
USAID | AMPATH

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PARTNERSHIP

# SEMI-ANNUAL RESEARCH REPORT
## July-December 2011

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| **Project Name:** | A pharmacokinetic Pharmacogenetic Study of HIV-positive Patients on Combined Anti-Retroviral Therapy With Kaposi's Sarcoma Being Treated With Single Agent Oral Etoposide. | | |
| **Investigator(s):** | R. M. Strother, P.J. Loehrer, N. Busakhala, E. Njiru | | |
| **Start Date:** | 3/31/2010 | **Project End Date:** | 3/14/2012 |
| **Site(s):** | MTRH, Chulaimbo, Webuye Hospital, Kitale, Busia, Port Victoria | | |
| **Project Description:** | The study explores the influence of genetic variability in drug metabolizing and transport enzymes on the pharmacokinetic parameters of etoposide on patients with cytological/histological confirmation of Kaposi's Sarcoma and should have been on cART for at least 8 weeks prior to enrollment. | | |
| **Update:** | The study has enrolled 22 males and 7 females totaling 29/30. These were all from Oncology clinic sites with Chulaimbo having the highest number of 11, Busia 7, Kitale 4, MTRH 4 and Webuye 3. Challenges focus mainly on recruitment. Some patients come to the clinic while very sick, with visceral Kaposi's Sarcoma. Recruitment process takes a minimum of 8 hours to collect samples. Some patients consider it too long. Some patients have problems with transport (fare) when needed to come back to the clinic for follow up. | | |
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| **Project Name:** | A Phase I/II Dose-Finding Study of High-Dose Fluconazole Treatment in AIDS-Associated Cryptococcal Meningitis. A5225/HiFLAC Protocol Version 1.0 | | |
| **Investigator(s):** | J. Sidle, A. M. Siika, K. Wools-Kaloustian, D. Lagat, D. Owino Ongo'r | | |
| **Start Date:** | 5/18/2011 | **Project End Date:** | 12/31/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | A5225/HiFLAC is a phase I/II dose escalation and validation study of the safety, tolerability, and therapeutic effect of an induction-consolidation strategy of high-dose fluconazole alone for the treatment of cryptococcal meningitis (CM) in HIV-infected participants. The study will proceed in two stages. In Stage 1, Dose Escalation, up to three induction doses of fluconazole will be tested in sequentially enrolled cohorts. Stage 2, Dose Validation, will not open until the maximum tolerated dose (MTD) of fluconazole has been identified in Stage 1. In Stage 2, induction doses of fluconazole that are found to be safe in Stage 1 will be tested in simultaneously enrolled cohorts. In each stage, participants will be randomized at entry into Step 1. Over the course of the study, participants will register to subsequents steps (Steps 2-4) based on their initial randomization and/or their response to treatment. The study steps are:<br>• Step 1: Induction therapy with either high dose fluconazole or ampho B<br>• Step 2: Induction following early ampho B intolerance (only for participants randomized to ampho B treatment in Step 1) (fluconazole at 400-800 mg daily)<br>• Step 3: Consolidation therapy (fluconazole 400 mg daily)<br>• Step 4: Maintenance therapy (fluconazole 200 mg daily) | | |
| **Update:** | Currently 9 participants have been enrolled. Five into cohort 1 ( Fluconazole 1200mg) and 4 into cohort 2 (Fluconazole 1600mg). | | |
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| **Project Name:** | A Population Based Study of Hypertension, Diabetes and Target Organ Damage in Western Kenya | | |
| **Investigator(s):** | E. Velazquez, S. Kimaiyo, C. Akwanalo, G. S Bloomfield, M. Maghasi, J. Hogan, C. Binanay | | |
| **Start Date:** | 12/15/2011 | **Project End Date:** | 12/3/2012 |
| **Site(s):** | Mosoriot | | |
| **Project Description:** | Hypertension is one of the increasingly important health challenges facing the African continent and yet data on true community prevalence of hypertension in sub-Saharan Africa (SSA) is limited. The prevalence of hypertension in truly rural populations was said to be a rarity but this must have changed because of adoption of Western lifestyle. Recent studies indicate that the prevalence of hypertension and its clinically important outcomes is steadily increasing in SSA, | | |

