# SEMI ANNUAL RESEARCH REPORT

July - December 2020

**Acknowledgements**

The AMPATH 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 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 the Kenyan people.<br>*https://www.ampathkenya.org/research* | |

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# 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 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 3 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 outside Kenya**

Based on these strategic priorities, the AMPATH 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 a the AMPATH Research Semi-Annual Report July – December 2019.

# Activities & Achievements in 2020

In 2020, the AMPATH Research Program made progress in a number of key areas in line with our strategic plan:

***Training and Mentoring –*** In 2020, the AMPATH Research Program conducted a comprehensive training and mentoring needs assessment at AMPATH (the final Training Needs Assessment Report was included in Appendix A of the previous Semi-Annual Report January – June 2020. Following the needs assessment, the AMPATH Research Program began developing training and mentoring programs for investigators and research staff. To support mentorship and grow the pipeline of investigators, a mentorship program is being designed in collaboration with leadership from Moi University Schools of Medicine and Public Health, which will include training for mentors and mentees using synchronous and asynchronous platforms. To support research staff, an onboarding course for new research coordinators and assistants is under development, which will provide new staff information on the AMPATH Research Program, its policies and procedures, various research offices, and best practices for research. We hope that the mentorship program and onboarding training will be launched mid-year 2021.

***Research Working Groups –*** AMPATH Research Working Groups (ARWG) were established to be an interface between clinical care and research, a platform for mentorship and collaboration particularly between Kenyan and North American investigators, and to ensure equitable access to research resources. Following a 2019 SWOT analysis, several challenges were identified by investigators in meeting these objectives, and in 2020 the AMPATH Research Program undertook a revision to the standard terms of reference for ARWG. This includes requiring ARWG to annually report on milestones and achievements in 5 core areas, advising ARWG to review their current governance structures and to promote leadership opportunities for younger investigators, and creating a two-tiered review process for proposals to streamline processes for review and approval of proposals by ARWG. New terms of references were discussed and agreed to by ARWG leaders by the end of 2020 and ARWG are in the process of instituting these changes that will be finalized by mid-year 2021.

***AMPATH Facility Fee –*** The AMPATH Research Program represents a robust and unique collaborative research infrastructure, including the AMPATH Research Program Office, Research and Sponsored Projects Office, Moi/MTRH Institutional Research and Ethics Committee, and research cores that offer expertise and services in laboratory and biobanking, informatics, data management and biostatistics, and qualitative research. To support this infrastructure, the AMPATH Research Facility Fee was established for research projects that is based on total % FTE of North American investigators (see SOP for Research Project and Grant Proposal Development) and is currently administered by the Indiana University Center for Global Health. In 2020, the AMPATH Research Program began a process of revising the AMPATH Research Facility Fee in an attempt to simplify the administration of the fee by moving it to Moi/MTRH and use a fee calculation model that more accurately represents the use of resources for a particular project while not increasing overall costs of doing research at AMPATH. A new facility fee policy should be rolled out in 2021.

***Collaboration with Indiana CTSI –*** The AMPATH Research Program continues to expand its footprint through engagement with stakeholders through the Indiana CTSI. In December 2020, an Indiana CTSI Reciprocal Innovation Stakeholders meeting was co-hosted by Co-Directors of Research Kara Wools-Kaloustian and Winstone Nyandiko. The virtual meeting was designed to bring together investigators in Indiana and East Africa to identify health priorities of the upcoming Indiana CTSI Global Health Reciprocal Innovation Demonstration and Planning Grants and create opportunities for new collaborations in reciprocal innovation. The Demonstration and Planning grant RFAs were released in early 2021.

***AMPATH Research Replication –*** Drs. Wools-Kaloustian and Winstone Nyandiko co-chair the AMPATH Research Replication Working Group, which was constituted in October 2020 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). Drawing on over 30 years of collaboration and partnership in Kenya, the group is developing various resources such as research infrastructure assessment tools and best practices that can be adapted by replication partners. The group will also serve as a unique platform to connect Kenyan investigators and research leaders with new partners in Ghana and México for collaborative research projects and developing research infrastructure.

***AMPATH Research Newsletter –*** 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 AMPATH Research Newsletter. The Newsletter was re-launched in 2020 as a monthly publication. Contact the AMPATH Research Program Office (research.manager@iukenya.org) to subscribe.

