The Kenya AIDS Vaccine Initiative (KAVI) was established in 1998 as a research unit within the Department of Medical Microbiology, College of Health Sciences, University of Nairobi, through a collaboration agreement between the University of Nairobi, University of Oxford, and IAVI, with the aim of conducting HIV vaccine clinical trials and basic science. With financial support from IAVI and the United States Agency for International Development (USAID), KAVI built its human and infrastructure capacity, resulting in tremendous growth in research conducted at the site and outreach to communities for recruitment of research participants.

KAVI-ICR administrative headquarters and its main laboratories are located at Kenyatta National Hospital (KNH) in Nairobi, collectively referred to as KAVI-KNH. To support the conduct of its community-based research activities, KAVI-ICR has established a clinical trials facility in a densely populated suburban area eight kilometers from its headquarters. The clinic is located at Nairobi County Council’s Kangemi Health Centre and is referred to as KAVI-Kangemi. This facility is used for conducting vaccine clinical trials and epidemiological studies.

With enhanced capacity for conducting clinical trials and other research, KAVI made a strategic decision to use this capacity to answer other research questions in health. Therefore, KAVI transformed from a research unit to an institute — the KAVI-Institute of Clinical Research (KAVI-ICR). KAVI-ICR, now a B-cell center of excellence, has expanded its research mandate to cover four thematic areas:

- **Clinical trials**
  - HIV vaccine
  - Expanded to other diseases — Ebola, bacterial vaginosis
  - Capacity strengthening (local and regional)

- **Communicable diseases**
  - Basic HIV/TB research; virology, immunology, and pathogenesis
  - Zoonotic disease research

- **Non-communicable diseases**
  - Stem cells and regenerative medicine
  - Tumor stem-like cells from brain and spinal cord tumors
  - Immunology of wounds

- **Knowledge translation**
  - Research, policy development, and implementation
  - Collaboration with a host of community cohorts and volunteers

KAVI-ICR is a center of excellence in mucosal immunology due to its capacity to conduct studies that enable understanding of early HIV immunology responses within mucosal surfaces of the genital tract. KAVI scientists collect and analyze mucosal samples to better understand transfusion that occurs within the mucosal tract and that of immune (B-cell and T-cell) responses that result from infections as well as immune responses to HIV candidate immunogens.

**Laboratory capacity**

KAVI-ICR’s laboratory section has the capacity for molecular biology and diagnostics for HIV and emerging infectious diseases (including more recently for COVID-19); cell imaging using high-resolution microscopy; and flow cytometry and cell-sorting. The laboratory based at KAVI-KNH is capable of HIV tests, hematology, serum biochemistry, STI testing, cryopreservation of lymphocytes, mucosal immunology assays, pregnancy tests, urinalysis, and enzyme-linked immunospot (ELISpot) assays. In addition to this, in 2018, KAVI-ICR laboratory established another mucosal facility to carry out mucosal explants and immunology.
studies in collaboration with Northwestern University in Chicago.

The KAVI-ICR laboratory works closely with industry and, as of 2021, is collaborating with Qiagen, Bio-Zeq Laboratories, Tenak Africa, Panasonic Biomedical, Fast-Track Diagnostics, and Hardy Diagnostics. Through this collaboration, there exists capacity for molecular biology testing. The lab is enrolled in a comprehensive External Quality Assessment program covering all assays facilitated by Contract Lab Services in Johannesburg, South Africa, and has been accredited in internationally recognized Good Clinical Laboratory Practice (GCLP) since 2004. KAVI-ICR’s quality system complies with the highest regulatory standards for licensed medicinal products such as Good Manufacturing Practice, Good Clinical Practice and GCLP.

People

KAVI-ICR staff includes physicians, pharmacy staff, nurses/counselors, laboratory technicians, a data management team, community mobilizers, and administrative personnel. The key personnel include Walter Jaoko, BChB, MTropMed, Ph.D, PGD, director; Ornu Anzala, MBChB, Ph.D, senior researcher; Gloria Omosa-Manyonyi, M.D., investigator — clinical trials; Marianne Mureithi, Ph.D, investigator — basic sciences. Other personnel include an IT and data manager, a finance manager, and an administration manager.

Community engagement

KAVI-ICR has a well-developed community outreach program and a wide range of research preparedness activities that are carried out both in Kangemi and throughout Nairobi.

These activities include a network to support community education and volunteer recruitment for clinical trials. KAVI-ICR has three active community advisory boards (CABs) for the KNH and Kangemi sites and a network of peer educators who participate in outreach activities through regular meetings and community events. Over the last two years, KAVI-ICR has constituted an adolescent CAB made up of 16 adolescents and their parents. This work is part of an effort to expand research into communities, such as adolescents, who have previously been on the fringe of research participation. KAVI-ICR continues to support and apply the principle of Good Participatory Practice in the engagement of new populations.

IAVI-supported activities

- Acute HIV infection
- Early infection and clinical outcomes cohort (Protocol C¹)
- Simulated vaccine efficacy trial
- Investigator-initiated research
- Research preparedness: engaging communities and cohorts
- Long-term follow-up studies
- T-cell immunogen design and assessment
- B-cell immunology assessment
- Next generation technologies and immune correlates
- Mucosal immunology
- Explant mucosal studies
- International training

IAVI gratefully acknowledges the generous support provided by the following major funders:

[Image of funders]

As of November 2022