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| | more in the urban compared to semi urban and rural communities. Similarly, the prevalence of diabetes mellitus is increasing and its presence augments the severity of renal and cardiac disease caused by hypertension. This study will be conducted in two phases. Phase one of the study will be a cross sectional study which will be conducted on persons aged 18yrs or older from Mutwot location, Kosirai division, to assess for hypertension and diabetes mellitus. In the second phase of the study those individuals who are newly diagnosed with hypertension will be assessed for target organ damage and compared to controls. | | |
| **Update:** | This study has been approved by all IRBs. We are waiting for approval from the sponsor before recruitment commences. | | |
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| **Project Name:** | A Retrospective Analysis of Pregnancy Outcomes of HIV-infected Women Enrolled in the AMPATH Program | | |
| **Investigator(s):** | A. Bell, E. Were, B. Musick, K. Lane, C. Shen, P. Akhaabi, J. Hogan, K. Wools-Kaloustian | | |
| **Start Date:** | 3/1/2006 | **Project End Date:** | 3/31/2012 |
| **Site(s):** | All Sites | | |
| **Project Description:** | This is a retrospective analysis of pregnancy outcomes of HIV-infected women enrolled in the AMPATH program from January 2006 to March 2009. Per protocol, pregnant women with CD4 < 200 begin cART immediately and those with a CD4 ≥ 200 start at 28 weeks gestation. The pregnancy outcomes are being compared between women pregnant at program enrollment (BE) and those who became pregnant after enrollment (AE). The specific hypotheses include:<br>1. Women who are already enrolled in the AMPATH program at the time of pregnancy diagnosis are more likely to initiate ART sooner (at a lower gestational age) than those who are not in the program prior to pregnancy diagnosis.<br>2. Women who are already enrolled in AMPATH at the time of pregnancy diagnosis are less likely to give birth to an HIV-infected baby than those who are not enrolled in the program prior to pregnancy diagnosis.<br>3. Women who are already enrolled in AMPATH at the time of pregnancy diagnosis will have better retention and adherence rates than those who are not enrolled in the program prior to pregnancy diagnosis.<br>4. Women who are already enrolled in the AMPATH program will have a lower rate of stillbirth and infant loss than those who are not enrolled in the program prior to pregnancy diagnosis. | | |
| **Update:** | The analysis is underway. The preliminary findings will be presented on January 10 at the 2nd International Conference on HIV and Women in Bethesda, Maryland. | | |
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| **Project Name:** | A Stage 2 Cognitive Behavioral Trial, Reduce Alcohol First in Kenya Intervention (RAFIKI) | | |
| **Investigator(s):** | R. Papas, B. Gakinya, J. Sidle, J. Baliddawa, S. Maisto, S. Martino, K. Carroll, J. Hogan | | |
| **Start Date:** | 11/1/2011 | **Project End Date:** | 8/31/2016 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited formal education and little or no relevant professional experience. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g., clinical officers, traditional birth attendants and peer counselors) are trained. | | |
| **Update:** | In November-December 2011, the project began start up activities in Kenya, including opening a research office, hiring counselors and RAs, beginning training and developing systems and standards of operation to be used during the study. Materials have been developed and RAs | | |

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| | have been trained to begin recruitment for Focus Group Discussions to be completed in January 2012 and February 2012. Recruitment for the trial will begin in May or June 2012. | | |
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| **Project Name:** | A5221/STRIDE 'A Strategy Study of immediate versus Deferred Initiation of Antiretroviral Therapy for HIV infected persons Treated for TB with CD4<200 cells/mm3' Version 1.0 dated 14 March, 2009. | | |