## COVID-19

Kenya reported its first case of COVID-19 on March 15, 2020, and the AMPATH Research Program provided continued guidance throughout the year to AMPATH investigators and research teams for the safe conduct of research. Following a program-wide suspension of in-person research activities (with the exception of clinical trials and other activities that may compromise research participant safety) on March 18, the AMPATH Research Program issued comprehensive guidelines for the safe re-opening of in-person research on July 1 (see Return to Work Policy for AMPATH Research Program Staff and the AMPATH Research Program – COVID-19 Restart Checklist). Infections among research staff and participants remained low and by the end of the reporting period, research activities were fully open provided that investigators and teams abided by guidance issues by RPO and local and national public health officials. Several AMPATH investigators started COVID-19 related research projects. Results of these studies are forthcoming, and we look forward to sharing their findings in the next semi-annual report.

## Grants

Despite challenges associated with COVID-19, AMPATH affiliated investigators received US$ 16.2 million in extramural funding for research and training activities in 2020. The amount awarded in 2020 increased AMPATH's cumulative total of research and training awards to over US$ 187 million (Figure 1). Consistent with previous years, the majority of funding for research and training activities in the US National Institutes of Health, which in 2020 accounted for over 80% of funding (Figure 2). See Appendix A. AMPATH Research & Training Extramural Awards Table, 2020, for a summary of projects funded this year 2020.

