SEMI ANNUAL RESEARCH REPORT

July - December 2021

Acknowledgements

The AMPATH Kenya Research Program Office is grateful to our sponsors and research partners who contribute to the success of our research program. Thank you to everyone who contributed to this report and our efforts to improve the health of people in Kenya and other resource-limited settings around the world.

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Please visit the AMPATH Research Program website to learn how our research programs are helping improve the health of people in Kenya and around the world. *https://www.ampathkenya.org/research*	

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Research Program Vision, Mission, & Values

Vision

We envision a vibrant, world-class, Kenyan-led community of researchers engaged in the continuous improvement of health globally.

Mission

Guided by the principle of leading with care, we work in partnership to develop local research talent and to identify, develop and disseminate relevant and timely information to improve the health of underserved populations.

Values

In our work we embrace:

- Service with humility
- A spirit of collaboration and partnership
- Integrity in relationships
- Mutual respect and mutual benefit in organizational partnerships
- Efforts to eliminate health disparities
- A sustainable infrastructure for research

Strategic Priorities

After internal and external stakeholders' surveys and interviews, the AMPATH Kenya Research Program Office (RPO) convened a two-day strategic planning meeting in September 2019 in Eldoret, Kenya. The meeting included more than 40 key research program leaders and stakeholders tasked with reviewing and evaluating the program's strategic priorities and developing a new strategic plan for the next three years. The following strategic priorities were identified:

1. Strengthen development of a **well-resourced and sustainable infrastructure for research** that enables the efficient conduct of high-quality research.
2. Increase the number of **successful independent investigators** working in collaborative, interdisciplinary research teams by providing better access to high-quality training and mentorship.
3. Enhance **supportive, research-intensive cultures** within the schools and departments of all AMPATH partners.
4. **Accelerate growth in relevant, high-yield research initiatives** that will improve policy and strengthen the health systems and communities we serve including biomedical innovations, health economics/equity, population health, informatics, and implementation science research.
5. Incorporate research into ongoing efforts to **expand AMPATH innovations to additional underserved populations beyond Kenya.**

Based on these strategic priorities, the AMPATH Kenya Research Program Office (RPO) created a 2020-2023 work plan with input from key stakeholders and leadership to implement the program's new strategic plan. The work plan was included in the AMPATH Kenya Research Semi-Annual Report July – December 2019.

Grants

In 2021, AMPATH-affiliated investigators received US$ 21.5 million in extramural funding for new and continuing research projects. This represents a single-year record and is up from US$ 16.6 million in 2020 (see Figure 1), with most (US$ 15.4 million) of the funding received during the reporting period July to December 2021. This increases AMPATH's cumulative total of research and training awards to over US$ 210 million. Consistent with previous years, NIH funding remained strong in 2021, representing 84% of total funding in 2021 compared to 81% in 2020 (see Figure 2).

2021 Award Metrics At-A-Glance

US$ 21.5 million

in total awards received (all time high)

58

extramurally-funded studies

84%

of total funding from the US National Institutes of Health

Figure 1. Ten-Year Trend in Total Awards, 2012 – 2021

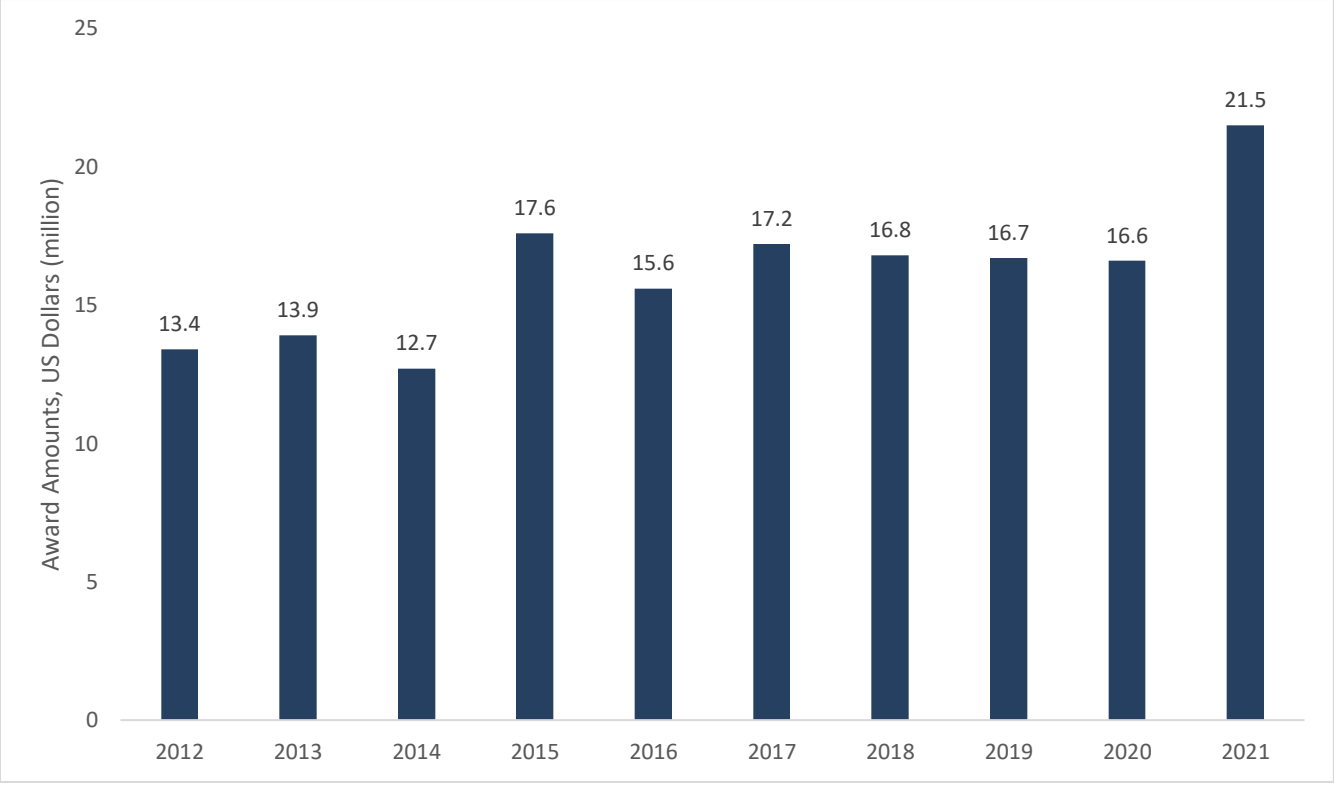


Figure 2. Percentage of Awards Received by Sponsor Type, 2021

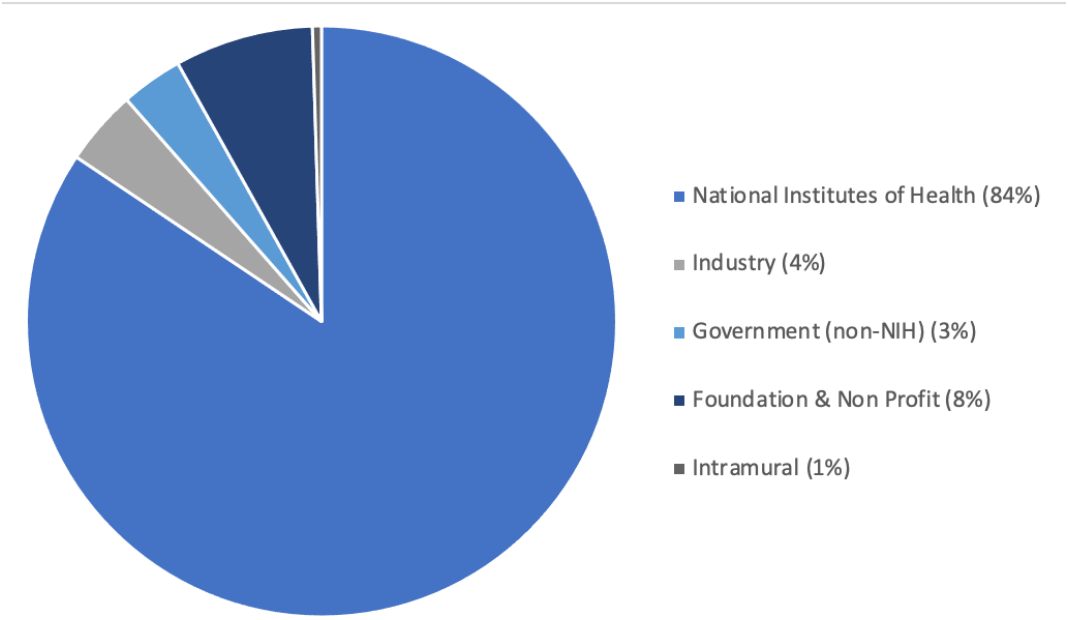


Table 1. New and Competitive Renewal NIH Research Awards Received in 2021

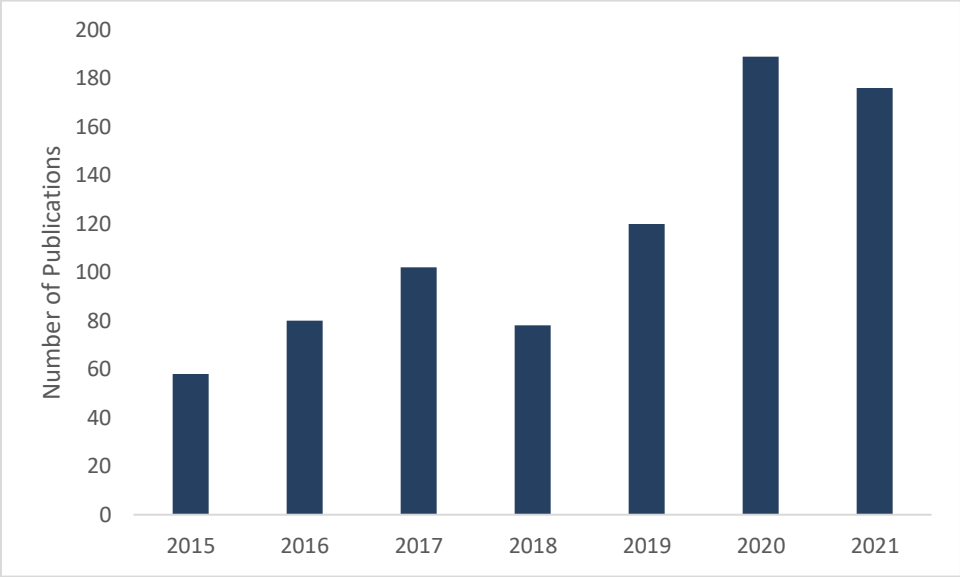
Investigators	Title	Sponsor
John Humphrey (Indiana) and **Mercy Maina** (Moi)	Adaptation, execution, and evaluation of a differentiated service delivery model for PMTCT	NIH-NICHD (K23)
Megan McHenry (Indiana) and **Eren Oyungu** (Moi)	Predicting neurodevelopmental risk in children born to mothers living with HIV in Kenya	NIH-NICHD (R01)
Rena Patel (Univ of Washington) and **Edwin Were** (Moi)	Co-benefits of co-delivery of long-acting antiretrovirals and contraceptives	NIH-NIAID (R01)
Joseph Hogan (Brown) and **Ann Mwangi** (Moi)	Brown Moi Partnership for Biostatistics Training in HIV-NAMBARI (Competitive Renewal)	NIH-FIC (D43)
Megan McHenry (Indiana) and **Eren Oyungu** (Moi)	Advancing the science of neurocognitive physiology in adolescents living with HIV	NIH-NIMH (R21)
Caitlin Bernard (Indiana) and **Wycliffe Kosgei** (MTRH)	The Desire to Avoid Pregnancy Postpartum (DAPP) Study – East Africa IeDEA Supplement Study	NIH-NIAID (U01)
Rumi Chunara (NYU), **Rajesh Vedanthan** (NYU), **Joseph Hogan** (Brown) and **Ann Mwangi** (Moi)	NYU-Moi Data Science for Social Determinants Training Program	NIH-FIC (U2)
Kara Wools-Kaloustian (Indiana), **Constantin Yiannoutsos** (Indiana), **Aggrey Semeere** (Makerere)	East Africa International Epidemiology Database to evaluate AIDS (IeDEA) Regional Consortium (Competitive Renewal)	NIH-NIAID (U01)
Joseph Hogan (Brown), **Hamish Fraser** (Brown), **Ann Mwangi** (Moi)	Data Science for Decision Support in the HIV Care Cascade	NIH-NIAID (R01)
Abraham Siika (Moi) and **Lawrence Corey** (Univ of Washington)	COVID-19 Prevention Network (CoVPN): Efficacy, Immunogenicity, and Safety of SARS-CoV-2 Recombinant Protect Vaccine (CoVPN 3005)	NIH-NIAID (UM1)
Abraham Siika (Moi) and **Lawrence Corey** (Univ of Washington)	COVID-19 Prevention Network (CoVPN): UBUNTU Study (CoVPN 3008)	NIH-NIAID (UM1)

Individual study reports provided by projects' principal investigator(s) or their designee that describes the study's specific aims, sites, project period, sponsors, and project status are available in the Appendix – Study Reports section.