| **Investigator(s):** | J. Sidle, A. M. Siika, F. Some | | |
| **Start Date:** | 1/12/2009 | **Project End Date:** | 8/10/2010 |
| **Site(s):** | MTRH | | |
| **Project Description:** | A5221 is a randomized, open-label study to determine whether the strategy of immediate [within approximately 2 weeks after starting treatment for tuberculosis (TB)] versus deferred (8-12 weeks after start of TB treatment) initiation of antiretroviral therapy (ART) reduces mortality and AIDS-defining events in participants being treated for TB. There will be two steps and two arms in this study. All participants will enter Step 1 within 2 weeks after starting therapy for TB and be randomized either to receive ART within 3 days after enrollment ('immediate' group; Arm A) or to have ART deferred ('deferred' group; Arm B). Participants in the deferred group will enter into Step 2 8-12 weeks after starting TB therapy, when they are about to initiate ART. | | |
| **Update:** | The study is closed to follow up and data analysis is ongoing. Publication: 1. Diane Havlir et al; 'Timing of Antiretroviral Therapy for HIV-1 infection and TB' N Eng J Med 365: 16, October 20, 2011, 1482-1491 | | |
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| **Project Name:** | A5221/STRIDE 'A Strategy Study of immediate versus Deferred Initiation of Antiretroviral Therapy for HIV infected persons Treated for TB with CD4<200 cells/mm3' Version 1.0 dated 14 March, 2009. | | |
| **Investigator(s):** | J. Sidle, A. M. Siika, F. Some | | |
| **Start Date:** | 1/12/2009 | **Project End Date:** | 8/10/2011 |
| **Site(s):** | MTRH | | |
| **Project Description:** | A5221 is a randomized, open-label study to determine whether the strategy of immediate [within approximately 2 weeks after starting treatment for tuberculosis (TB)] versus deferred (8-12 weeks after start of TB treatment) initiation of antiretroviral therapy (ART) reduces mortality and AIDS-defining events in participants being treated for TB. There will be two steps and two arms in this study. All participants will enter Step 1 within 2 weeks after starting therapy for TB and be randomized either to receive ART within 3 days after enrollment ('immediate' group; Arm A) or to have ART deferred ('deferred' group; Arm B). Participants in the deferred group will enter into Step 2 8-12 weeks after starting TB therapy, when they are about to initiate ART. | | |
| **Update:** | The study is closed to follow up and data analysis is ongoing.<br>Publication: Diane Havlir et al; 'Timing of Antiretroviral Therapy for HIV-1 infection and TB' N Eng J Med 365: 16, October 20, 2011, 1482-1491 | | |
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| **Project Name:** | Acceptance of HIV Testing for Children Identified Through a Program of Voluntary Home-Based HIV Counseling and Testing in Western Kenya | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, P. Braitstein, M. Were, S. Wiehe | | |
| **Start Date:** | 1/1/2009 | **Project End Date:** | 12/31/2012 |
| **Site(s):** | Turbo, Burnt Forest, Webuye Hospital | | |
| **Project Description:** | Analyses of rates of acceptance of pediatric HIV testing and prevalence of pediatric HIV determined through home-based counseling and testing. | | |
| **Update:** | Initially conducted a multivariable analysis of HCT data from Turbo and assessed which factors are associated with pediatric testing uptake. These findings were published in Journal of | | |

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| | Acquired Immune Deficiency Syndromes in October of 2010. Planning additional analyses with data being collected prospectively on barriers to acceptance of pediatric testing in HCT and data from Webuye and other sites to assess the variance in pediatric testing acceptance in HCT. | | |
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| **Project Name:** | Adherence to ART among HIV-infected children in East Africa | | |
| **Investigator(s):** | R. Vreeman, S. Ayaya, W. Nyandiko, B. Musick, C. Yiannoutsos, D. Nash, S. Wiehe | | |
| **Start Date:** | 1/1/2011 | **Project End Date:** | 6/30/2012 |
| **Site(s):** | Sio Port, 8 IeDEA clinical sites in Kenya, Uganda and Tanzania | | |
