



CAPACITY STATEMENT

24 March 2025

Johns Hopkins Research Project *affiliate of Kamuzu University of Health Sciences* **Blantyre, Malawi**

I. Overview

The Johns Hopkins Research Project (**JHP**) in Blantyre, Malawi is a collaborative research project between the Johns Hopkins University Bloomberg School of Public Health (JHSPH) in Baltimore, Maryland, USA and multiple institutions in the Republic of Malawi, namely the Ministry of Health and Kamuzu University of Health Sciences (formerly College of Medicine). Together with our partners, we strive to contribute meaningfully to improving health care practices and policy in the region. The overall co-Principal Investigators are Dr. Taha E. Taha (Professor of Epidemiology) and Dr. Jacky Jennings (Professor of Pediatrics with joint appointments in Epidemiology; Health, Behavior and Society; and Population, Family and Reproductive Health) at Johns Hopkins University.

JHP has a multidisciplinary team of more than 110 people, and 37 years of quantitative and qualitative research experience. It has the administrative, regulatory, and audit-ready scientific and financial infrastructure to carry out multiple clinical trials, longitudinal observational studies, implementation science research, capacity-building and training projects, and other stakeholder engagement initiatives. We have implemented more than 39 clinical research studies supported by the U.S. NIH. The site's capacities include a CAP-Accredited research laboratory, research pharmacy, data team and several study clinics. All departments are internally and externally monitored and operated by credentialed staff. The site also has a quality management department, which supports QA/QC checklists and standard operating procedures, as well as a community outreach and education department with strong, long-standing ties to a range of governmental and non-governmental national and local stakeholders. The clinic staff and community outreach team work closely to recruit, retain and trace study participants, and to support HIV status disclosure, couples HIV testing or family-level sensitization about research participation. All technical staff are certified in responsible conduct of research. The JHP administration building and research spaces are located on the grounds of the Queen Elizabeth Central Hospital (QECH), the main teaching and tertiary referral hospital in the Southern Region. JHP has also fostered collaborations with surrounding health centers for more than 20 years. Studies are led by a team of experienced senior clinician-investigators. The Country Director, Dr. Sufia Dadabhai, is a Johns Hopkins-trained epidemiologist, and full-time resident in Blantyre.

II. Office Space

The Project has modern office space dedicated for research, project management and training.

Situated within a three-story, 13,000 sq. feet office complex at QECH, our facilities offer a conducive environment for innovation and collaboration. The office space includes dedicated areas for offices, supply storage, server rooms, a small auditorium accommodating up to 60 individuals, and multiple webinar-enabled meeting rooms. To ensure uninterrupted operations, the building is equipped with a robust central power generator.

We have a range of essential services such as domestic and international telephone lines, both landlines and cell phones, printing, fax, scanning, and photocopying facilities. Additionally, we offer conference call and webinar equipment to support seamless communication and engagement.

III. Clinic Facilities

JHP operates multiple study clinics at QECH and within four health centers in Blantyre city. These clinical facilities include examination rooms, waiting room areas, specimen collection rooms and data collection workstations with privacy measures. There are dedicated research staff within the clinics to implement study protocols. Our clinic space includes a DXA bone density scanner. The personnel are adequately trained and assessed on protocol procedures, and certified in Human Subjects Protection (HSP) and Good Clinical Practice (GCP). Clinical oversight is provided by our expert team of Consultant Physicians, including Obstetrician/Gynecologists, Internal Medicine specialists (including a Dermatologist and an Emergency Medicine specialist), a senior Paediatrician (also the Vice Chancellor of the Kamuzu University of Health Sciences), and a Clinical Psychologist.

IV. Community

The Community Engagement (CE) Department coordinates outreach and education activities for all studies conducted at the site. While the outreach activities and messages for each study are unique, a centralized approach acknowledges that all potential study participants, their peers and families should be educated about research ethics, the purpose and value of infectious disease and reproductive health studies, and concepts related to participant rights and protections. Similarly, broad issues of stigma and disclosure affect participants and are addressed through time-tested strategies embraced by the CE team. This centralized model is both cost-effective and useful for sharing skills and community connections. It ensures that community educators are disseminating consistent messages as a single coherent unit. The team consists of highly-experienced community nurses and social workers and is led by a senior community educator. The CE team also attends Blantyre District Health Office meetings, Blantyre City Council meetings and is often called upon by Media to participate in radio and TV shows.

V. IT Infrastructure

JHP maintains a robust IT infrastructure with a 120 Mbps internet bandwidth supporting five servers. These servers are powered by uninterruptible power supplies and backed by generators to ensure continuous operation during power outages. The LAN serves as the core network, enabling JHP personnel to access email, databases, cloud files, printers, and the internet. External communications are facilitated through satellite internet, providing a highly reliable connection. JHP is also working to secure a second connection to enhance redundancy and ensure 24/7 high-speed internet access. The organization is well-equipped with sufficient desktop computers, laptops, printers, and scanners to meet the needs of its administrative, clinical and data staff, and training functions. For mobile data collection, JHP has both Android tablets and iPads. Online data entry and transfer capabilities are also available. For local studies that are not multi-center in

design, the Data team develops user-friendly data entry interfaces using a suitable platform, such as Microsoft Access, REDCap, or OpenDataKit (ODK). The IT and data capture infrastructure is managed by an IT/Data Manager, who leads a team of two Senior IT/Data Officers and five Data Officers (DOs). DOs are cross-trained on multiple platforms, support research nurses to learn new technologies, and play a critical role in ensuring the quality control of research data.