**Figure 1: Cumulative AMPATH Research and Training Grant Dollars (US $) 1998 - 2020**

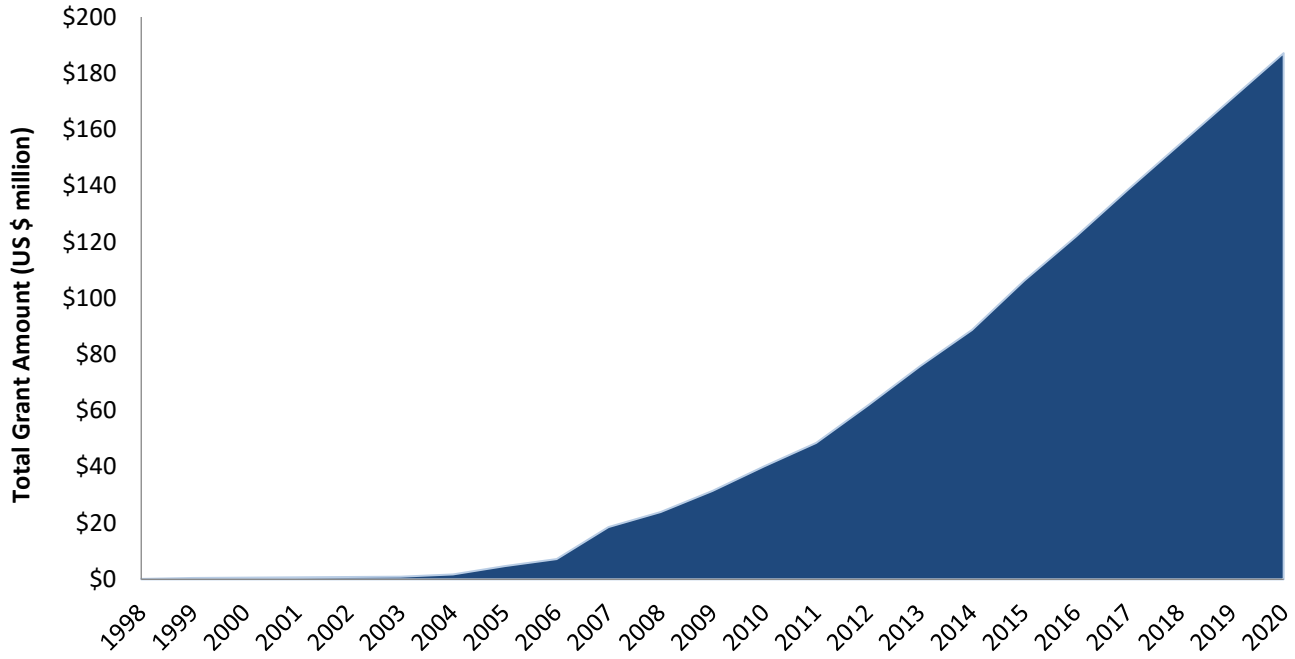
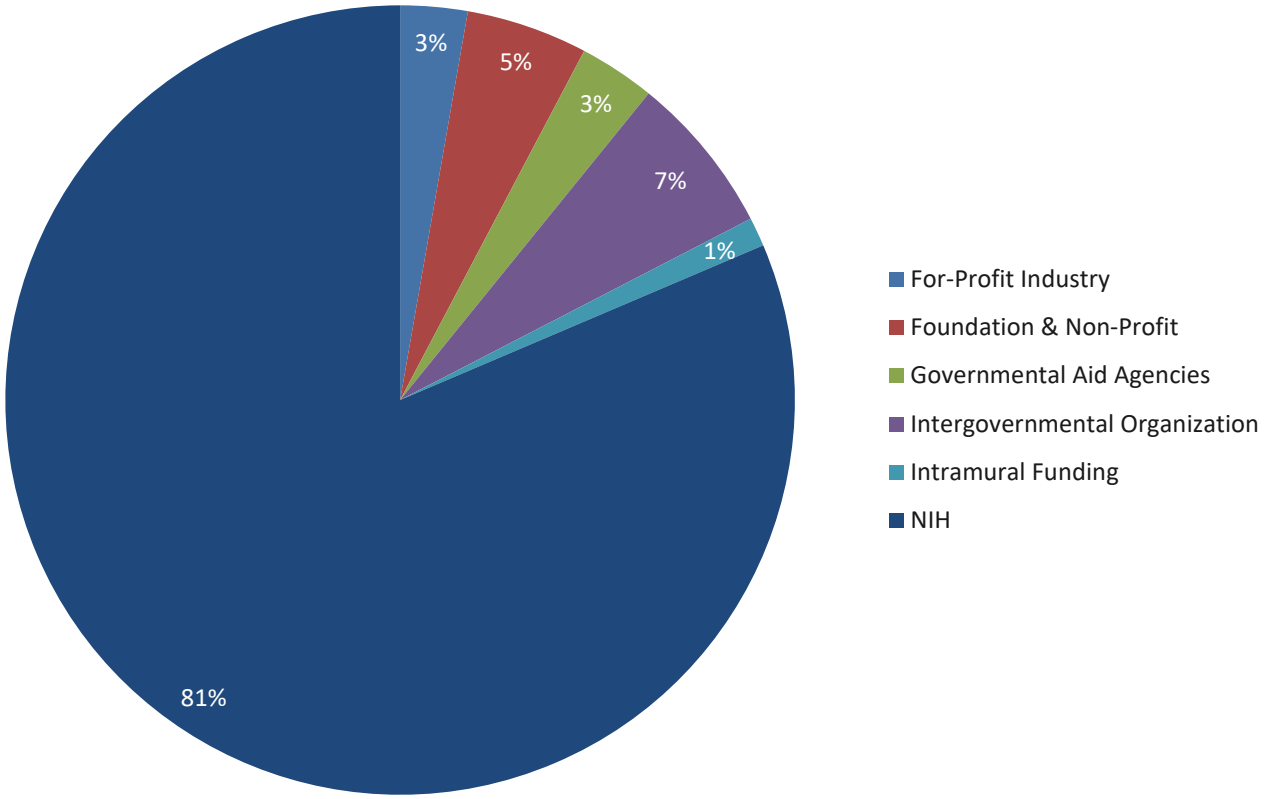