| **Project Description:** | The objective of this analysis was to describe pediatric ART adherence within the clinic sites that are part of the East Africa IeDEA consortium and to investigate factors associated with increased risk of ART nonadherence. This was a retrospective study from eight IeDEA clinical sites in Kenya, Uganda and Tanzania. Patients included were seen between 01/2002-01/2009, <13 years of age, HIV-infected, had initiated ART, and had at least one ART adherence measure. | | |
| **Update:** | Among 3,308 children, 51.9% were male. Mean age at ART initiation was 5.4 years (SD 3.4). 88.2% of children had good mean adherence (greater than or equal to 90%), ranging from 75.7%-100% by site. Sites using pill counts to estimate adherence had the highest adherence rates. Describing adherence by time on ART, nonadherence was highest in the first 3 months on ART (11.3% nonadherence) and for after 12 months on ART (9.9-12.1% nonadherence). The abstract for this project was presented at three meetings: IeDEA global meeting (02/2011); 3rd International Workshop in Pediatric HIV in Rome, Italy (07/2011); and the International AIDS Society (07/2011). The manuscript is currently underway. | | |
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| **Project Name:** | Anticoagulation Project | | |
| **Investigator(s):** | S. Pastakia, I. Manji, M. N. Ouma, R. Karwa, C. Akwanalo, C. Saina, E. Schellhase, M. Miller, M. Maina | | |
| **Start Date:** | 12/1/2008 | **Project End Date:** | 12/31/2012 |
| **Site(s):** | MTRH, Webuye Hospital | | |
| **Project Description:** | A comprehensive pharmacist run anticoagulation care management system customized to a resource constrained setting has been created and implemented. The primary interventional element of this program is the creation of an organized system for INR monitoring of patients requiring anticoagulation with warfarin. | | |
| **Update:** | In October, an article on the performance outcomes of the program was published in the Journal of Thrombosis and Haemostasis: Manji I, Pastakia SD, Do AN, Ouma MN, Schellhase E, Karwa R, Miller ML, Saina C, Akwanalo C. Performance outcomes of a pharmacist-managed anticoagulation clinic in the rural, resource-constrained setting of Eldoret, Kenya. J Thromb Haemost 2011; 9: 2215-20. This analysis has demonstrated that the anticoagulation monitoring service is able to provide care similar to clinics in a resource rich setting. Another paper describing the interaction between warfarin and rifampicin is currently under development. The program intends to expand to other sites outside of MTRH in the next year. | | |
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| **Project Name:** | ART Treatment Failure and Drug Resistance in HIV-Infected Patients on Second Line Regimens in Western Kenya | | |
| **Investigator(s):** | R. Kantor, L. Diero, N. Buziba | | |
| **Start Date:** | 11/30/2011 | **Project End Date:** | 9/1/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | ART treatment failure and drug resistance in HIV-infected patients on second line regimens in Western Kenya studies the prevalence and implications of 2nd line failure in a diverse HIV in resource limited settings. It aims at providing data for future design of regimens and | | |

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| | identification of treatment failure and drug resistance. Specific aims are:- (1)to determine prevalence and correlates of second line virological failures (2) to study research patterns and implications of drug resistance (3) to examine predictors of drug resistance evolution. The study enrolls patients who are HIV positive, have been on second line medicine for at least six months, over 18 years of age and willing to consent. On the first visit, participants are drawn blood for CD4 and Viral load tests and on the second visit only participants with detectable viral loads will be followed for drug resistance test. | | |
| **Update:** | No major events have taken place since we started. Intensive enrollment has been going on since July 2011. | | |
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| **Project Name:** | Assessing Impact of Kenya Post-Election Crisis on Children in AMPATH | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, S. Wiehe, R. Smith Yoder, S. Ayaya, P. Gisore, C. Tenge, P. Braitstein | | |