Publications

AMPATH investigators published 170 articles in 2021, increasing the total number of AMPATH publications to 1,140 since the beginning of the AMPATH partnership. AMPATH investigators continued to produce publications in a wide range of research areas including basic and clinical science research, epidemiology, implementation science, health services and systems research, and bioethics to improve programs, practice, and policy in Kenya and around the world. Research into the clinical and social aspects of HIV, malaria, cardiovascular and metabolic diseases, oncology, mental health, maternal and child health and COVID-19, among other areas, illustrate the breadth of research at AMPATH. Researchers at AMPATH also contributed to multi-region and global publications through research collaborations and networks such as the Global Network for Women's and Children's Health Research, International Epidemiology Databases to Evaluate AIDS (IeDEA), Neuropsychiatric Genetics of African Population (Neuro-GAP), and new clinical trials networks like the COVID-19 Prevention Network (Co-VPN) funded by the US National Institutes of Health. AMPATH investigators contributed to publications to inform national and international policy and guidelines, including to the Kenya Non-Communicable Diseases and Injury (NCDI) Poverty Commission. A complete list of publications by AMPATH investigators in 2021 is available in the Appendix – Bibliography section.

Figure 3. Articles Published by AMPATH Affiliated Investigators, 2015-2021



Geographic Reach of AMPATH Research Activities

A total of 72 research projects at AMPATH completed requests for information related to new or ongoing studies during the reporting period, July to December 2021. As shown in the table below (Table 2), while Uasin Gishu County (home to Eldoret and MTRH) is the most common location for research activities, AMPATH researchers are engaged in research activities across western Kenya. As noted earlier, AMPATH investigators are also part of regional and global research and training activities through a number of projects and consortia, including the National Institute of of Child Health and Human Development (NICHD)-funded Global Network for Women's and Children's Health Research, National Institute of Allergy and Infectious Diseases (NIAID)-funded IeDEA Consoritum, the NIH Fogarty-funded Global Health Program for Fellows and Scholars, and clinical trials such as BREATHER-Plus funded by the European and Developing Countries Clinical Trials Partnership, among others.

Table 2. Location of Research Activities by County* in Kenya

Uasin Gishu County – 36 projects	Kakamega County – 9 projects
Trans Nzoia County – 30 projects	Elgeyo Marakwet County – 7 projects
Bungoma County – 25 projects	Homa Bay County – 6 projects
Busia County – 23 projects	West Pokot County – 5 projects
Nandi County – 11 projects	Other Counties (Bomet, Kericho, Kisii, Migori, Nakuru, Siaya, Turkana, Vihiga) – 12 projects
Kisumu County – 10 projects	Moi Teaching and Referral Hospital – 47 projects

**Several projects take place in more than one county. Projects reported all counties where research activities were taking place. Research projects taking place at Moi Teaching and Referral Hospital (MTRH) were captured separately.*

Response to COVID-19

The AMPATH Research Program office continued to provide guidance to AMPATH investigators and research teams for the safe conduct of research amidst the ongoing COVID-19 pandemic. Investigators and research teams are encouraged to remain flexible and have contingency plans in place should in-person research activities need to be restricted. Investigators and research teams continue to adhere to minimum safety requirements as described in the Return to Work Policy for AMPATH Research Program Staff. AMPATH-affiliated investigators are contributing in various ways to the local and global COVID-19 response. A few highlights are listed below (additional COVID-related studies can be found in the Study Reports section in Appendix 2).

- The Moi University Clinical Research Centre led by Dr. Abraham Siika is participating in two COVID-19 related clinical trials through the COVID-19 Prevention Network funded by the US National Institutes of Health.
- Dr. Kirtika Patel (Moi University) participates in the COVID-19 Clinical Research Coalition as a working group member and participated as a speaker in the event "Setting up biorepositories and increasing sequencing capacity to respond to SARS-CoV-2 in LMICs" in September 2021.
- Investigators with the East Africa International Epidemiology Databases to Evaluate AIDS (EA IeDEA) lead a study to assess the impact of COVID-19 using several prospective cohorts living with HIV through telephone survey. The survey tool has been adapted by other studies in East Africa and in Indiana.
- The AMPATH/Moi site of the Global Network for Women's and Children's Heath contributed to a global survey on knowledge, attitudes and practices of pregnant women related to COVID-19.
- Several AMPATH affiliated investigators published articles and commentaries related to COVID-19 in 2021, including COVID-19 and social stigma, impact of the pandemic on adolescents living with HIV, access to medicines for non-communicable diseases and supply-chain strategies, maintaining care delivery for non-communicable diseases, and mental health among frontline health providers.

Other Activities & Achievements

In the second half of 2021, the AMPATH Kenya Research Program made progress in several key areas in line with the strategic plan:

Restructuring AMPATH Kenya Research Working Groups (ARWG) – In early 2021, the AMPATH Kenya RPO undertook a strategic effort to restructure ARWG to better fulfill their original mandate. During the reporting period, several ARWG submitted updated terms of reference and annual work plans and presented these to the AMPATH Research Executive Committee. In addition, several interest groups were formed in new areas of adolescent health, nursing, and surgery that may organize into formal ARWG at a later date. Finally, RPO has created a small funding mechanism to support ARWG in restructuring and strengthening their activities in 2022. ARWG may apply for grants up to $2,000 to support mentorship, professional development, peer review, pilot project(s), or other activities.

Developing a Research Mentorship Curriculum – A curriculum for academic research mentorship for mentors and mentees was developed by the AMPATH Kenya RPO in collaboration Eider Africa, a firm in Nairobi that specializes in academic research mentorship program development. The goal is to strengthen the investigator pipeline at Moi and expand research collaborations at IU and other AMPATH Consortium schools. The curriculum will be presented to the Moi College of Health Sciences and Medicine, Public Health, and Nursing School Boards for review and adoption in early 2022.

Supporting Professional Development – The AMPATH Kenya RPO restarted monthly Works In Progress meetings to provide opportunities for investigators and other research staff to present on proposed, ongoing, or recently completed research studies. In addition, RPO organized a professional development series for the upcoming year which includes sessions for conducting literature reviews, grant writing and development, manuscript writing, and data management and analysis. In addition, RPO in partnership with the AMPATH Population Heath Initiative are hosting an online course for research and program staff on Monitoring and Evaluation in Global Health through the University of Washington's Department of Global Health e-Learning Program. The course will start in January and other course offerings may be available in the future.

Onboarding Course for AMPATH Research Staff – New AMPATH Kenya research coordinators, assistants, and other research staff continue to participate in a new Onboarding Course for the AMPATH Kenya Research Program. The course was launched in June 2021 and is hosted on Indiana University's Canvas e-learning platform with modules consisting of video presentations from program leaders, downloadable presentation slides for reference, additional readings and a short quiz. The course can be accessed by going to this link and registering for a Guest account. At the end of 2021, a total of seven colleagues (six in Kenya and one in Indiana) had completed the course.

New SOP on Exchange Rates – In 2021, the Research and Sponsored Projects Office (RSPO) created an SOP on Exchange Rates Management. The purpose of the SOP is to ensure the efficient and effective management of exchange rates, outline the general rules and regulations guiding applicable exchange rates, and to ensure exchange losses are avoided or minimized. This SOP applies to all grants on cost reimbursement contracts in a currency other than Kenya Shillings and is effective for applicable grants after September 1, 2021.

Revising AMPATH Research Facility Fee – The AMPATH Research Facility Fee applied to extramurally-funded research awards supports a robust and unique collaborative research infrastructure at AMPATH Kenya (see SOP for Research Project and Grant Proposal Development). To strengthen this Fee, RPO is working on a new fee structure and moving administration of the fee from the IU Center for Global Health to RSPO. At the end of the reporting period, the new fee

structure was under review by AMPATH and Moi/MTRH leadership. The new AMPATH Research Facility Fee is planned to be rolled out in July 2022.

Supporting AMPATH Research Replication – Drs. Wools-Kaloustian and Winstone Nyandiko continued to co-chair the AMPATH Research Replication Working Group to support the replication of AMPATH in Ghana (led by New York University and the University of Development Studies) and in México (led by University of Texas Austin and Benemérita Universidad Autónoma de Puebla). The group created a comprehensive Research Infrastructure Assessment Strategy and Tool to assess research infrastructure at replication partner sites and identify areas for collaboration as they build their respective research programs. During the reporting period, the tool is being piloted by replication partners and a manuscript describing the creation of the strategy, tool and its adaptation by replication partner sites is planned for 2022.

Continued Collaboration with Indiana CTSI – The AMPATH Kenya Research Program continues to collaborate with the Indiana CTSI Global Health Program specifically around efforts in "reciprocal innovation," an approach largely informed by experiences from the AMPATH partnership that describes the power of mutual learning and benefits that emerge from long-standing, equitable global heath partnerships. Several AMPATH investigators participated in the third annual Indiana CTSI Reciprocal Innovation Stakeholder Meeting on October 12-13, 2021, with a theme of "Health Systems Resiliency." Dr. Roger Glass, Director of Fogarty International Center at NIH, was the meeting's keynote speaker. A recording is available. An RFA for Reciprocal Innovation Demonstration Grants was released in November 2021. The program currently supports two research projects at AMPATH on a community-based caregiver training intervention for children with autism (PIs: Drs. Megan McHenry, Indiana University and Eren Oyungu, MTRH) and community-based, peer-led interventions for mental health among youth in Eldoret (PIs: Drs. Matthew Turissini, Indiana University and Edith Kwobah, MTRH).

To stay updated on important activities at the AMPATH Research Program as well as new grant and funding opportunities, published articles from AMPATH investigators, and calendar events such as the AMPATH Works in Progress meetings, please be sure to subscribe to the monthly AMPATH Research Newsletter. Contact the AMPATH Research Program Office (research.manager@iukenya.org) to subscribe.

Appendix - *Bibliography and Study Reports*

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The following bibliography includes AMPATH research publications published in 2021. Please contact the Research Program Office at research.manager@iukenya.org for a complete bibliography of AMPATH research publications published since 1989 along with full text articles.