VI. Project Management and Financial Oversight

JHP has established project management and financial structures for overseeing projects and funds. The Country Director, Deputy and local PIs provide technical leadership to ensure project milestones are met. Weekly meetings with all technical departments promote communication and coordination. The Chief Operating Officer oversees all administrative support for JHP research, including grants review, contracts, HR, procurement, facilities, IT, and accounts. To enhance transparency and accountability, the Accounts department manages project funds in both local and foreign currency, cost allocation, cost allowability, financial reporting, and compliance with grant rules. We are stewards of grant funds from multiple sources (including USG and BMGF) and we maintain audit-ready record-keeping systems, dual signatory checks, and use QuickBooks for financial tracking. Audits by KPMG, Deloitte and Audit Consult from 2016 to 2023 were unqualified with no material findings.

VII. Pharmacy

The main JHP research pharmacy is located at QECH, adjacent to the main laboratory and less than a 5-minute walk from most study clinics. The pharmacy is staffed by three qualified pharmacists registered and in good standing with the Malawi Pharmacy and Medicines Regulatory Authority. The facility has a total space of 1184 sq ft. with six separate rooms, including a room for aseptic procedures containing two routinely-serviced biosafety cabinets for vaccine, monoclonal antibody and chemotherapy preparation. The site has a spacious drug storage area for room temperature storage, and a back-up room, where temperature is controlled using multiple air conditioner/heater units. In both drug storage rooms, temperature is monitored 24 hours a day using multiple Sensaphones (with direct dial, text and email capabilities), Escort Temperature Data Loggers and digital Minimax thermometers for backup. Two -70°C freezers, two -20°C freezers and two 2-8°C refrigerators are available for temperature-sensitive storage. The pharmacy is connected to an automated generator to safeguard against power failure. The main pharmacy also has the capacity to conduct studies with directly-observed therapy requirements or to establish satellite pharmacies at off-site study clinics, depending on the needs of each study. JHP pharmacists have also supported training and competency evaluation for pharmacy students from local universities.

VIII. Laboratory (Accredited by the *College of American Pathologists*)

The JHP laboratory occupies a two-story 8,890 square ft² comprised of 10 large laboratory rooms fully equipped to conduct serology, hematology, chemistries, virology, microbiology, flow cytometry and PBMC processing. In use for current studies, we have fourteen -80°C freezers, twelve -20°C freezers and eight refrigerators for storage of samples and reagents, with appropriate temperature control. Platforms include the Abbott m2000, four Gene Xperts, BD FacsLyric, two Roche c311, Roche e411, the Beckman Coulter Dxx500 among others. Freezers, refrigerators and air conditioners undergo preventive service every 3 months. Biosafety hoods are serviced every 6 months. Universal precautions and biohazard management best practices are followed per written standard

operating procedures. There is also a large seminar room for trainings and meetings. Specimen management is automated through our commercial LIS (Lab Information System) for logging, testing and reporting of results. The Laboratory Data Management System (LDMS), which has been operational for more than 15 years, provides complete specimen and results management, including archiving and specimen retrieval. The laboratory houses its own server and a hub for a dedicated Local Area Network (LAN). Also onsite is a Liquid Nitrogen (LN2) Plant to cryopreserve samples for shipping. Two large backup generators are available to minimize the risk of disruptions to daily activities and to maintain the integrity of samples and reagents. There is one centralized, large capacity Uninterruptible Power Supply (UPS) as an additional back-up system and stabilizer for the Lab. The laboratory participates in multiple external quality assurance programs and is independently audited on an annual basis by lab experts.

IX. Quality Management

A core activity at JHP is to understand and minimize the potential for error in our research practices, in order to ensure the safety of participants and integrity of the research data. Our Quality Management (QM) team has extensive experience supporting collaborative multi-country clinical trials and epidemiologic studies. The QM team works closely with all study clinics, the laboratory, pharmacy and data officers to identify and analyze challenges, and to implement best practices in protocol compliance and documentation. QM also liaises with research sponsors, auditors, monitors and regulatory authorities to ensure JHP research implementation meets rigorous local and international standards. The QM team brings decades of training and experience in public health, research, nursing and data management. They orient new staff to research-specific concepts, such as source documents, organize clinical research trainings and staff development workshops, and provide ad-hoc advising on all aspects of research study preparation and conduct, at both the site-level and study-level. QM is a hub for JHP's research compliance activities, as the site strives for participant protections and data integrity at all times.