV and related opportunistic infections. Our vision is to contribute to healthy, long lives for all through high-quality, collaborative research and training. Our purpose is to effect positive change in policy and practice through research, training, infrastructure development and community engagement. This is accomplished through teamwork among a diverse group of staff; respect and care for research participants; and partnerships with local and international stakeholders.

The RAMP scholar will work with clinical investigators and our Community Engagement (CE) team on a mixed methods study to understand knowledge and attitudes among health care workers and community members towards analytical treatment interruption (ATI) research, which is a key area of the HIV Vaccine Trial Network (HVTN) research agenda, in order to prepare better materials and sensitization tools for HCW and the community as we roll our ATI studies for VTN and other networks.

Project Summary: Blantyre CRS is currently participating in a paediatric ATI study called IMPAACT 1115 and an adult ATI study called HPTN 093/HVTN 805, with more ATI studies planned in the near future, including HVTN 806. Participants of the current trials are from Blantyre District and their ART providers are mostly from Umodzi Lighthouse ART Clinic, an ART clinic based at the Queen Elizabeth Central Hospital (QECH), a tertiary level health facility. Despite our site's involvement in these ATI studies, the knowledge and attitudes within the Blantyre community and of their ART providers have not been characterized. This project therefore aims to evaluate knowledge of ATI and attitude towards ATI research among health care workers and community members. The project will recruit from two sources: 1) ART providers from the Umodzi Lighthouse ART Clinic (ART specialists, internists, pediatricians, clinical officers, nurses and HIV testing counsellors); and 2) Community gatekeepers such as cultural leaders and religious leaders, Community Advisory Board representatives, and HIV advocacy group leaders. Qualitative and quantitative data will be collected through in-depth interviews and socio-demographic and other structured questionnaires. Sample size is 15 – 20, divided equally between the two groups.

Regulatory requirements for the project and plans for completing them: The protocol, informed consent forms (English and Chichewa) and other study materials will be submitted to the College of Medicine Research Ethics Committee (COMREC) by mid-March 2024. Approval is anticipated by May, before the project start date between June and August 2024.

Expected Deliverables: Prior to arriving in Malawi: a) complete Human Subjects Protection and Good Clinical Practice trainings; b) attend online trainings for mixed methods study design; c) work with the Community Engagement Department to develop a recruitment strategy; d) review and contribute to the already-drafted IRB package; e) prepare medical school IRB application; f) draft the enrollment and demographics case report forms (not required for IRB application) e) draft data quality checklist.

While on-site: a) draft materials for, and deliver study training for study staff; b) conduct practice interview sessions with the research assistants; c) track and report on recruitment progress d) prepare interview readiness checklists (e.g. Has the audio recorder been tested? Is the transport reimbursement money available?); e) coordinate closely with the transcriber/translator on secure transfer of audio files and timely turnaround times; f) conduct quality checks of the consent forms and the transcribed/translated data in real time and report any trends to mentor; g) sketch an outline of the primary manuscript; h) participate in weekly team meetings; i) qualitative analysis may begin onsite if there is time; j) presenting the study overview to different stakeholders for public speaking practices; k) tour the clinical research site for exposure to a wide array of research activities; and l) clinical shadowing with our site IORs, who represent Medicine, Pediatrics, Emergency Medicine, Obs/Gyn and Mental Health.

After the scholar returns to the US: a) Complete analysis; b) disseminating at one of our student grand rounds); c) preparing presentation for the Full Group Meeting for May 25; d) writing manuscript.

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