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Study Reports

The following study reports provide summaries of active AMPATH research projects at the end of the reporting period (December 31, 2021). Study reports and updates for 72 studies were provided by the projects' principal investigator(s) or their designee and provide details on study team specific aims, sites, project period, sponsors, project status, and publications. Summaries are organized alphabetically by study title and a linked index is listed below for easy navigation.

Table of Contents (Study Reports)

Study Title	**A cluster randomized trial of 'Teach HADITHI' teacher training intervention to reduce classroom HIV-related stigma in Kenya.**
Principal Investigator(s)	Rachel Christine Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Juddy Wachira (Moi University), Wanzhu Tu (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Assemble a multimedia teacher training curriculum package, focused on HIV and HIV stigma and adapted for maximum cultural relevance, curricular cohesion and impact among Kenyan primary and secondary school teachers. Aim 2: Assess the impact of the Teach HADITHI intervention on Kenyan teachers' attitudes, beliefs and knowledge about HIV and the level of HIV-related stigma among teachers. Aim 3: Examine whether HIV-infected children and adolescents in classrooms with teachers who have received the Teach HADITHI intervention report less perceived, enacted or internalized stigma compared to those in classrooms with teachers who have not. Aim 4: Examine the impact of HIV stigma training on stigmatizing knowledge, attitudes and beliefs about COVID-19.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	7/1/2018 - 4/30/2021
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction and follow-up. Research activities are limited to data analysis.

Study Title	**A Phase 3, Double-Blind, Randomized, Multicenter, Placebo-Controlled Study to Evaluate the Efficacy and Safety of TNX-102 SL in Participants with PTSD Taken Daily at Bedtime**
Principal Investigator(s)	Lukoye Atwoli (Moi University)
Collaborator(s)	Edith Kwobah, Frank Njenga, Linet Ongeri, Sylvia Kemunto, Gabriel Kigen
Study Type	Double-blind randomized clinical trial.
Specific Aim(s)	Aim 1: To evaluate the efficacy of TNX-102 SL (cyclobenzaprine HCI sublingual tablets) in treatment of PTSD. Aim 2: To evaluate the safety of TNX-102 SL (cyclobenzaprine HCI sublingual tablets) in the treatment of PTSD.
Site(s)	Moi Teaching and Referral Hospital, KEMRI Nairobi, Aga Khan University
Project Period	7/1/2020 - 6/30/2023
Sponsor(s)	TONIX Pharmaceuticals
Status	Not started -- Study activities have not begun.

Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 1**
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	The objective of this experiment is to identify the combination of RDT and conditional (diagnosis-dependent) ACT subsidies that maximize the percent of clients receiving an RDT. We will test two different RDT price levels and two discounted ACT price levels in a factorial design. ACT discounts are conditional on a positive RDT result. The primary outcome measure is the decision to purchase an RDT before purchasing a drug. Secondary outcome measures are: Decision to purchase an ACT stratified by testing status: (a.) Positive mRDT (b.) Negative mRDT (c.) No malaria test. All outcomes will be measured by interviewing the participant after they make their decision about whether to be tested and which medicines to purchase.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**A randomized experiment of malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial AIM 2**
Principal Investigator(s)	Jeremiah Laktabai (Moi University)
Collaborator(s)	Diana Menya (Moi University), Wendy O'Meara (Duke University)
Study Type	Randomised controlled trial
Specific Aim(s)	The objective of this study is to test the effect of provider-directed and patient-directed incentives on improving the management of suspected malaria fevers that receive care in the retail sector. Provider-directed incentives include small payments for taking the time to conduct malaria-RDT testing for participants with malaria-like illness. Patient-directed incentives are inexpensive RDT testing coupled with a conditional ACT discount. Outcomes will be measured by exit interviews on random days each month at each participating outlet. The primary outcome will be the proportion of all ACTs that are sold to individuals with a positive malaria diagnostic test. The major secondary outcome is the proportion of suspected malaria cases that are tested. This outcome will allow us to determine whether the conditional subsidy can drive demand for testing.
Site(s)	Bungoma, Trans Nzoia
Project Period	10/1/2018 - 9/30/2023
Sponsor(s)	NIH-NIAID

Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**A5300B/I2003B/PHOENIx Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Patients (PHOENIx MDR-TB)**
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	David Lagat (Moi University)
Study Type	Phase III, open-label, multicenter trial with a cluster-randomized superiority design
Specific Aim(s)	Aim 1: To compare the efficacy of 26 weeks of DLM versus 26 weeks of INH for preventing confirmed or probable active TB during 96 weeks of follow-up. Aim 2: To compare the safety (permanently stopping study drug due to treatment-related adverse events) of 26 weeks of DLM versus 26 weeks of INH for the treatment of presumed latent TB infection (LTBI) with MDR-TB.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Kericho, Kisumu, Moi Teaching and Referral Hospital, Nakuru, Nandi, Siaya, Trans Nzoia, Uasin Gishu, Vihiga, West Pokot
Project Period	10/21/2020 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**A5381 Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir (TLD) for First- or Second-Line ART or with Rifampicin-Containing TB Treatment**
Principal Investigator(s)	Abraham Siika (Moi University)
Collaborator(s)	Fatuma Some (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Among participants still on TLD at 6 months of followup, to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations in each of the following groups: (a) Participants switching from first-line NNRTI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 1a); (b) Participants switching from second-line PI-containing therapy with HIV-1 RNA >1000 copies/mL at start of TLD (Group 2a); (c) Participants switching from first-line NNRTI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 1b); (d) Participants switching from second-line PI-containing therapy with HIV-1 RNA ≤1000 copies/mL at start of TLD (Group 2b); (e) Participants who are ART-naïve when starting TLD (Group 4). Aim 2: Among participants taking concomitant TLD (including an additional daily dose of DTG 50 mg) and RIF-containing TB treatment (Group 3), to estimate the proportion achieving virologic success (HIV-1 RNA ≤1000 copies/mL) and the proportion with new DTG resistance mutations at the end of concomitant treatment.
Site(s)	Busia, Elgeyo Marakwet, Homa Bay, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	10/5/2020 - ongoing

Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Addressing bioethical research gaps in research with young people living with HIV (YPLWH) in Kenya**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Violet Naanyu (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Examine ethical issues in longitudinal clinical research with YPLWH in Kenya from the patient, caregiver, and other key informant perspective. Aim 2: Identify and analyze key bioethics guidelines and policies, as well as academic and grey literature relevant to research with YPLWH across key areas: children and YPLWH, people living with HIV, biological sampling and biobanking, and research in resource-limited settings.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/18/2020 - 5/30/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Addressing HIV drug resistance research gaps in a cohort of perinatally infected Kenyan children and adolescents**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai), Joseph Hogan (Brown University), Vladamir Novitsky (Miriam Hospital)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate genotype-phenotype correlations in HIV-1 subtypes A, C and D. Aim 2: Evaluate etiologies for treatment failure in the presence of a 'susceptible genotype'. Aim 3: Evaluate etiologies for treatment success in the presence of a 'resistant genotype'.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/27/2021 - 5/31/2024
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**An Overview of the Mental Health Care System in 4 Counties in Western Kenya: Findings from an Assessment Using the World Health Organization's Assessment Instrument for Mental Health Systems (WHO-AIMS)**
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)
Collaborator(s)	Matthew Turissini (Indiana University), Florence Jaguga (Moi Teaching & Referral Hospital), Julius Barasa, Richard Matundura, Joyce Nato (World Health Organization)
Study Type	Cross-Sectional
Specific Aim(s)	To collect systems-level mental health care data using the WHO-AIMS in Uasin Gishu, Bungoma, Trans-Nzoia and Busia Counties in western Kenya.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	07/02/2020 - Ongoing
Sponsor(s)	
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**APPROACH Study**
Principal Investigator(s)	Hussein Elias (Moi University)
Collaborator(s)	Eric Finkelstein (Duke University)
Study Type	Prospective
Specific Aim(s)	To understand the perspectives of patients with advanced cancer regarding their quality of life and end of life care. We amended our sample size to 217 patients with stage IV admitted at the inpatient and outpatient clinic. We also amended the inclusion criteria to 1. All patients and races will be included in the study as long as they seek treatment at MTRH during the study period, meet the inclusion criteria and consent to participate in the study. 5. Can understand and speak English or Swahili
Site(s)	Moi Teaching and Referral Hospital
Project Period	1/1/2021 - 12/31/2021
Sponsor(s)	Duke Global Health
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Bridging Income Generation with Group Integrated Care (BIGPIC)**
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Jemima Kamano (Moi University), Violet Naanyu (Moi University), Sonak Pastakia (Purdue University), et al.

Study Type	Prospective
Specific Aim(s)	Aim 1: Identify the contextual factors, facilitators, and barriers that may impact integration of group medical visits and microfinance for CVD risk reduction, using a combination of qualitative research methods: 1) baraza (traditional community gathering) form of inquiry; and 2) focus group discussions among individuals with diabetes or at increased risk for diabetes, microfinance group members, and rural health workers. Aim 2: Evaluate the effectiveness of group medical visits and microfinance groups for CVD risk reduction among individuals with diabetes or at increased risk for diabetes, by conducting a four-arm cluster randomized trial comparing: 1) usual clinical care; 2) usual clinical care plus microfinance groups only; 3) group medical visits only (no microfinance); and 4) group medical visits integrated into microfinance groups. The primary outcome measure will be one-year change in systolic blood pressure (SBP), and a key secondary outcome will be change in QRISK2 CVD risk score, which has been validated for Black Africans. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the trial, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per disability-adjusted life year saved. 1. Study Population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF). 2. Study end date: The anticipate study end date is now September 30th, 2022.
Site(s)	Busia, Kisumu, Trans Nzoia, Uasin Gishu
Project Period	4/1/2015 - 9/30/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Chamas for Change: Adapting a community-based peer-support and health education model for pregnant and parenting adolescents in Kenya**
Principal Investigator(s)	Julia Songok (Moi University)
Collaborator(s)	Laura J. Ruhl (Indiana University), Lauren Y. Maldonado (USC), Michael Scanlon (Indiana University), Julie Thorne (University of Toronto), Edith Apondi (MTRH), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To adapt the Chamas for Change model and curriculum for community-based, peer-support groups to specifically meet the needs of pregnant adolescents, adolescent mothers, and their children. Aim 2: To assess the feasibility and acceptability of an adapted adolescent Chamas for Change program; Aim 3: To assess the impact of participation on maternal, newborn, and child health outcomes, psychosocial outcomes (i.e. mental health, social support), school re-enrollment, and financial stability among adolescent participants; and Aim 4: To develop a case study to inform possible adaptations of the Chamas for Change model for adolescents to a North American context. For Phase II of the study this includes pregnant and parenting adolescents aged 15-19 with children aged 6 months or below and not only pregnant adolescents as initially stated.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	11/4/2019 - ongoing
Sponsor(s)	Indiana CTSI

Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Chamas for Change: Validating an integrated community-based strategy of peer support in pregnancy and infancy**
Principal Investigator(s)	Julia Songok (Moi University)
Collaborator(s)	Laura Ruhl (Indiana University), Astrid Christoffersen-Deb (University of British Columbia)
Study Type	Prospective Randomized Controlled Trial
Specific Aim(s)	Validate Chama cha MamaToto as a scalable and effective population-wide strategy to rapidly and sustainably achieve high coverage of facility delivery, quality antenatal and postnatal care, long-term FP and EBF. The primary target was to demonstrate a 30% decrease in maternal (MMR), perinatal (PNR), and newborn (NMR) mortality rates.
Site(s)	Trans Nzoia
Project Period	11/1/2017 – 12/31/2020
Sponsor(s)	Grand Challenges Canada-Saving Lives at Birth
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	**Clinical Assessment for Retention and Engagement (CARE Study)**
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Refine a conceptual model for adolescent disengagement from HIV care in East Africa. Aim 2: Develop and pilot an instrument to assess adolescent risk for disengagement from HIV care - the Clinical Assessment for Retention and Engagement (CARE). Aim 3: Develop an evidence-based algorithm to support clinical evaluation and intervention for adolescents at risk for disengagement.
Site(s)	Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	10/25/2018 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Co-Benefits of Co-Delivery of Long-Acting Antiretrovirals and Contraceptives**
Principal Investigator(s)	Rena Patel (University of Washington)

Collaborator(s)	Edwin Were (Moi University), Beatrice Jakait (MTRH), Edith Apondi (MTRH), Caitlin Bernard (Indiana University), Kimberly Scarsi (University of Nebraska Medical Centre), David Erickson (Oregon Health & Science University), Kenneth Sherr (University of Washington), Deborah Donnell (University of Washington), Randy Stalter (University of Washington), Catherine Ngugi (NASCOP)
Study Type	Prospective
Specific Aim(s)	Aim 1: To collect foundational data to better inform design of an effectiveness-implementation trial. Aim 1a: To determine if combined cabotegravir/rilpivirine injectable use has bidirectional drug-drug interactions with injectable (depot medroxyprogesterone acetate [DMPA]) or implantable (etonogestrel or levonorgestrel) contraceptives. Aim 1b: To qualitatively explore points of convergence and divergence, preferences and values, and health systems readiness around wider-scale co-delivery of LA ART and contraceptives. Aim 2: To evaluate the impact of clinic-provided, co-delivery of LA ART and contraceptives among AGYWLHIV. Aim 2a: To evaluate the impact on effectiveness outcomes of HIV treatment (viral suppression and adherence/persistence) and contraception (uptake and continuation rates). Aim 2b: To evaluate the impact on implementation outcomes of acceptability, feasibility, and fidelity.
Site(s)	MTRH
Project Period	4/1/2021 – 3/31/2026
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Comparison of Nutritional status of children aged 5 to 59 months in community based education and service (COBES)-AMPATH and non AMPATH centres post covid-19**
Principal Investigator(s)	Arthur Kwena (Moi University)
Collaborator(s)	J. Ballidawa (Moi University), K. Taylor (Notre Dame), M. McDowell (Notre Dame), S. Mining (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	To determine the nutritional status of children in selected COBES centres post Covid-19 and compare the nutritional status in AMPATH and non-AMPATH centres.
Site(s)	Bungoma, Busia, Elgeyo Marakwet, Kakamega, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/1/2014 - ongoing
Sponsor(s)	None
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**Compassion Fatigue, Satisfaction and Burnout Among Healthcare workers in the Context of the COVID 19 pandemic in Uasin Gishu County**
Principal Investigator(s)	Edith Kwobah (Moi Teaching and Referral Hospital)

Collaborator(s)	Jane Kariuki (Moi Teaching and Referral Hospital), Florence Jaguga (Moi Teaching and Referral Hospital)
Study Type	Cross-Sectional
Specific Aim(s)	1. To determine the prevalence of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County; 2. To determine social demographic factors associated with development of compassion fatigue, compassion satisfaction and burnout among health care workers in the context of the COVID 19 pandemic Uasin Gishu County; 3. To determine the association between health care workers' previous training in disaster/ emergency response and development of compassion fatigue and burnout among health care workers in the context of the COVID 19 pandemic in Uasin Gishu County
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2021-Ongoing
Sponsor(s)	Mental Health RDF funds
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Data Science for Decision Support in the HIV Care Cascade**
Principal Investigator(s)	Joseph Hogan (Brown University), Ann Mwangi (Moi University), Hamish Frasier (Brown University)
Collaborator(s)	Juddy Wachira (Moi University), Edwin Sang (AMPATH), Lameck Diero (Moi University), Jonathan Dick (Indiana University), Rami Kantor (Brown University), Jonathan Teich (Brigham and Women's Hospital), Arman Oganisian (Brown University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Develop and validate statistical machine learning models and algorithms for clinical and programmatic decision support. Aim 2. Develop, implement and field test decision support and data visualization tools to enhance data-driven decision making by physicians and program managers. Aim 3: Conduct evaluation of the impact and efficacy of the clinical decision support tools in Kenya.
Site(s)	All AMPATH sites
Project Period	11/1/2021 - 10/31/2026
Sponsor(s)	NIH
Status	Ongoing -- The first phase of the study deals with development of statistical methodology. That work has started.
Study Title	**Determining The Frequency of Cytogenetic Abnormalities among Multiple Myeloma Patients in Kenya using an Artificial Intelligence-based Approach: A Retrospective Cohort Study.**
Principal Investigator(s)	Teresa Lotodo (Moi University)
Collaborator(s)	Mercy Atieno Oduor (AMPATH), Kelvin Manyega (Kabarak University), Beatrice Melly (MTRH), Austin Omondi (AMPATH), Diana Flora Namaemba (AMPATH), Yvette Oyolo (AMPATH), Ola Landgren (University of Miami), Francesco Maura (University of Miami)

Study Type	Retrospective
Specific Aim(s)	Aim 1. To determine, by using AI methods, the frequency of suspected cytogenetic abnormalities in multiple myeloma patients at diagnosis based on scanned images of H&E and CD138 stained slides. Aim 2. To correlate the AI classification of MM patients at diagnosis with their survival.
Site(s)	Uasin Gishu (MTRH)
Project Period	10/1/2021 - 12/1/2022
Sponsor(s)	University of Miami
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Developing Capacity of Moi Teaching and Referral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct**
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Jepchirchir Kiplagat (Moi University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Estimate the prevalence of and explore stakeholder perceptions on research misconduct and how it can best be addressed in Kenya. Aim 2: Explore the perceptions on capacity to prevent, detect and manage research misconduct and the perceived critical components of a model framework for managing research misconduct. Aim 3. Develop and pilot test a model framework for detecting and managing research misconduct.
Site(s)	Kisumu, Moi Teaching and Referral Hospital, KNH, Research Ethics Committees in Kenya
Project Period	8/1/2017 - 7/31/2022
Sponsor(s)	NIH-FIC
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**EA-IeDEA: A longitudinal survey study of the impact of COVID-19 preparedness and response efforts on people living with HIV in East Africa**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Lameck Diero (Moi University), Constantin Yiannoustos (Indiana University School of Medicine), Aggrey Sameere (College of Health Sciences Makerere University)
Study Type	Longitudinal observational cohort study
Specific Aim(s)	Aim 1: Assess COVID-19 related knowledge, attitudes, and beliefs among a diverse cohort of people living with HIV in East Africa. Aim 2: Describe the impact of COVID-19 on socio-economic well-being, health status, health services utilization, and health behaviors among a diverse cohort of people living with HIV in East Africa.

Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/9/2020 - ongoing
Sponsor(s)	None
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: ACE Study**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Kara Wools-Kaloustian (Indiana University), Edith Apondi (MTRH), Batya Elul (Columbia University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Giorgos Bakoyannis (Indiana University), Leslie Enane (Indiana University), Zachary Kwena (FACES -KEMRI)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Describe the engagement status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU), virologic suppression status (viral suppression or viral non-suppression), and vital status (alive, dead, or LTFU) for PIA. Aim 2: Provide in-depth characterization of the populations of PIA engaged in and disengaged from care, including describing current HIV care-related characteristics (ART regimen, adherence to treatment, experiences of HIV-related stigma, HIV care preferences); virologic outcomes (viral suppression, viral failure, and drug resistance patterns); pregnancy status; and mental and behavioral health characteristics (depression, substance use). Aim 3: Describe virologic, mental and behavioral health outcomes and HIV care preferences by HIV care status (engaged, LTP with care disengagement, LTP with re-engagement, or LTFU). Aim 4: Identify patient-level factors (including clinical characteristics, mental and behavioral characteristics, and HIV care preferences) associated with HIV care status (engaged, LTP with care disengagement, or LTP with re-engagement), viral suppression, and death.
Site(s)	Moi Teaching and Referral Hospital, Trans Nzoia
Project Period	8/1/2018 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**EA-IeDEA: Jozi Study (Determining Long-Term Clinical Outcomes for HIV-Affected Mother-Infant Dyads in Western Kenya: Jozi Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study)**
Principal Investigator(s)	Jimmy Carlucci (Indiana University)
Collaborator(s)	Audrey Chepkemoi (Kenyan Co-PI; Moi University) John Humphrey (parent MANGO study PI; Indiana University) Kara Wools-Kaloustian (EA-IeDEA PI overseeing MANGO and sub-studies; Indiana University) Rena Patel (University of Washington) Megan McHenry (Indiana University) Edwin Were (Moi University)

Study Type	Prospective
Specific Aim(s)	SA-1: Ascertain maternal outcomes in the prevention of mother-to-child transmission of HIV (PMTCT) service continuum, with emphasis on virologic outcomes for pregnant and postpartum women living with HIV (WLHIV). Hypothesis 1: Virologic failure will be more common in WLHIV who are lost to follow-up (LTFU) from the PMTCT program compared to WLHIV who are retained in care. SA-2: Ascertain infant outcomes in the PMTCT service continuum, with emphasis on early infant diagnosis (EID) and definitive determination of HIV status of HIV-exposed children after cessation of breastfeeding. Hypothesis 2: Favorable maternal virologic and retention outcomes will be associated with completion of EID testing, definitive testing after cessation of breastfeeding, and HIV seronegative status (i.e., mitigation of vertical transmission) among HIV-exposed infants.
Site(s)	Uasin Gishu (MTRH)
Project Period	8/1/2021 - 7/31/2023
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Main Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Constantin Yiannoutsos (Indiana University), Lameck Diero (Moi University), Samuel Ayaya (Moi University)
Study Type	Retrospective
Specific Aim(s)	To collaborate with clinical sites to identify and define key variables, harmonize and effectively analyze the data to generate large datasets.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu, West Pokot
Project Period	8/1/2006 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Measuring Adverse Pregnancy and Newborn Outcomes (MANGO)**
Principal Investigator(s)	Edwin Were (Moi University)
Collaborator(s)	Rena Patel, Julia Songok, Bett Kipchumba, Audry Chepkemboi, Wycliffe Kosgei, Joy Marsha, Catlin Bernard, Beverly Musick, Laura Oyiengo, Elvis Oyungi, Molly MacPheron, Meghan McHenry, Edward Leichty, Ushma Mehta, Emma Kalk, Amy Slogrove, Andrew Boulle, Mary-Ann Davieis, Constantine Yiannoultsos, Kara Wools-Kaloustian, Jimmy Carlucci (IU) and Audrey Chepkemoi (Moi University College of Health Sciences)