| **Start Date:** | 1/1/2008 | **Project End Date:** | 12/31/2011 |
| **Site(s):** | MTRH, Mosoriot, Turbo, Burnt Forest, Amukura, Naitiri, Chulaimbo, Webuye Hospital, Teso, Kitale, Mt. Elgon, Iten, Kabarnet, Busia, Port Victoria, Khunyangu, Uasin Gishu, Moi's Bridge, Moi University, Soy, Nambale, Mukhobola, Ziwa, Bumalaa, Sio Port | | |
| **Project Description:** | This project involves several retrospective analyses of the medical records of pediatric HIV-infected patients in AMPATH to determine the degree of changes in clinic adherence and medication adherence following the post-election crisis in Kenya and the factors associated with non- adherence. It also involves a qualitative component with key informant interviews with pediatric healthcare providers regarding clinic and medication adherence in the post-crisis time period. | | |
| **Update:** | We completed two retrospective analyses of the de-identified medical records of pediatric HIV-infected patients in the AMPATH program in western Kenya to determine changes in antiretroviral therapy adherence and clinic adherence following the post-election crisis in Kenya and the factors associated with their return to clinic or with adherence to medications. One analysis focused on the immediate post-crisis period (through April 2008), and the second looking longitudinally through December 2008. We also completed nine key informant interviews with healthcare providers in the AMPATH system in Kenya in order to offer complementary information on what factors constituted barriers or facilitators for returning to clinic or taking the antiretroviral medicines during this time. Findings were published in Conflict and Health, entitled 'Impact of the Kenya post-election crisis on clinic attendance and medication adherence' (2009 April 4:3(1):5.) Findings of the longitudinal analyses will be presented at the 2011 International AIDS Society meeting as a poster presentation in Rome, Italy. Manuscript was published in Journal of Acquired Immune Deficiency Sydroms (JAIDS) in October of 2011 (Authors and title: Yoder RB, Nyandiko WM, Vreeman RC, Ayaya SO, Gisore PO, Braitstein P, Wiehe SE. 'Long-term impact of the Kenya post-election crisis on clinic attendance and medication adherence for HIV-infected children in western Kenya') | | |
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| **Project Name:** | Assessment and Treatment of Pain at Moi Teaching and Referral Hospital | | |
| **Investigator(s):** | G. Gramelspacher, C. Owino, K. Huang, R. Vreeman, F. Njuguna, R. M. Strother, M. Hagembe | | |
| **Start Date:** | 3/26/2011 | **Project End Date:** | 8/1/2011 |
| **Site(s):** | MTRH | | |
| **Project Description:** | Pain assessment is not routinely conducted at Moi Teaching and Referral Hospital (MTRH) in Eldoret, Kenya, and underutilization of analgesics, particularly strong opioids, remains a significant problem. The objectives of this study are to assess the prevalence and intensity of pain in patients at MTRH, and to describe the utilization of pain medications in this setting. The rationale for measuring pain and pain treatment in hospitalized patients is to develop a baseline understanding of the extent of pain in this population and of whether that pain is being | | |

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| | recognized and treated by clinicians. In this study, will assess pain in pediatric and adult inpatients at MTRH using two well-established pain scales, the Numerical Rating Scale and the Faces Pain Scale-Revised, and gather pertinent patient data such as admission diagnosis and pain medications received. In our analysis, we will describe the prevalence and intensity of pain among patients surveyed, report any differences in pain levels among subcategories of patients, and determine whether pain is being adequately treated using the Pain Management Index. We expect to find that inpatients at MTRH experience a considerable amount of untreated or undertreated pain. | | |
| **Update:** | We completed Phase 2 of the study and finished recruiting the remaining 30 of 385 patients. We are now in the process of data analysis and publication. | | |