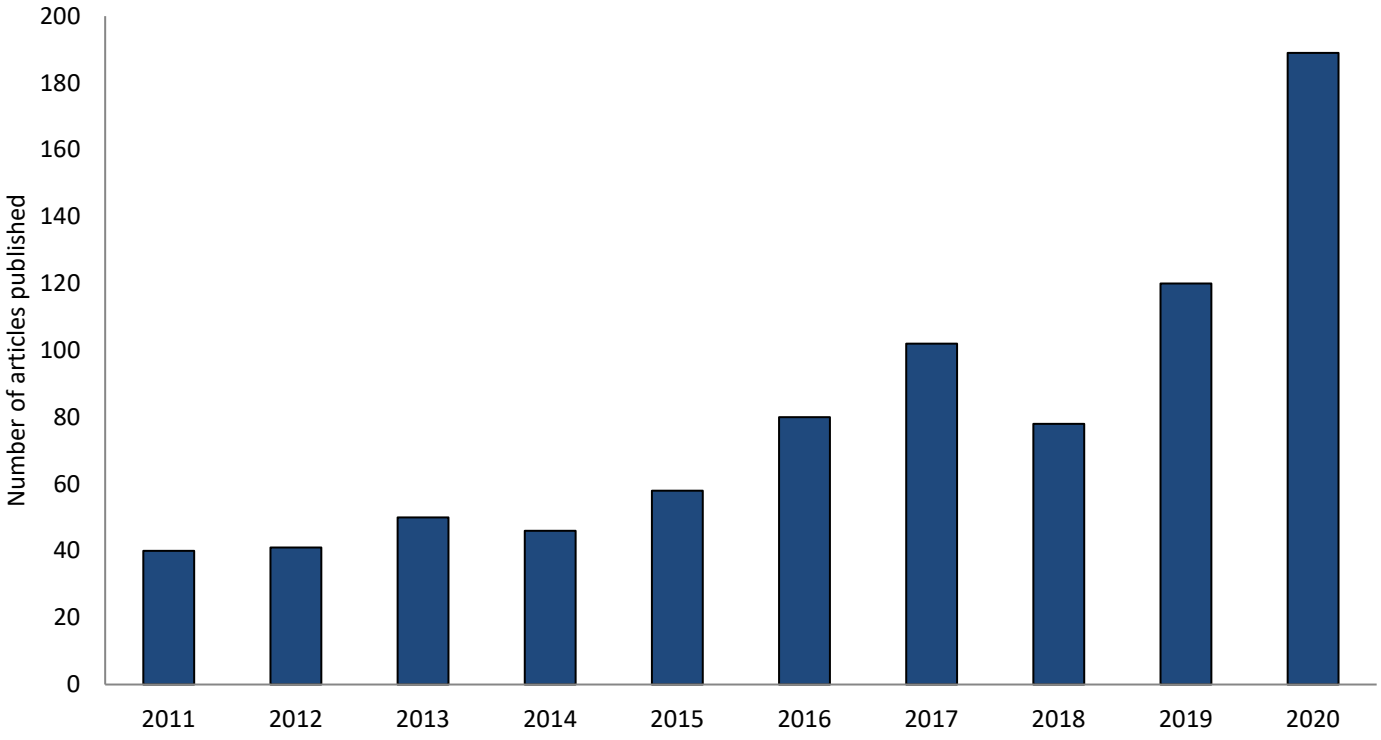

**Figure 2: AMPATH Research Funding Received by Sponsor in 2020**



# Publications

AMPATH investigators published a record 189 articles in 2020, increasing the total number of AMPATH publications to 970 since the beginning of the partnership in 1989 (see Figure 3 for publications by year between 2011 and 2020). AMPATH investigators continued to produce publications in a wide range of research in basic and clinical science research, epidemiology, implementation science, health services and systems research, and bioethics. The Moi University Clinical Research Centre was one of 11 AIDS Clinical Trials Group sites in Brazil, Kenya, Malawi, South Africa, Uganda, and Zimbabwe to participate in a three-arm, randomized, non-inferiority trial for the treatment of advanced AIDS-associated Kaposi sarcoma, which was published in April 2020 in *The Lancet*. In addition to research in the area of HIV, publications in the areas of maternal and child health, substance use, mental health, and non-communicable diseases such as hypertension and heart disease illustrate the variety of research being conducted at AMPATH. A bibliography of publications in 2020 can be found in Appendix B. Bibliography.

**Figure 3: Articles Published by AMPATH Affiliated Investigators, 2011-2020**



# Research Project Snapshot

A total of 61 research projects at AMPATH completed AMPATH Research Program Office requests for updates on their study and submitted information. Individual study reports provided by the projects' Principal Investigator(s) or their designee that describes the study's specific aims, sites, project period, sponsors, and project status are available in Appendix C. Study Reports.

*Institutional affiliation of Principal Investigators*

Studies were led by principal investigators at various AMPATH affiliated institutions including Moi University (23 studies) or Moi Teaching and Referral Hospital (1 study), Indiana University (14 studies), Mount Sinai (7 studies), Duke University (4 studies), Brown University (5 studies), New York University (2 studies), as well as several non-AMPATH Consortium member institutions (University of California – Riverside, Albert Einstein College of Medicine, University of Alabama, University of Washington, and Karolinska Institute, with each institution leading 1 study, respectively).