Study Type	Mixed prospective and retrospective cohort study
Specific Aim(s)	1. Determine event rates for adverse pregnancy outcomes, congenital abnormalities (CAs) and other abnormal conditions in infants born to HIV+ and HIV- women and determine the associations between adverse pregnancy and infant outcomes and ART exposures during conception and pregnancy 2. To create standardized protocols and data exchange standards within IU and IeDEA. - By leveraging the existing and extensive IeDEA Data Exchange Standard (DES) and creating a Data Standards Task Force and a Data Coordinating Center for PV, we will add new tables and expand existing ones, as necessary, to include new concepts and fields responsive to the needs of pharmacovigilance among pregnant women.
Site(s)	Uasin Gishu
Project Period	8/3/2020 - 7/31/2025
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**EA-IeDEA: Networks In Kenya**
Principal Investigator(s)	Jennifer Syvertsen (University of California, Riverside, USA)
Collaborator(s)	Lukoye Atwoli (Moi University/Aga Khan University), Edith Kwobah (MTRH), Suzanne Goodrich (Indiana University), Karla D Wagner (University of Nevada), Maurice Aluda (KEMRI/FACES), Jayne Kulzer (UCSF), Kara Wools-Kaloustian (Indiana University)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To examine how social network factors (e.g., network size, structure, composition) are associated with patterns of alcohol and other drug use (AOD), sexual behaviors, engagement in care, and HIV clinical outcomes among a sample of EA IeDEA-affiliated clinic patients who screen positive for alcohol and/or drug use and a comparison group. Aim 2: To qualitatively describe the nature and overlap of key relationships (e.g., risky and supportive) within patients' networks and assess their associations with HIV outcomes. Aim 3: To use mixed methods to explore the feasibility and acceptability of developing a social network intervention to reduce AOD risk behaviors, improve HIV clinical outcomes, and increase linkages to testing and care among people who use alcohol and/or drugs in East Africa.
Site(s)	Moi Teaching and Referral Hospital
Project Period	10/29/2019 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**EA-IeDEA: NIDA Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)

Collaborator(s)	Lameck Diero (Moi University), Suzanne Goodrich (Indiana University), Edith Kwobah (MTRH), Patrick Oyaro (FACES/RCTP/KEMRI), Maurice Aluda (FACES/RCTP/KEMRI), Jayne Kulzer (UCSF)
Study Type	Prospective
Specific Aim(s)	Aim 1: Estimate the prevalence of hazardous alcohol consumption in patients enrolling in HIV- care and compare their baseline characteristic with those of non-drinkers. Aim 2: Compare clinician and research assistant collected AUDIT screening data at one clinic within the East African IeDEA consortium. Aim 3: Assess the impact of hazardous drinking on patient outcomes including time to antiretroviral therapy (ART) initiation, medication adherence, retention in care, and death at 6 months and again at 24-36 months. Aim 4: Assess strategies utilized by patients to address their hazardous alcohol use.
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/31/2017 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**EA-IeDEA: PHQ 9 Study**
Principal Investigator(s)	Marcel Yotebieng (Albert Einstein College of Medicine)
Collaborator(s)	Kathryn Lancaster (Ohio State University); Lukoye Atwoli (Moi University); Jennifer Syvertsen (University of California, Riverside), Kara Wools-Kaloustian (Indiana University), et al.
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: Determine the region-specific differences in the quality of measurement afforded by the PHQ-9. Aim 2: Determine the dimensionality of PHQ-9 and assess whether a different scoring system or cut-point is needed among PLWH. Aim 3: Describe how PLWH in both region express mental distress and determine whether reformulation/adaptation of questions in PHQ-9 will improve its performance
Site(s)	Moi Teaching and Referral Hospital
Project Period	11/23/2020 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**EA-IeDEA: PMTCT Plus Study: Improving Estimates of Mother-to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Bett Kipchumba, Marsha Alera, Libby Pfeiffer, Julia Songok, Winfred Mwangi, Wycliffe Kosgei, Beverly Musick, Constantin Yiannoutsos, Juddy Wachira, Kara Wools Kaloustian
Study Type	Prospective

Specific Aim(s)	Aim 1. Determine the barriers and enhancers to retention in care and viral suppression for postpartum women. Sub-Aim 1a: identify factors influencing retention and viral suppression using (i) statistical methods for observational data that incorporate LTFU outcomes, and (ii) qualitative interviews among 30 postpartum women and 15 of their male partners; Sub-Aim 1b: determine the prevalence of HIV resistance and its association with viral non-suppression by genotyping postpartum blood samples with detectable viremia and stored samples collected during pregnancy and earlier postpartum. We are now conducting follow-up study visits at 3 years postpartum for all enrolled women and infants.
Site(s)	Busia, Trans Nzoia, Uasin Gishu
Project Period	2/1/2021 - 2/1/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**EA-IeDEA: Predicting Neurodevelopmental Risk in Children born to Mothers Living with HIV in Kenya: Sub-Study to the Measuring Adverse Pregnancy and Newborn Congenital Outcomes (MANGO) Study**
Principal Investigator(s)	Megan McHenry (Indiana University)
Collaborator(s)	Eren Oyungu-Moi University Rachel Vreeman-Mt Sinai Winstone Nyandiko-Moi University Patrick Monahan-Indiana University Alka Khaitain-Indiana University Zeruesenay Desta-Indiana University Amy Slogrove-Stellenbosch University Rena Patel-Univ. of Washington
Study Type	Longitudinal follow up of the enrolled study participants for 2 years.
Specific Aim(s)	Evaluate potential risk factors for worse ND outcomes in young Kenyan children who are HEU and HUU Compare ND outcomes between 24-month-old children who are HEU and HUU in Kenya Create a risk assessment tool to predict which children are at risk for worse ND outcomes at 24 months
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2021-6/30/2026
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: Syndemics Study**
Principal Investigator(s)	Kara Wools-Kaloustian (Indiana University)
Collaborator(s)	Suzanne Goodrich (Indiana University), Jennifer Syvertsen (University of California Riverside), Jayne Kulzer (UCSF), Maurice Aluda (FACES/RCTP/KEMRI), Lukoye Atwoli (Moi University), Edith Kwobah (MTRH)
Study Type	Prospective
Specific Aim(s)	Aim 1: Identify community and clinic-based services available for treatment of substance use and mental health disorders in the three research sites. Aim 2: Determine the prevalence of substance use (drug and

	alcohol) and mental health disorders in patients enrolling into care. Aim 3: Assess the impact of substance use, mental health disorders and dual diagnoses on patient adherence and retention in the cascade. Aim 4: Conduct qualitative interviews with a sub-sample of cohort patients to explore access, use, and experiences with substance use and mental health services.
Site(s)	Moi Teaching and Referral Hospital
Project Period	12/17/2018 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**EA-IeDEA: The Desire to Avoid Pregnancy Post-partum (DAPP Study)**
Principal Investigator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital)
Collaborator(s)	Caitlin Bernard (Indiana University)
Study Type	Tool development/validation
Specific Aim(s)	The aim of this study development of a DAPP tool and subsequent follow up with patients. We will leverage the cohort of women enrolled in the MANGO-Kenya study, which plans to recruit up to 400 women living with HIV and 400 women not living with HIV enrolling in ANC at MTRH. The 800 participants will be contacted and asked to participate in this sub-study during the postpartum period.
Site(s)	Uasin Gishu (Moi Teaching and Referral Hospital)
Project Period	9/7/2020 -
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Enhancing Preventive Therapy of Malaria in children with Sickle Cell Anemia (SCA) in East Africa (EPiTOMISE)**
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Steve Taylor (Duke University), Wendy O'Meara (Duke University)
Study Type	Randomized, three-arm, open-label, clinical trial
Specific Aim(s)	Aim 1: Compare the efficacy of daily Proguanil with that of monthly sulfadoxine/pyrimethamine-amodiaquine (SP-AQ) or monthly dihydroartemisinin-piperaquine (DP) to prevent P. falciparum malaria in children with sickle cell. Aim 2: Compare the efficacy of daily Proguanil, monthly SP-AQ, and monthly DP to prevent painful events in children with sickle cell anemia. Aim 3: Compare the impact of malaria chemoprophylaxis regimens on molecular markers of parasite drug resistance to Proguanil, SP-AQ, and DP.

Site(s)	Homa Bay
Project Period	6/1/2016 - 2/28/2021
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Estimating the relative effectiveness of contraceptive implants for HIV-positive women on antiretroviral therapy**
Principal Investigator(s)	Rena Patel, University of Washington
Collaborator(s)	Beatrice Jakait (Moi Teaching and Referral Hospital), Caitlin Bernard (Indiana University)
Study Type	Retrospective
Specific Aim(s)	To assess the relative effectiveness of Levonorgestrel-based (LNG) implants with concomitant efavirenz-based ART among a random subsample of HIV-positive women attending AMPATH-supported HIV treatment facilities using chart reviews and phone interviews.
Site(s)	All AMPATH sites.
Project Period	5/1/2016-1/25/2021
Sponsor(s)	NIH - NIAID
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	**Ethnic Specific Risk Stratification in Early Pregnancy for Identifying Mothers at Risk of Gestational Diabetes Mellitus in Eldoret Kenya**
Principal Investigator(s)	Wycliffe Kosgei (Moi Teaching and Referral Hospital)
Collaborator(s)	Astrid Christoffersen (University of Toronto), Sonak Pastakia (Purdue University),
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence rates of GDM in rural and urban populations. Aim 2: To assess the impact of the risk factors of interest (age, BMI and family history) for GDM in early pregnancy. Aim 3: To develop and validate of composite risk score for GDM with the risk factors of interest and/or point-of-care HbA1c.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	6/13/2016 - ongoing
Sponsor(s)	UK Medical Research Council; Warwick University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Evaluating reproductive and HIV outcomes and decision-making among HIV-positive women on dolutegravir: A prospective, observational cohort at AMPATH, Kenya**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Rena Patel, Mercy Maina, Julie Thorne, Beatrice Jakait, Caitlin Bernard
Study Type	Retrospective analysis of AMRS data and telephone surveys
Specific Aim(s)	Aim 1. To evaluate key reproductive health and HIV outcomes among women initially on DTG-containing ART. Aim 2: To investigate factors facilitating provider and patient decision-making for HIV-infected women choosing between ART and contraceptive choices.
Site(s)	
Project Period	7/9/2020 - ongoing
Sponsor(s)	NIH; Indiana University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Evaluation of Chronic Hypoxemia from Cardiopulmonary Disease Among Patients Admitted to a Referral Hospital in Western Kenya and Their Perspectives on Oxygen Use**
Principal Investigator(s)	Neelima Navuluri (Duke University)
Collaborator(s)	David Lagat (Moi University), Peter Kussin (Duke University), Lameck Diero (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Determine the prevalence of chronic hypoxemia from cardiopulmonary disease and the associated in-hospital mortality rate among patients admitted to Moi Teaching and Referral Hospital (MTRH) inpatient medicine wards from August 2019 - June 2021. Aim 2: Characterize patients with chronic hypoxemia admitted to MTRH by determining demographic and environmental risk factors, associated co-morbidities such as HIV, and underlying etiologies. Aim 3: Assess quality of life measures among patients with chronic hypoxemia and their perspectives on oxygen therapy.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	9/1/2019 - ongoing
Sponsor(s)	NIH-Fogarty
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Feasibility and acceptability of Enhanced Patient Care (EPC) for adult HIV patients with unsuppressed viral loads in western Kenya**
Principal Investigator(s)	Juddy Wachira (Moi University)
Collaborator(s)	Becky Lynn Genberg (John Hopkins University), Ira Wilson (Brown University), Abraham M. Siika (Moi University), Omar Galarraga (Brown University), Paula Braitstein (University of Toronto) Ann Mwangi