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| **Project Name:** | Biomarkers Of Vincristine Peripheral Neuropathy In Kenyan Children With Cancer | | |
| **Investigator(s):** | J. Rennberger, F. Njuguna, J. Skiles | | |
| **Start Date:** | 6/1/2011 | **Project End Date:** | 11/1/2011 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This project is aimed at assessing peripheral neuropathy among children with various malignancies and who are receiving vincristine as part of their therapy | | |
| **Update:** | We have finished the recruitment of the study participants and samples taken for genetic analysis have been shipped to the USA. | | |
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| **Project Name:** | Biomarkers of Vincristine Toxicity in Kenyan Children | | |
| **Investigator(s):** | J. Renbarger, F. Njuguna, J. Skiles, G. Olbara | | |
| **Start Date:** | 6/27/2011 | **Project End Date:** | 7/1/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | We are evaluating biomarkers of vincristine toxicity in any HIV negative child who is receiving vincristine as part of their cancer care. We are specifically collecting specimens of blood and saliva to assess the pharmacokinetics and pharmacogenetics of vincristine metabolism and toxicity. We are additionally conducting detailed serial neuropathy exams on subjects enrolled to assess for toxicity. | | |
| **Update:** | Participant accrual is going well. We have not really encountered any significant problems with the study to date. We have enrolled 78 patients to date and are in the process of performing an interim analysis to determine if we need to recruit more patients. No presentations or publications have come from this study yet given that we are just beginning interim analysis. We will continue to follow those patients who have already enrolled by doing serial neuropathy assessments at each visit when they come for chemotherapy. | | |
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| **Project Name:** | Building Competencies through Bilateral International Exchanges-Using Qualitative Methods to Measure the Impact on Pediatric Residents from Host and Visiting Countries in Professionalism, Communication and Systems-Based Care | | |
| **Investigator(s):** | D. Litzelman, S. Ayaya, R. Umoren, J. Woodward, R. Vreeman, E. Liechty, D. Lorant, S. Stelzner, M. Palmer | | |
| **Start Date:** | 11/27/2009 | **Project End Date:** | 6/30/2012 |
| **Site(s):** | MTRH, IU, UAEH | | |
| **Project Description:** | Focus groups are being held to assess the impact of resident exchange project on participating residents from Indiana University School of Medicine (IUSOM), Moi University School of Medicine (MUSM), and Universidad Autonoma del Estado de Hidalgo Health Sciences Campus (UAEH) particularly related competencies in Professionalism, communication, Systems Based | | |

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| | Practice, and Practice Based learning and improvement. | | |
| **Update:** | Ongoing recruitment of study participants continues with the goal of comparing experiences between the participating foreign institutions.<br>*Poster Presentation* The IIMPS Factors: Residents' Perception of the Factors Influencing their Acquisition of ACGME Competencies through a Global Health Elective RA Umoren, ME Riner, M Palmer, JF Woodward, RC Vreeman, S Stelzner, DE Lorant, SO Ayaya, EA Liechty, and DK Litzelman. 2011 Global Health Conference co-sponsored by the Global Health Education Consortium, Canadian Society for International Health and the Consortium of Universities for Global Health, Montreal, Canada - November 13-15, 2011<br>*Papers under review* 1. Umoren R, Einterz R, Litzelman D, Pettigrew R, Ayaya SO, Liechty EA. Reciprocity in Global Health Partnerships: Hosting International Exchange Physicians. 2. Umoren, RA, Woodward, J, Vreeman, RC, Palmer MM, Stelzner, S, Lorant, DE, Riner, ME, Liechty, EA, Litzelman D. Can Core ACGME Competencies Be Learned Through Global Health Experiences? | | |
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| **Project Name:** | Cervical Cancer See and Treat: How Best to Follow-Up | | |