*Study characteristics*

Most research employed a prospective study design (72%), while 18% of studies were cross-sectional and 8% were retrospective. Most studies took place in a clinical setting (57%), although an increasing number of studies were also based in the community, with 31% reporting that their study's primary setting was both clinic and community and 8% of reporting that their study was entirely community-based.

*Geographic distribution of study activities*

Over half of studies (54%) had activities at Moi Teaching and Referral Hospital (MTRH) or in other parts of Uasin Gishu County (47%), however, many studies reported activities in other Counties illustrating the reach of AMPATH Research Program activities across many parts of western Kenya. Among the most frequently cited study locations outside of Uasin Gishu included Trans Nzoia County (39% of studies), Bungoma County (38%), Busia County (33%), Kakamega County (15%), Nandi County (15%), and Kisumu County (13%), among others.

*Study status*

The majority of studies were either still open to enrollment and with participants receiving research-related intervention or follow up (41% of studies) or ongoing but in data analysis only (33%). There were a number of studies (15%) that reported study activities had not yet begun.

## Appendix - (*see AMPATH Research and Training Extramural Grants Table, Bibliography, and Study Reports*)

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# Appendix A. AMPATH Research and Training Extramural Grants Table, 2020

| Title | PIs | Prime | Sponsor | Amount (USD)* | Project Dates | Link |
|---|---|---|---|---|---|---|
| A case study of integrated delivery of selected non-communicable diseases in Kenya | Jemima Kamano | Moi Teaching and Referral Hospital | World Bank | 775,000 | 2/1/2018 - 3/31/2021 | Click here. |
| Addressing HIV Drug Resistance Research Gaps in a Cohort of Perinatally Infected Kenyan Children and Adolescents | Rami Kantor, Winstone Nyandiko, Rachel Vreeman | Miriam Hospital | NIAID | 967,487 | 6/27/2019 - 5/31/2024 | Click here. |
| Addressing HIV Drug Resistance Research Gaps in a Cohort of Perinatally Infected Kenyan Children and Adolescents [Supplement: Addressing Bioethical Research Gaps with Young People Living with HIV in Kenya] | Rami Kantor, Winstone Nyandiko, Rachel Vreeman | Miriam Hospital | NIAID | 166,607 | 6/27/2019 - 5/31/2024 | Click here. |
| BREATHER Plus - A randomised open-label 3-arm, 96-week trial evaluating the efficacy, safety and acceptability of weekends off dolutegravir-based antiretroviral therapy (ART) and monthly long-acting injectable ART compared to daily dolutegravir-based ART in virologically suppressed HIV-infected children and adolescents in sub-Saharan Africa | Abraham Siika | Baylor College of Medicine Children's Foundation - Uganda | European & Developing Countries Clinical Trials Partnership (EDCTP2) | 154,635 | 1/1/2020 - 12/31/2025 | Click here. |
| Brown/Moi Training Program for the Prevention of HIV related Cervical Cancer | Susan Cu-Uvin, Omenge Orang'u | Brown University | FIC / NCI | 300,572 | 4/16/2019 - 3/31/2024 | Click here. |
| Brown/Moi Training Program for the Prevention of HIV related Cervical Cancer – Supplement 1 | Susan Cu-Uvin | Brown University | FIC / NCI | 75,000 | 4/19/2019 - 3/31/2024 | Click here. |