	(Moi University), Sylvestor Kimaiyo (Moi University), Jonathan Dick (Indiana University), Michael Bart Laws (Brown University)
Study Type	Randomized Controlled Trial
Specific Aim(s)	Aim 1. Determine the impact of system-level factors on patient engagement (clinic adherence) among adult HIV patients. Aim 2. Assess the feasibility and acceptability of enhanced patient care (EPC) clinics for promoting patient engagement (clinic adherence) among patients with unsuppressed viral load (≥400). Aim 3. Determine the cost effectiveness of EPC for engagement of patients with unsuppressed viral load.
Site(s)	Busia
Project Period	7/3/2017 - 12/30/2022
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups in Kenya**
Principal Investigator(s)	Omar Galárraga (Brown University)
Collaborator(s)	Becky Lynn Genberg (Johns Hopkins University), Juddy Wachira (Moi University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the extent to which integrated community-based HIV care with group microfinance affects retention in care and viral suppression among PLHIV in rural western Kenya using a pragmatic cluster randomized intervention design of 40 existing (majority HIV+) microfinance groups to receive microfinance plus either: (A) integrated community-based HIV care, or (B) standard care. Aim 2: To identify specific mechanisms through which microfinance and integrated community-based care impact viral suppression. Aim 3: To assess the cost-effectiveness of microfinance and integrated community-based care delivery to maximize future policy and practice relevance of this promising intervention strategy.
Site(s)	Busia, Trans Nzoia
Project Period	7/5/2019 - 4/30/2024
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**HIV-related outcomes at the AMPATH Drug Resistance Clinic in Kenya**
Principal Investigator(s)	John Humphrey (Indiana University)
Collaborator(s)	Shamim Ali, Bilal Syed, Suzanne Goodrich, Celia Ngetch, Beatrice Jakait, Rami Kantor, Adrian Gardner

Study Type	Retrospective
Specific Aim(s)	Aim 1: Describe the clinical characteristics of patients attending the AMPATH HIV Drug Resistance Clinic, including the prevalence of drug resistance mutations. Aim 2: Describe the virologic and ART outcomes of patients failing second and third-line ART, including the proportion of patients who achieve viral suppression following enrollment in the clinic and the proportion experiencing an ART regimen change.
Site(s)	Uasin Gishu
Project Period	3/3/2020 - ongoing
Sponsor(s)	None
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**IeDEA: Sentinel Research Network (SRN)**
Principal Investigator(s)	Niharika Samala (Indiana University)
Collaborator(s)	Kara Wools-Kaloustian, Lameck Diero, Suzanne Goodrich, Edith Kwobah, Mercy Karoney, Ayub Barasa, Alexa Monroy, Samir Gupta, Fatuma Some
Study Type	Prospective
Specific Aim(s)	To establish a network of research sites, the Sentinel Research Network (SRN), and to capture and analyze standardized data among PLHIV in LMICs. Through this network, we further seek to implement studies on cardiovascular risk factors, mental health, alcohol and other substance use disorders, as well as liver disease prevalence and associated factors among PLHIV accessing care in LMICs.
Site(s)	Moi Teaching and Referral Hospital
Project Period	8/1/2020 - 7/31/2022
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	**Impact of COVID-19 on adolescents living with HIV in Kenya**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Winstone Nyandiko (Moi University), Rachel Vreeman (Mount Sinai)
Study Type	Prospective
Specific Aim(s)	Aim 1: Investigate changes in ART adherence, mental health and socio-economic well-being related to COVID-19, and their association with viral failure and DR outcomes in Kenyan ALWH. Aim 2: Estimate exposure to COVID-19 and association with viral failure and DR outcomes among Kenyan ALWH enrolled in the parent grant.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu

Project Period	8/20/2020 - 5/31/2024
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Implementing a Model of Improved Care for Infectious Diseases and Antibiotic Stewardship across Multiple Levels of the Health System in Western Kenya**
Principal Investigator(s)	Charles Kwobah (Moi University)
Collaborator(s)	Shamim Ali (Moi University), Suzanne Goodrich (Indiana University), Adrian Gardner (Indiana University)
Study Type	Prospective
Specific Aim(s)	To optimize appropriate antibiotic use in order to improve clinical outcomes while minimizing unintentional consequences of use, including the emergence of antimicrobial resistance.
Site(s)	Bungoma, Elgeyo Marakwet, Moi Teaching and Referral Hospital
Project Period	10/1/2019 - 9/30/2022
Sponsor(s)	Pfizer
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Integrating hypertension and diabetes screening and management with HIV care services for older adults: Feasibility study**
Principal Investigator(s)	Jepchirchir Kiplagat, Moi University
Collaborator(s)	Kara Wools-Kaloustian, Jemimah Kamano, Sonak Pastakia, Violet Naanyu, Rajesh Vedanthan
Study Type	mixed-methods (Retrospective analysis of medical records, qualitative interviews and observational checklist)
Specific Aim(s)	To lay the groundwork for integrated HIV and NCD services, this project aims to; i) Determine unmet needs for hypertension and diabetes screening and treatment in older adults living with HIV (OALWH) ii) Assess feasibility and acceptability of utilizing AMPATH's HIV care platform to provide diabetes and hypertension screening and treatment services to OALWH
Site(s)	Moi Teaching and Referral Hospital
Project Period	7/1/2021-6/30/2022
Sponsor(s)	NIH-FIC
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Labor organizing and strikes by health care workers in Kenya**

Principal Investigator(s)	Michael Scanlon (Indiana University)
Collaborator(s)	Lukoye Atwoli (Aga Khan University)
Study Type	Qualitative case study
Specific Aim(s)	Aim 1. Describe labor relations and conflict in the Kenyan public health sector, with specific attention to: (a) key institutions, stakeholders, and their interests; (b) collective bargaining agreements and dispute resolution mechanisms; and (c) health systems governance and policy. Aim 2. Explore the perspectives of key actors (e.g., health workers, union/professional association representatives, health management and government officials, academics) on labor relations and strikes in the Kenyan health sector using a grounded theory approach with specific attention to health systems governance and policy.
Site(s)	Elgeyo Marakwet, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, Samburu County
Project Period	12/6/2018-12/5/2021
Sponsor(s)	None
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Making Inroads to Strengthen the Health of Adolescents (MAISHA)**
Principal Investigator(s)	Leslie Enane (Indiana University)
Collaborator(s)	Edith Apondi (Moi University), Rachel Vreeman (Mount Sinai), Winstone Nyandiko (Moi University), Elizabeth Lowenthal (University of Pennsylvania)
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1. To quantify missed opportunities along the HIV care cascade among adolescents prior to hospitalization in western Kenya, by examining timing and outcomes of HIV diagnosis, linkage to and retention in care, and viral suppression. (Secondary Aim: To determine the causes of hospitalization and mortality among adolescents with HIV in western Kenya); Aim 2. To define critical barriers contributing to delays or failures in the care cascade, as well as facilitators to care, and to identify areas of potential intervention.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/12/2017 - ongoing
Sponsor(s)	Indiana University
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Maternal Newborn Health Registry**
Principal Investigator(s)	Fabian Esamai (Moi University)

Collaborator(s)	Sherri Bucher (Indiana University), Edward Liechty (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University)
Study Type	Prospective
Specific Aim(s)	A multicenter (8 sites in 7 countries) prospective, population-based registry which enrolls women during pregnancy and tracks pregnancy, delivery, and postnatal maternal and neonatal outcomes through 42 days postpartum. A vital registry system allows the Global Network to document maternal and neonatal mortality, design trials to address the major causes of poor outcomes, assess the outcome of our interventions, and ultimately, disseminate the results as the basis of public health policy.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/15/2008 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Mobile Mental Health Monitoring and Support for Adolescents with HIV in Kenya**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Edith Apondi (MTRH), Bree Weaver (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: Assess the feasibility, acceptability, and usability of a cell phone-based intervention to provide mental health services (tele-therapy and tele-peer support) for HIV-infected adolescents in Kenya. Aim 2: Evaluate the user engagement with both the cell phone-based intervention and the clinical care system throughout the monitoring period using counselor reports, usage tracking, and clinical database evaluation. Aim 3: Describe key clinical, mental, and emotional health outcomes for this cohort during the monitoring period, including medication and clinic adherence, viral suppression, depression symptoms and other behavioral or emotional symptom reports, and engagement with support services such as peer support groups.
Site(s)	Uasin Gishu
Project Period	1/1/2017 - 12/31/2018
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**Multicenter Study of Pomalidomide Monotherapy in HIV-Infected Individuals with Kaposi Sarcoma (KS) in Sub-Saharan Africa (SSA)**
Principal Investigator(s)	Naftali Busakhala (Moi University)
Collaborator(s)	Dr. Evangeline Njiru Dr. Susan Krown Dr. Samantha Vogt

Study Type	Prospective
Specific Aim(s)	The study objective is to determine if pomalidomide monotherapy induces an antitumor efficacy and whether it is safe and tolerable, in order to justify its further development for treatment of HIV-associated KS in sub-Saharan Africa.
Site(s)	Kisumu, Moi Teaching and Referral Hospital
Project Period	7/15/2021-Ongoing
Sponsor(s)	NIH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**NeoInnovate Collaborative Consortium**
Principal Investigator(s)	Sherri Bucher (Indiana University)
Collaborator(s)	Saptarshi Purkyastha (Indiana University), Fabian Esamai (Moi University)
Study Type	n/a
Specific Aim(s)	The NeoInnovate Collaborative Consortium is a multi-disciplinary international coalition of faculty, students, and post-graduate trainees led by IU School of Medicine and Alupe University College (Moi University) and partnering with Moi Teaching and Referral Hospital (Kenya), IUPUI, Purdue University, and University of Notre Dame. The Consortium builds, deploys, and evaluates innovative solutions by which to equip, empower, and strengthen health care providers, communities, and health systems. These efforts supply partners and stakeholders with the knowledge, skills, and tools by which to successfully disseminate, implement, scale-up, and sustain evidence-based, life-saving interventions to improve maternal and newborn outcomes.
Site(s)	n/a
Project Period	n/a
Sponsor(s)	None
Status	Preparing grant submissions.
Study Title	**Neurodevelopmental Screening in Children Born to HIV-Infected Mothers in Kenya**
Principal Investigator(s)	Megan McHenry (Indiana University)
Collaborator(s)	Eren Oyungu (Moi University)
Study Type	Prospective
Specific Aim(s)	AIM 1: Determine and compare the reliability and validity of neurodevelopmental screening tools and assessments for use among children aged 18-36 months in Kenya. The objective for this aim is to identify an optimal screening tool and assessment for use in Kenya. AIM 2: Evaluate neurodevelopmental screening implementation in an existing healthcare system in Kenya. •Sub-aim 2a: Develop a contextualized implementation plan and Sub-aim 2b: Pilot a ND screening program at one MCH clinic in

	Kenya. In addition, we will assess effectiveness of ND screening, as determined by sensitivity; specificity; and positive and negative predictive values.
Site(s)	Uasin Gishu
Project Period	9/30/2018 - 8/31/2022
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Neuropsychiatric Genetics of African Populations -Psychosis (NEUROGAP-P)**
Principal Investigator(s)	Lukoye Atwoli (Moi University/Aga Khan University)
Collaborator(s)	Gabriel Kigen, Edith Kwobah, Wilfred Emonyi
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1: To determine the phenotypic presentation of psychotic disorders in African populations. Aim 2: To describe the genetic variation between patients with psychotic disorders and those without in African populations. Aim 3: To examine the association between genetic variation and risk for schizophrenia and bipolar disorder in African populations Aim 4: To provide opportunities for training of African scientists in neuropsychiatric genetics research. Target number of participants has since been reviewed to 5,200
Site(s)	Bungoma, Elgeyo Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pokot
Project Period	7/1/2017 - 6/30/2022
Sponsor(s)	Broad Institute of MIT; Harvard University
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Optimizing HIV treatment monitoring strategies under resource constraints**
Principal Investigator(s)	Rami Kantor (Brown University)
Collaborator(s)	Ann Mwangi (Moi University), Lameck Diero (Moi University), Joseph Hogan (Brown University)
Study Type	The research will use previously collected data and blood samples stored from previously IREC approved AMPATH studies.
Specific Aim(s)	1) Develop and apply scalable statistical framework for optimal targeting of gold standard diagnostic tests used to monitor HIV treatment under resource constraints; 2) Apply causal inference techniques to calibrate decision rules using estimated decision utilities; 3) Develop methods to optimize pooling strategies for viral load testing in resource limited settings; 4) Establish and implement pooling protocols using extant samples from AMPATH patients
Site(s)	Samples stored at The Miriam Hospital, USA

