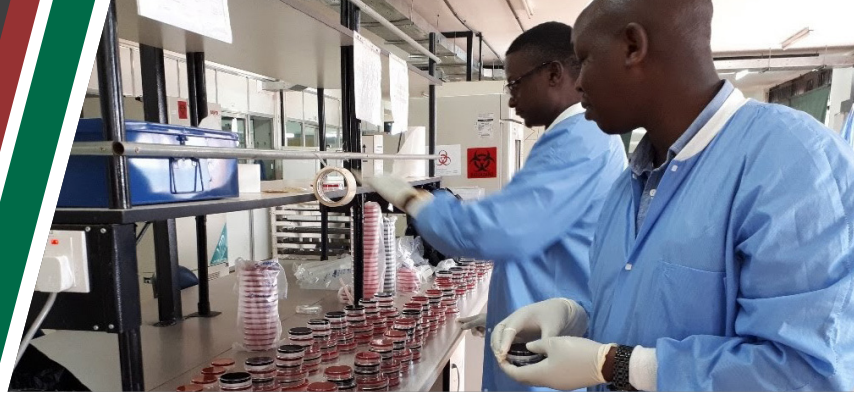
CLINICAL RESEARCH CENTRE (CRC)

Kericho, Kenya



The Kericho CRC is a regional research leader that helps characterize, prevent and counter infectious disease threats. A partnership between the Kenyan and U.S. governments, the Centre attracts scientists, clinicians and students to collaborate on innovative solutions to global health challenges.

WRAIR's primary partner in Kericho is the Kenya Medical Research Institute (KEMRI), and they launched a joint international HIV vaccine research program in 1999, followed by the opening of the Kericho CRC in 2012. It has three integrated main components: 1) HIV and other infectious diseases vaccine and therapeutics research, 2) HIV treatment and prevention and 3) enteric and microbiology research.

The CRC has a qualified, stable and experienced research team and has conducted diverse studies including randomized, double-blind, placebo-controlled and IND/FDA-regulated studies. The site is a member of two National Institutes of Health research networks for HIV and maintains the high caliber standards and accreditations required for those activities. The site established Kenya's first College of American Pathologist (CAP)-accredited laboratory and has worked extensively with WRAIR's U.S. Military HIV Research Program (MHRP) with support from HJFMRI.

KERICHO CRC BY THE NUMBERS:

5-9
studies conducted per year

1000+
up to 1000 participants per study

80
participant visits per day at peak

52
studies completed since 2012

CURRENT AND ONGOING STUDIES:

- **TB treatment:** RV467: Rifapentine containing treatment shortening regiments for pulmonary tuberculosis: A randomized, open-label, controlled Phase III clinical trial
- **HIV vaccine:** RV469 (HPX2003/ HVTN118) - A study of 2 Different Regimens of Tetravalent AD26. Mos4.HIV Prime Followed by Boost with Modified Vaccinia Ankara (MVA)-Mosaic OR Ad26.Mos4.HIV Plus a Combination of Mosaic and Clade C gp140 Protein in Human Immunodeficiency Virus Type 1 Infected Adults on Suppressive Antiretroviral Treatment

COMPLETED STUDIES:

- **HIV treatment:** RV186 - Antiretroviral Therapies in Women after Single-Dose Nevirapine Exposure
  - Findings from this study influenced WHO guidelines, significantly impacting global health policy and practices
- **HIV/TB co-infection:** RV249 - Timing of Antiretroviral Therapy for HIV-1 Infection and Tuberculosis
  - To conduct this study, the Kericho CRC pioneered an integrated system to manage HIV and tuberculosis in one clinic
- **Ebola vaccine:** RV456 - Phase II Ebola Vaccine Study
  - Investigated safety and immunogenicity of two Ebola vaccine regimens in healthy and HIV-1 infected subjects

Other studied diseases include malaria, Kaposi's sarcoma, polio, cryptococcal meningitis, oral candidiasis, respiratory infections and diarrheal diseases.

The site has been able to conduct studies that require complex procedures such as biopsies, lumbar punctures, PK evaluations, vaccines administration by biojector and electroporation, and monoclonal antibody administration.