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| Developing an Instrument to Assess Adolescent Risk for Disengagement from HIV Care | Leslie Enane | Indiana University | NICHD | 156,739 | 8/1/2018 - 7/31/2023 | Click here. |
| East Africa International Epidemiologic Databases to Evaluate AIDS (IeDEA) Regional Consortium | Kara Wools-Kaloustian, Constantin Yiannoutsos | Indiana University | NIAID | 3,826,050 (includes non-AMPATH sites) | 8/5/2006 - 7/31/2021 | Click here. |
| East Africa International Epidemiologic Databases to Evaluate AIDS (IeDEA) Regional Consortium – Supplement 1 | Kara Wools-Kaloustian, Constantin Yiannoutsos | Indiana University | NIAID | 150,000 | 8/5/2006 - 7/31/2021 | Click here. |
| Estimating the Cascade of HIV Care Under Incomplete Outcome Ascertainment | Giorgos Bakoyannis, Lameck Diero | Indiana University | NIAID | 196,875 | 6/17/2019 - 5/31/2021 | Click here. |
| Feasibility and acceptability of Enhanced Patient Care (EPC) for adult HIV patients with unsuppressed viral loads in western Kenya | Juddy Wachira | Moi University | FIC | 110,641 | 9/15/2018 - 1/31/2023 | Click here. |
| Global Network for Women's and Children's Health Research | Edward Liechty, Sherri Bucher, Fabian Esamai | Indiana University | NICHD | 610,185 | 5/25/2013 - 5/31/2023 | Click here. |
| Harambee: Integrated Community-Based HIV/NCD Care & Microfinance Groups In Kenya | Omar Galarraga, Becky Genberg, Juddy Wachira | Brown University | NIMH | 500,816 | 7/5/2019 - 4/30/2024 | Click here. |
| HIV Drug Resistance, Monitoring and Transmission | Rami Kantor, Lameck Diero, Nathan Buziba | Miriam Hospital | NIAID | 138,943 | 3/1/2018 - 2/28/2023 | Click here. |
| Immune Exhaustion In Perinatal HIV Infection | Alka Khaitan | Indiana University | NICHD | 315,859 | 4/1/2020 - 3/31/2022 | Click here. |
| Improving the care cascade for HIV associated Kaposis Sarcoma in Sub-Saharan Africa | Esther Freeman, Naftali Busakhala | Massachusetts General Hospital | NIAID | 199,279 | 7/19/2018 - 6/30/2023 | Click here. |

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| Investigating interactions between efavirenz-based antiretroviral therapy and contraceptive implants | Rena Patel, Beatrice Jakait | Univesity of Washington | NIAID | 147,927 | 7/1/2015 - 6/3/2020 | Click here. |
| Malaria Chemoprevention in Children with Sickle Cell Anemia in Western Kenya | Steve Taylor, Festus Njuguna | Duke University | NHLBI | 518,962 | 6/1/2016 - 2/28/2022 | Click here. |
| Malaria diagnostic testing and conditional subsidies to target ACTs in the retail sector: the TESTsmART trial | Wendy Prudhomme-O'Meara | Duke University | NIAID | 894,519 | 9/14/2018 - 8/31/2023 | Click here. |
| Neurodevelopmental screening in children born to HIV-infected mothers in Kenya | Megan McHenry, Eren Oyungu | Indiana University | NIMH | 181,595 | 9/21/2018 - 8/31/2022 | Click here. |
| Once Bitten; A longitudinal, observational study of Succesful Malaria Parasite transmission events between humans and Mosquitos | Wendy Prudhomme-O'Meara, Steve Taylor, Andrew Obala | Duke University | NIAID | 600,701 | 7/16/2019 - 6/30/2024 | Click here. |
| PT4A (Peers and Technology For Adherence, Access, Accountability, and Analytics) | Rajesh Vedanthan, Sonak Pastakia, Benson Njuguna | New York University | NHLBI | 697,887 | 9/25/2020 - 8/31/2021 | Click here. |
| Smartphone-Based Diagnostic for HIV Self-Testing | Jacqueline Linnes, Ronald Tonui | Purdue University | NIAID | 370,285 | 8/6/2018 - 7/31/2021 | Click here. |
| Strengthening Referral Networks for Management of Hypertension Across the Health System (STRENGTHS) | Constantine Akwanalo, Jemima Kamano | Moi University | NHLBI | 321,760 | 9/1/2017 - 5/31/2022 | Click here. |
| The East Africa Consortium For HPV and Cervical Cancer In Women Living With HIV/AIDS | Patrick Loehrer, Darron Brown, Miriam Nakalembe, Omenge Orango | Indiana University | NCI | 995,284 | 9/7/2020 - 8/31/2025 | Click here. |
| Training in STIs and Infections of Global Health Significance | Kara Wools-Kaloustian | Indiana University | NIAID | 210,437 | 7/1/2001 - 8/31/2021 | Click here. |

# Appendix B. Bibliography

The following bibliography includes AMPATH research publications that were published in 2020. A complete bibliography of AMPATH research publications published since 1989 along with full text articles is available online through the AMPATH Research Member Access Portal.