Project Period	2/3/2016 - ongoing
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK)**
Principal Investigator(s)	Valentin Fuster (Mount Sinai)
Collaborator(s)	Jemima Kamano (Moi University), Violet Naanyu (Moi University), Diana Menya (Moi University), Sylvester Kimaiyo (Moi University), Rajesh Vedanthan (NYU Grossman School of Medicine), et al.
Study Type	Prospective
Specific Aim(s)	The objective of this project is to utilize a multi-disciplinary implementation research approach to address the challenge of linking and retaining hypertensive individuals to a hypertension management program. Aim 1: Identify the facilitators and barriers to linking and retaining individuals with high blood pressure to a hypertension care delivery program, using a combination of qualitative research methods. Aim 2: Evaluate the effectiveness of CHWs equipped with a tailored behavioral communication strategy and a smartphone-based tool in improving linkage and reducing blood pressure among hypertensive patients, by conducting a cluster randomized trial comparing: 1) usual care (CHWs with standard training on recruitment of individuals with any chronic condition); 2) CHWs with an additional tailored behavioral communication strategy; and 3) CHWs with a tailored behavioral communication strategy an also equipped with smartphone-based tool linked to the AMRS. Aim 3: Evaluate the incremental cost-effectiveness of each intervention arm of the cluster randomized trial. Study population: Enrollment remains closed for this study. 2890 individuals (69.9% women) were enrolled (708 UC, 709 MF, 740 GMV, and 733 GMV-MF).
Site(s)	Nandi, Uasin Gishu
Project Period	4/1/2012 - 3/31/2022
Sponsor(s)	NHLBI; NYU Grossman School of Medicine
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Patient-Centered Disclosure Intervention for HIV-Infected Children, Helping AMPATH Disclose Information and Talk about HIV Infection (HADITHI)**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University),
Study Type	Prospective
Specific Aim(s)	Aim 1: Expand and modify an existing pediatric HIV disclosure intervention used in Kenya to include patient-centered components. Aim 2: Perform a randomized trial to compare the impact of clinic implementation of the culturally adapted, pediatric disclosure intervention on the prevalence of

	disclosure and on the medical, psychological and social outcomes for HIV-infected Kenyan children ages 10-15 years compared to children exposed to standard clinical care.
Site(s)	Bungoma, Busia, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	1/9/2012 - 1/9/2016
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Prevalence and Impact of SARS-CoV-2 Among Pregnant Women in Low- and Middle-income Countries**
Principal Investigator(s)	Fabian Esamai (Moi University)
Collaborator(s)	Edward Liechty, Sherri Bucher (Indiana University), Irene Marete (Moi University), Constance Tenge (Moi University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of COVID-19 antibodies in pregnant/recently delivered women in 8 Global Network sites using antibody testing. Aim 2: To compare the maternal, fetal, and neonatal outcomes of COVID-19 antibody positive women vs. antibody negative women including low-birthweight, preterm birth, fetal growth restriction, stillbirth, and neonatal mortality. Aim 3: To assess knowledge, attitudes and practices of pregnant women related to COVID-19 and its prevention during pregnancy.
Site(s)	Bungoma, Busia, Kakamega
Project Period	11/15/2020 - ongoing
Sponsor(s)	NIH-NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**Prevalence of hypertension among postpartum women with preeclampsia (PET) in Kenya: a prospective cohort study**
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Felix Barasa (MTRH), Rebecca Lumsden (Duke University)
Study Type	Prospective
Specific Aim(s)	Aim1: To determine the prevalence of hypertension at 6 months postpartum among Kenyan mothers with preeclampsia. Sub-aim 1.1: To define the BP trajectory during the postpartum period among Kenyan mothers with preeclampsia. Aim 2: To identify risk factors associated with persistent hypertension among Kenyan mothers with preeclampsia. Aim 3: To characterize the acute cardiac structural and functional abnormalities among Kenyan mothers with preeclampsia. Aim 4: To explore post-delivery follow-up care for women with PET, including knowledge, location, barriers and rates of follow up

Site(s)	Moi Teaching and Referral Hospital
Project Period	1/6/2020 - ongoing
Sponsor(s)	NIH-FIC
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. We completed study follow-up and data collection as of May 31, 2021. We are now in the process of data cleaning and analysis and will be preparing for manuscript writing over the next 6 months.
Study Title	**Prevention of maternal and neonatal death/infections with a single oral dose of Azithromycin in women in labor (in low- and middle-income countries): a Randomized Controlled Trial (The A-PLUS study)**
Principal Investigator(s)	Alan Tita (University of Alabama at Birmingham)
Collaborator(s)	Fabian Esamai (Moi University), Paul Nyongesa (Moi University), Ed Liechty (Indiana University), Sherri Bucher (Indiana University), Osayame Ekhaguere (Indiana University)
Study Type	Prospective
Specific Aim(s)	Aim 1: To test the effectiveness of a single dose of prophylactic intrapartum azithromycin compared to placebo in reducing the risk of the composite outcome of maternal death or sepsis. Aim 2: To separately test the effectiveness of a single oral dose of intrapartum azithromycin prophylaxis (2 g) compared to placebo in reducing the risk of the composite outcome of intrapartum/neonatal death or sepsis.
Site(s)	Bungoma, Busia, Kakamega
Project Period	10/30/2019 - ongoing
Sponsor(s)	NIH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Primary Health Integrated Care Project For Chronic Conditions In (PIC4C) Kenya: Pilot Project**
Principal Investigator(s)	Jemima Kamano (Moi University)
Collaborator(s)	Thomas Andale (MTRH), Nicholas Kirui (MTRH), Imran Manji (MTRH). Ann Mwangi (Moi University), Peter Itsura (Moi University), Philip Tonui (Moi University), Kibet Keitany (MTRH), Violet Naanyu (Moi University)
Study Type	Prospective
Specific Aim(s)	1. Explore perceived barriers and facilitators to the prevention and management of select NCDs (Diabetes, hypertension, cancers of cervix and breast) at the primary health care level by; patients, community members and health providers in Busia and Trans Nzoia counties. 2. Describe the process of implementation of the integrated hypertension, diabetes, cervical cancer and breast cancer prevention and management model within primary health care setting in Trans Nzoia and Busia counties. 3. Evaluate the effectiveness of the integrated chronic care model for hypertension, diabetes, cervical and

	breast cancers within primary health care setting in Busia and Trans Nzoia counties of western Kenya. 4. Estimate the incremental cost and budget impact of scaling up the proposed project in Busia and Trans Nzoia counties of western Kenya.
Site(s)	Busia, Trans Nzoia
Project Period	8/1/2018 - 1/31/2022
Sponsor(s)	World Bank (Access Accelerated)
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**Prospective study of Lopinavir based ART for HIV Infected children globally (LIVING study) 2**
Principal Investigator(s)	Winstone Nyandiko (Moi University)
Collaborator(s)	Dalton Wamalwa (University of Nairobi), Samwel Ayaya (Moi University)
Study Type	Prospective
Specific Aim(s)	Primary objective: Evaluate the effectiveness of LPV/r pellets in addition to AZT/3TC (or ABC/3TC) paediatric fixed dose combination (FDCs) tablet under routine treatment conditions in HIV infected infants and young children who cannot swallow tablets. Secondary objectives: (1) Document the safety of LPV/r pellets and AZT/3TC or ABC/3TC; (2) Assess the population pharmacokinetics of LPV/r and NRTIs when administered as LPV/r pellets plus AZT/3TC or ABC/3TC; (3) Measure adherence to the new formulation; (4) Evaluate children acceptability of the LPV/r pellets and associated dual NRTIs as well as ease of use by the care giver.
Site(s)	Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	4/14/2016 - ongoing
Sponsor(s)	Drugs for Neglected Diseases initiative (DNDi)
Status	Complete -- Follow up and data analysis are complete and the study is closed.
Study Title	**PT4A (Peers and Technology for Adherence, Access, Accountability, and Analytics)**
Principal Investigator(s)	Rajesh Vedanthan (New York University)
Collaborator(s)	Sonak Pastakia (Purdue University), Antoinette Schoenthaler (NYU), Andrea Troxel (NYU), Benson Njuguna (MTRH), Jeremiah Laktabai (MTRHI), Imran Manji (MTRH), Ann Mwangi (MTRH), Jonathan Dick (Indiana University), Dustin Duncan (Columbia), Tina Tran (Temple University), Becky Genberg (Johns Hopkins University)
Study Type	Prospective
Specific Aim(s)	The overall objective of this project is to utilize the PRECEDE-PROCEED framework to conduct transdisciplinary, translational implementation research focused on improving medication adherence for hypertension control. Aim 1: will identify micro- and macro-level contextual factors that might influence the implementation of the PT4A strategy (individual, family, clinician, health system, and environment), using qualitative methods. Aim 2: We will then use a human-centered design approach to refine the

	PT4A intervention using the findings from Aim 1. Sub-Aim 2.1: will evaluate the intervention for acceptability and appropriateness using focus group discussions with patients, peers, and clinical staff. In Sub-Aim 2.2: we will then conduct a pilot of the intervention and conduct focus group discussions with patients, peers, and clinical staff to evaluate feasibility. We will also evaluate impact on systolic blood pressure, medication adherence, and fidelity of implementation.
Site(s)	Bungoma, Trans Nzoia, Uasin Gishu
Project Period	9/25/2020 - 8/31/2021
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**SAFI (Stigma in AIDS Family Inventory) Validation Study**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	WinstoneNyandiko (Moi University), Irene Marete (Moi University), Violet Nanyu (Moi University), Hai Liu (Indiana University)
Study Type	Prospective
Specific Aim(s)	The specific aims for the SAFI validation study were: Aim 1: Identify and modify HIV/AIDS stigma questionnaire items for maximum reliability and content validity to measure perceived, enacted and internalized HIV/A stigma among Kenyan families with HIV-infected children. Aim 2: Assess the validity of the measures of perceived, enacted and internalized H/A stigma compared to independent construct measures including pediatric adherence to therapy and children's physical, psychological and social outcomes. Aim 3: Examine whether disclosure of a child's HIV status reduces perceived, enacted, or internalized stigma for families with disclosed children compared to families with non-disclosed children.
Site(s)	Bungoma, Busia, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu
Project Period	12/17/2013 - 12/31/2015
Sponsor(s)	NIH-NIMH
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.
Study Title	**Scaling Up Primary Health Integrated Care for Chronic Conditions in Kenya: An Implementation Research Project (PIC4C Scale Up Study)**
Principal Investigator(s)	Pablo Perel (London School of Hygiene and Tropical Medicine)
Collaborator(s)	Jemima Kamano (Moi University), Edwine Barasa (Kenya Wellcome Trust Research Programme), Ellen Nolte (London School of Hygiene and Tropical Medicine), Gasparrini (London School of Hygiene and Tropical Medicine), Adrianna Murphy (London School of Hygiene and Tropical Medicine), Ruth Willis (London School of Hygiene and Tropical Medicine), Prof. Hanson (London School of Hygiene and Tropical Medicine), Anthony Etyang (Kenya Wellcome Trust Research Programme), Vincent Were (Kenya Wellcome Trust Research Programme), Violet Naanyu (Moi University), Nicholas Kirui (Moi University)