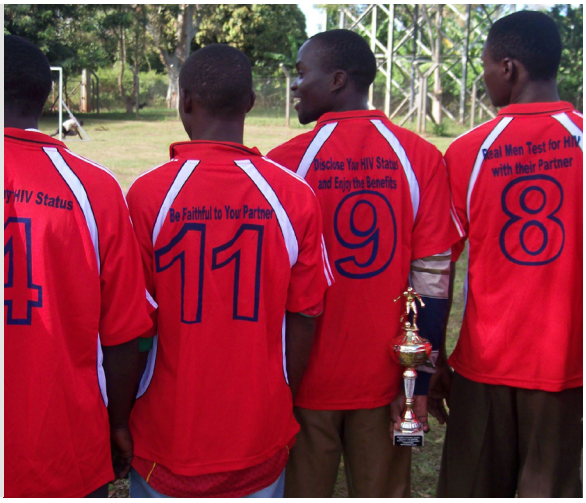
CRC | Kericho, Kenya

INTEGRATED PREVENTION AND TREATMENT

In 2004, the Kericho HIV research program expanded to offer care and treatment services supported by the President's Emergency Program for AIDS Relief (PEPFAR). It was one of the first programs in Africa to provide ART. PEPFAR integration ensures an ethical environment to conduct research, bolsters public health infrastructure and is critical to building trust within the community.

PEPFAR RESEARCH:

- RV239-AFRICOS (ongoing): Fifteen-year cohort longitudinal study that evaluates the impact of clinical, biological and socio-behavioral issues on HIV infection and disease progression. The CRC supports local health facilities with this multi-site study.



DISEASE PREVALENCE AND EXPERIENCE:

Prevalence (approx.): HIV (Adult): 3.8%, **Tuberculosis:** 558/100000, **Malaria:** 19,868 cases over last 5 years in Kericho County

Research Experience: The site has participated in studies on HIV, malaria, tuberculosis, Kaposi's sarcoma, polio, Ebola, *Shigella*, cryptococcal meningitis and oral candidiasis. The comprehensive list of studies on these diseases is attached.

FUTURE RESEARCH PLANS:

- **3 *Shigella* vaccine studies:** Aims to enroll more than 1100 volunteers
- **Yellow fever vaccine study:** In planning stages, aims to enroll more than 1600 volunteers
- **HIV adjuvant study:** RV460 - Comparative Adjuvant Study for DNA/ Protein Prime/Boost HIV-1 Vaccine using GP145 to begin May 2020
- Planning to partner for an enteric *Shigella* controlled human infection model study (CHIMS) and vaccine efficacy challenge studies, a new field of enteric vaccine development in Kenya

SITE FEATURES:

- Uninterrupted power supply systems
- 4 back-up generators
- Liquid nitrogen plant for cold storage
- 20 -80°C freezers
- Stand-alone functional tuberculosis clinic
- CAP accreditation
- Community Advisory Board
- 27 vehicle fleet for patient and participant transportation
- Secure fiber optic internet access

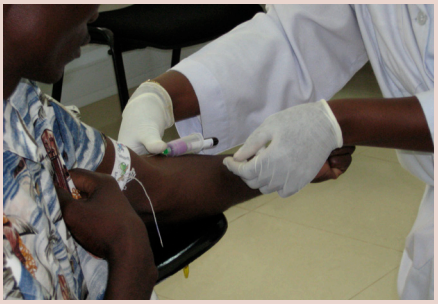
INTERNATIONAL RESEARCH PARTNERS:

Walter Reed Army Institute of Research | Kenya Medical Research Institute | U.S. Infectious Disease Clinical Research Program | Boston University-Center for International Health | World Health Organization | Armed Forces Research Institute of Medical Sciences | Office of the United States Global AIDS Coordinator | National Institute of Allergy and Infectious Diseases | PATH | HJF and HJFMRI | NIH-Eunice Kennedy Shriver National Institutes of Health and Human Development | LIMATECH Biologics | Institut Pasteur | GSK Vaccines for Global Health | Janssen | Bill and Melinda Gates Foundation | Wellcome Trust | U.S. Naval Medical Research Center | National Institutes of Health | Department of Defence-Global Emerging Infections Surveillance | BATUK-British Army Training Unit-Kenya

SUCCESS STORY: RV217 – EARLY CAPTURE HIV COHORT STUDY

MHRP's ambitious RV217 study followed a group of high-risk volunteers, tracked their HIV status and characterized progression through the acute stages of HIV infection. This prospective study captured samples from the earliest stages of HIV — in some cases within days of infection.

The Kericho site enrolled more than 900 volunteers in the study for twice-weekly blood collections with 34 incident acute infections observed. The high rate of volunteer visit compliance was key to study success. RV217 concluded in 2018 and provided the first characterization of acute HIV infection.



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