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# Appendix C. Study Reports

The following study reports provide summaries of active AMPATH research projects at the end of 2020. Study reports 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 based on the study title.

| | |
|---|---|
| **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)** | US National Institutes of Health |
| **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 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) |

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|---|---|
| **Collaborator(s)** | Lameck Diero (Moi University), Constantin Yiannoustos (Indiana University School of Medicine), Aggrey Sameere (College of Health Sciences Makerere University), et al. |
| **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 -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
| | |
| **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 |
| **Project Period** | 7/1/2020 - 6/30/2023 |
| **Sponsor(s)** | TONIX Pharmaceuticals |
| **Status** | Not started -- Study activities have not begun. |
| | |
| **Study Title** | A prospective cohort among people living with HIV (IeDEA-SRN) |

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| **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 |
| **Status** | Not started -- Study activities have not begun. |

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|---|---|
| **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)** | National Institute of Allergy and Infectious Diseases (NIAID) |

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| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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)** | National Institute of Allergy and Infectious Diseases (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 |

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| **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, 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, Marakwet, Homa Bay, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu, West Pokot |

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| **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. |
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| **Study Title** | Addressing bioethical research gaps in research with young people living with HV 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)** | National Institute of Health (NIH) |
| **Status** | Not started -- Study activities have not begun. |
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| **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 |

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| | '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)** | National Institute of Health |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **Study Title** | APPROACH |
| **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. |
| **Site(s)** | Moi Teaching and Referral Hospital |
| **Project Period** | 1/1/2021 - 12/31/2021 |
| **Sponsor(s)** | Duke Global Health |
| **Status** | Not started -- Study activities have not begun. |
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| **Study Title** | Bridging Income Generation with Group Integrated Care (BIGPIC) |
| **Principal Investigator(s)** | Rajesh Vedanthan (New York University) |
| **Collaborator(s)** | Jemima Kamano (Moi University School of Medicine), Violet Naanyu (Moi University School of Medicine), 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 |

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| | 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. |
| **Site(s)** | Busia, Kisumu, Trans Nzoia, Uasin Gishu |
| **Project Period** | 4/1/2015 - 1/31/2022 |
| **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. |
| **Site(s)** | Busia, Trans Nzoia, Uasin Gishu |

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| **Project Period** | 11/4/2019 - ongoing |
| **Sponsor(s)** | Clinical and Translational Science Institute (CTSI) - Indiana University |
| **Status** | Ongoing |
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| **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. |
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| **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. |

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| **Site(s)** | Bungoma, Kisumu, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, Uasin Gishu |
| **Project Period** | 10/25/2018 - ongoing |
| **Sponsor(s)** | NIH |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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, Marakwet, Kakamega, Nandi, Trans Nzoia, Uasin Gishu |
| **Project Period** | 1/1/2014 - ongoing |
| **Sponsor(s)** | None |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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 |

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| | 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 - 7/31/2021 |
| **Sponsor(s)** | NIH |
| **Status** | Ongoing -- In addition to data analysis, other project-related activities including trainings, sensitization workshop, and project evaluation and dissemination are planned for this year. |
| | |
| **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 |

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| **Project Period** | 8/1/2018 - ongoing |
| **Sponsor(s)** | NIH/NIAID |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **Study Title** | EA-IeDEA Main |
| **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 |
| **Status** | Ongoing-- Data continues to be generated through POC from the AMPATH care clinics; data from EMR from FACES and from sites in Uganda and Tanzania |
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| **Study Title** | EA-IeDEA Networks In Kenya |
| **Principal Investigator(s)** | Jennifer Syvertsen (University of California, Riverside, USA) |
| **Collaborator(s)** | Lukoye Atwoli (Moi 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 |

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| | 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 |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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 |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |

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

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| **Study Title** | EA-IeDEA Syndemics |
| **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- |

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| | 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 |
| **Status** | Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up. |
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| **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)** | The U.S. National Institutes of Health/ National Heart, Lung and Blood Institute (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. |
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| **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) |

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| **Collaborator(s)** | Astrid Christoffersen (University of Toronto), Sonak Pastakia (Purdue University), Wycliffe Kosgei (MTRH) |
| **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)** | Medical Reserach Counsel-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. |
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| **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 and 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. |
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| **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 -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up. |
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| **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 |

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| | (≥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. |
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| **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. |
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| **Study Title** | HIV-related outcomes at the AMPATH Drug Resistance Clinic in Kenya |