Study Type	Cross-Sectional
Specific Aim(s)	1) To understand the implementation process to assess the quality of leadership and management; levels of stakeholder involvement; adequacy of support mechanisms and resources; ability to adapt the intervention locally; and quality of communication and of monitoring and feedback; 2) To understand the experiences of patients to assess whether and how well the PIC4C model meets the needs of those affected by the selected NCDs; 3) To assess the health benefits (on hypertension, diabetes and cancer control) and potential unintended consequences (on HIV viral suppression) of the implementation of the PIC4C pilot 4) To evaluate the effectiveness of the NHIF chronic care benefit package to provide financial risk protection, to be responsive to the needs of individuals, to influence equity, efficiency, quality of care, and service delivery.
Site(s)	Busia, Trans Nzoia
Project Period	8/1/2020 – 8/31/2022
Sponsor(s)	UK Medical Research Council (MRC) through Global Alliance for Chronic Diseases
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**Spatial scales of Plasmodium falciparum generations; implications for elimination**
Principal Investigator(s)	Andrew Obala (Moi University)
Collaborator(s)	Wendy O'Meara (Duke University), Diana Menya (Moi University)
Study Type	Prospective cohort
Specific Aim(s)	The overall goal is to match infections in malaria-infected mosquitoes to malaria infections in humans in order to understand what persons infected each mosquito and the distance between the donor and the location where the mosquito was trapped. Aim 1: Measure the genetic relatedness of infections within the same household compared to the relatedness of infections at further distances to determine whether this relationship differs in fever 'hotspots' (geographic clusters of high fever incidence) and fever 'coldspots'. Aim 2: Trap malaria mosquito vectors and identify infected mosquitoes to determine the source of the mosquito's infection by sequencing parasites in the mosquito salivary glands and comparing to parasite genotypes in humans.
Site(s)	Bungoma
Project Period	7/1/2019 - 6/30/2021
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**Stated Preference Analysis to Refine PMTCT Service Delivery in Kenya (SPARK) study**
Principal Investigator(s)	John Humphrey (Indiana University)

Collaborator(s)	Edwin Were, Winstone Nyandiko, Violet Naanyu, Bett Kipchumba, Marsha Alera, Alan McGuire, Beverly Musick, James Carlucci, Constantin Yiannoutsos, Gregory Zimet, Kara Wools-Kaloustian
Study Type	Cross-Sectional
Specific Aim(s)	Aim 1. Identify the relative importance of key PMTCT services according to PPHIV in western Kenya. Aim 2. Explore the influence of various characteristics of PPHIV on their preferences for different PMTCT services.
Site(s)	Busia, Moi Teaching and Referral Hospital, Uasin Gishu
Project Period	6/1/2021 - ongoing
Sponsor(s)	NICHD
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.

Study Title	**Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS)**
Principal Investigator(s)	Constantine Olieba Akwanalo (Moi University)
Collaborator(s)	Jemima Kamano, Benson Njuguna, Violet Naanyu, Ann Mwangi, Timothy Mercer, Rajesh Vedanthan, Sonak Pastakia, Jonathan Dick, Makeda Williams
Study Type	Cluster randomized controlled trial
Specific Aim(s)	Aim 1: Evaluate the effectiveness of HIT and peer support on one-year change in SBP and CVD risk reduction. Aim 2: Conduct mediation analysis to evaluate the influence of changes in referral network characteristics on intervention outcomes, and a moderation analysis to evaluate the influence of baseline referral network characteristics on the effectiveness of the intervention. Aim 3: Conduct a process evaluation using the Saunders framework, evaluating key implementation measures related to fidelity, dose delivered, dose received, recruitment, reach, and context. Aim 4: Evaluate the incremental cost-effectiveness of the intervention, in terms of costs per unit decrease in SBP, per percent change in CVD risk score, and per DALY saved.
Site(s)	Bungoma, Busia, Nandi, Trans Nzoia, Uasin Gishu
Project Period	9/1/2017 - 5/31/2022
Sponsor(s)	NIH-NHLBI
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.

Study Title	**Subclinical Cardiac Dysfunction in Children and Adolescents with and without HIV**
Principal Investigator(s)	Gerald Bloomfield (Duke University)
Collaborator(s)	Winstone Nyandiko (Moi), Myra Maghasi Koech, (MTRH), Andrew McCrary (Duke), Piers Barker (Duke), Svati Shah (Duke), Nathan Thielman (Duke)

Study Type	Prospective
Specific Aim(s)	To determine if advanced echocardiographic measures of cardiac function can detect early stages of cardiomyopathy in CALHIV and if the burden of subclinical changes on echocardiography is dissimilar from HEU and HU children.
Site(s)	Uasin Gishu (MTRH)
Project Period	9/21/2021 - 8/30/2022
Sponsor(s)	NIH-NHLBI
Status	Not started -- Study activities have not begun.

Study Title	**The Effect of Weekly Text Messaging to Improve Retention across the PMTCT Cascade for Pregnant HIV- infected Women: Study Protocol for a Randomized Controlled Trial (WelTel PMTCT)**
Principal Investigator(s)	Anna Mia Ekström (Karolinska Institutet)
Collaborator(s)	Edwin Were (Moi University)
Study Type	Prospective
Specific Aim(s)	The primary objective is to determine the effectiveness of the WelTel SMS intervention on retention of women living with HIV and their newborns in PMTCT care in urban and rural Kenya. Secondary Objectives 1: To assess adherence to the WelTel SMS intervention among pregnant women and newly delivered mothers living with HIV. Objective 2: To determine adherence to single components of PMTCT among pregnant women and newly delivered mothers living with HIV (ARVs, facility-based delivery, early infant HIV testing, and exclusive breastfeeding). Objective 3: To explore facilitators for and barriers to using WelTel SMS in order to inform any improvements on the model for PMTCT among pregnant women and newly delivered mothers living with HIV as well as PMTCT staff. Objective 4: To evaluate costs from a payer's perspective, of the WelTel SMS for retaining women living with HIV and HIV-exposed infants in clinical follow-up until 24 months post-delivery (discharge from PMTCT).
Site(s)	Busia, Kisumu, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	6/25/2015 - ongoing
Sponsor(s)	Swedish Research Council
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**The Impact of Using Hemotype SCTM in Screening for Sickle Cell Disease in Neonates, Infants, and Children under Five Years of Age in a Resource-Limited Setting**
Principal Investigator(s)	Christopher Mwaniki (Duke University)
Collaborator(s)	Festus Njuguna (Moi University), Ann Greist (Indiana Hemophilia and Thrombosis Centre), Chris Roberson (Indiana Hemophilia and Thrombosis Centre)
Study Type	Prospective
Specific Aim(s)	Aim 1: To evaluate the uptake of HSST among immunization population. Aim 2: To evaluate the proportion of those screened with HSST and get followed up through the Hb Electrophoresis. Aim 3:

	To determine the rate of enrollment of those found to have sickle cell into the comprehensive sickle cell clinic. Aim 4: To evaluate the prevalence of sickle cell among screened children age 5 and below presenting in the immunization clinic at the Homabay county referral hospital.
Site(s)	Homabay County Referral Hospital
Project Period	12/1/2020 - 12/1/2022
Sponsor(s)	None
Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.
Study Title	**The Prevalence of and Risk Factors for Non-Alcoholic Fatty Liver Disease in Kenya**
Principal Investigator(s)	Fatuma Some (Moi University)
Collaborator(s)	Naga Chalasani, Niharika Samala, Suzanne Goodrich, Mercy Karoney, Alexa Monroy
Study Type	Prospective
Specific Aim(s)	Aim 1: To determine the prevalence of steatosis and hepatic fibrosis in PLHIV and in individuals without HIV infection where diagnosis is based on predefined clinical, laboratory, and imaging criteria. Aim 2: To develop a bio-specimen bank comprised of serum, plasma, and DNA obtained from PLHIV and in individuals without HIV infection to support the evaluation the independent effects of ART, HIV factors, gene variants, and metabolic abnormalities on risk of fatty liver.
Site(s)	Moi Teaching and Referral Hospital
Project Period	3/1/2021 - ongoing
Sponsor(s)	Indiana University
Status	Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up.
Study Title	**The Role of PD-1 Pathway and Tissue Microenvironment in HIV-Kaposo Sarcoma and Endemic Kaposi Sarcoma Cohort in Western Kenya**
Principal Investigator(s)	Patrick Loehrer (Indiana University)
Collaborator(s)	Toby Maurer, MD (Indiana University), Chite Asirwas (International Cancer Institute)
Study Type	Prospective
Specific Aim(s)	To look for the PD-1 pathway in Kaposis sarcoma (KS) tissue from an HIV cohort and endmic cohort
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/1/2015-8/31/2019
Sponsor(s)	NCI supplemental gratn
Status	Complete -- Follow up and data analysis are complete and the study is closed.

Study Title	**Virologic Treatment Failure and Drug Resistance in HIV-infected Kenyan Children**
Principal Investigator(s)	Rachel Vreeman (Mount Sinai)
Collaborator(s)	Winstone Nyandiko (Moi University), Rami Kantor (Brown University), Samuel Ayaya (Moi University), Joe Hogan (Brown University)
Study Type	Prospective cohort (with additional retrospective analyses)
Specific Aim(s)	Aim 1: Determine prevalence of viral failure and examine resistance mutations among a retrospective study cohort of 685 prenatally HIV-infected Kenyan children on 1st-line ART. Aim 2: Investigate associations between specific adherence patterns, ART drug levels and other demographic and clinical factors, with viral failure and drug resistance. Aim 3: Study long-term immunologic, virologic and drug resistance outcomes and their associations in prospectively re-enrolled study participants Aim 4: Enhance analyses of viral failure, drug resistance accumulation and associated demographic and clinical factors by examining the longitudinal banked samples available for a subset of the study cohort (n=327). Aim 5: Develop a data-driven intervention algorithm to identify children at risk for viral failure and resistance.
Site(s)	Bungoma, Moi Teaching and Referral Hospital, Trans Nzoia, Uasin Gishu
Project Period	8/2/2017 - 7/31/2020
Sponsor(s)	NIH-NIAID
Status	Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis.

Study Title	**World Bleeding Disorders Registry (WBDR)**
Principal Investigator(s)	Festus Njuguna (Moi University)
Collaborator(s)	Donna Coffin (World Federation of Hemophilia), Glenn Pierce (World Federation of Hemophilia), Alain Baumann (World Federation of Hemophilia)
Study Type	Prospective
Specific Aim(s)	WBDR will aim to address the following: Aim 1: Identify gaps in evidence related to diagnosis, access to care, treatment, and outcomes in patients that include: • Comparative evaluation of preventative treatment regimens (e.g., prophylaxis) • Identification of high-risk populations • Inhibitors and other complications of BD • Trends in treatment patterns over time • Discrepancies in quality of care • Data on factor utilization. Aim 2: Collection of data to support advocacy initiatives aimed at improving diagnosis and access to care around the world, such as: • Burden of disease data: • Annual bleeding rate • Functional assessment • Hospitalization • Lost days of school/work • Educational/employment attainment • Between country discrepancies in factor usage.
Site(s)	Moi Teaching and Referral Hospital
Project Period	9/6/2018 - ongoing
Sponsor(s)	None

Status	Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up.