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| **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. |

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| **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** | Not started -- Study activities have not begun. |

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| **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, Marakwet, Moi Teaching and Referral Hospital |
| **Project Period** | 10/1/2019 - 9/30/2022 |
| **Sponsor(s)** | Pfizer Foundation |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |

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| **Study Title** | Improving Estimates of Mother-to-Child Transmission in Western Kenya: A Mixed Methods Prospective Cohort Study - Plus (IeDEA PMTCT Plus study) |
| **Principal Investigator(s)** | John Humphrey (Indiana University) |
| **Collaborator(s)** | John Humphrey, 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. |
| **Site(s)** | Busia, Trans Nzoia, Uasin Gishu |

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| **Project Period** | 2/1/2021 - 2/1/2022 |
| **Sponsor(s)** | Internal |
| **Status** | Not started -- Study activities have not begun. |
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| **Study Title** | Making Inroads to Strengthen the Health of Adolescents |
| **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. |
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| **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 |

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| | 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 -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **Study Title** | Measuring adverse pregnancy and newborn outcomes (MANGO); An IeDEA collaboration study |
| **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 |
| **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 |

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| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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)** | NIMH |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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 |

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| | 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)** | - |
| **Project Period** | - |
| **Sponsor(s)** | None |
| **Status** | n/a |
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| **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. |
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| **Study Title** | NEUROPSYCHIATRIC GENETICS OF AFRICAN POPULATIONS - PSYCHOSIS (NEUROGAP-P) |

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| **Principal Investigator(s)** | Lukoye Atwoli (Moi 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 |
| **Site(s)** | Bungoma, Marakwet, Kakamega, Moi Teaching and Referral Hospital, Nandi, Trans Nzoia, West Pokot |
| **Project Period** | 7/1/2017 - 6/30/2021 |
| **Sponsor(s)** | Broad Institute of MIT & Harvard |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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 |

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| **Status** | Data cleaning stage |
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| **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. |
| **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. |
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| **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) |

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| **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)** | NIMH |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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) |

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| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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 -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up. |
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| **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 |

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| | 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 -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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)** | Fabian Esamai (Moi University) |
| **Collaborator(s)** | Paul Nyongesa (Moi University), Edward Liechty (Indiana University), Sheri Bucher (Indiana University) |
| **Study Type** | Randomised clinical trial |
| **Specific Aim(s)** | To study the effect of use of Azithromycin during labour on maternal and neonatal infection postpartum |
| **Site(s)** | Bungoma, Busia, Kakamega |
| **Project Period** | 9/1/2020 - 9/30/2023 |
| **Sponsor(s)** | NICHD |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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 |

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| | routine treatment conditions in HIV infected infants and young children who cannot swallow tablets.<br><br>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** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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 (MTRHl), 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. |

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| **Site(s)** | Bungoma, Trans Nzoia, Uasin Gishu |
| **Project Period** | 9/25/2020 - 8/31/2021 |
| **Sponsor(s)** | NHLBI |
| **Status** | Not started -- Study activities have not begun. |
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| **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)** | National Institute of Mental Health |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **Study Title** | Spatial scales of Plasmodium falciparum generations; implications for elimination |
| **Principal Investigator(s)** | Andrew Obala (Moi University) |

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| **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)** | National Institute of Allergy and Infectious Diseases (NIAID) |
| **Status** | Ongoing -- Follow Up Continues. Enrollment has finished but participants are still receiving research-related intervention, interaction, or follow up. |
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| **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)** | None |
| **Status** | Not started -- Study activities have not begun. |

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| **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)** | The National Heart Lung and Blood Institute (NHLBI) Grant Number: U01HL138636 |
| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |

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| **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 |

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| | 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. |
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| **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)** | Homa Bay |
| **Project Period** | 12/1/2020 - 12/1/2022 |
| **Sponsor(s)** | None |

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| **Status** | Ongoing -- Open to Enrollment. Participants are being enrolled and receiving research-related intervention, interaction, or follow up. |
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| **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** | Not started -- Study activities have not begun. |
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| **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 |

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| | 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 |
| **Status** | Ongoing -- Data Analysis Only. Participants have completed all research-related intervention, interaction, and follow up. Research activities are limited to data analysis. |
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| **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), Festus Njuguna (Moi University) |
| **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)** | - |
| **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. |