| **Investigator(s):** | S. Cu-Uvin, E. O'rango, H. Mabeya, S. Washington | | |
| **Start Date:** | 9/1/2011 | **Project End Date:** | 8/31/2012 |
| **Site(s):** | MTRH, Mosoriot, Turbo | | |
| **Project Description:** | This is a cross sectional study involving 660 HIV-infected women attending 3 AMPATH-CCSPP (Cervical cancer Screening and Prevention Program) sites who have undergone VIA and cryotherapy >6 months for cervical dysplasia. Demographic information as well as a full medical history will be obtained. They will undergo a gynecologic examination. Women with suspected frank cervical cancer or current genital tract infection will not be enrolled and will be referred for standard of care. Women with genital tract infection will undergo syndromic treatment and will be eligible to be enrolled 3 weeks after treatment if they have cleared the infection. During the gyn exam, the following will be done for all study participants: VIA, conventional Pap smear, endocervical cytobrush for HPV typing. All women with positive VIA result will undergo colposcopy and biopsy at the next available colpo/biopsy clinic day. Those with negative VIA result will return in 4-6 weeks to receive the results of their Pap smear and HPV typing. If either the Pap smear or HPV typing is abnormal, they will undergo colposcopy with biopsy on the next available colpo/biopsy clinic day. Women with negative VIA , PAP smear and HPV will follow standard of 8 care that is annual screening with VIA. Histological diagnosis will be the gold standard. Women will be asked several questions regarding their experience. | | |
| **Update:** | The project has put up an amendment for inclusion of one more consultant as a co-investigator. Study recruitment started officially on 14th September 2011 6 months after cryotherapy as per the study protocol. The study has currently enrolled 14 participants (2.12%) without any reported incidence. The Main challenge being low numbers recorded who meet cryotherapy criteria across the three study sites. The study staff were taken through study initiation training on 13th and 14th of November 2011. | | |
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| **Project Name:** | Comparison of Protein-Energy Malnutrition and *P. falciparum* Malaria levels in AMPATH and Non- AMPATH COBES centres in Western Kenya | | |
| **Investigator(s):** | K. Taylor, A. Kwena, M. A. McDowell, S. Mining, J. Wakhisi | | |
| **Start Date:** | 8/1/2011 | **Project End Date:** | 8/1/2013 |
| **Site(s):** | Mosoriot, Turbo, Amukura, Naitiri, Chulaimbo, Nambale | | |
| **Project Description:** | There are a number of AMPATH Centres that are also used for Community-Based Education and Service (COBES) student placement by the Moi University School of Medicine on an annual basis. The main objective of the proposed study is to compare the levels of protein energy malnutrition and malaria in these centres using non- AMPATH COBES centres as controls. This may elucidate | | |

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| | the role played by AMPATH in the study areas. | | |
| **Update:** | Stunting, Wasting and Underweight appeared to be lower in AMPATH centres when compared to non-AMPATH centres. Only results from 2 AMPATH centres (Mosoriot and Chulaimbo) were available for the analysis. Further data collection and analysis is hoped to be carried out in the next quarter in more centres to confirm the results and suggest possible reasons for the trends. The results reported here do not include P. Falciparum levels. | | |
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| **Project Name:** | Computerized Counseling to Promote Positive Prevention and HIV Health in Kenya (CARE+ Kenya) | | |
| **Investigator(s):** | A. Kurth, A. M. Siika, D. Ayuku, J. Baliddawa, J. D. Fortenberry, J. Sidle, K. Wools-Kaloustian, S. Braithwaite | | |
| **Start Date:** | 8/14/2009 | **Project End Date:** | 6/30/2013 |
| **Site(s):** | MTRH, Burnt Forest | | |
| **Project Description:** | Specific Aim 1: Adaptation. Adapt a theoretically driven computerized counseling intervention (CARE+_Kenya) for use in western Kenya. [1st 18 months]<br>• 2.1.A. Conduct interviews with up to 25 HIV-positive urban and up to 25 rural patients (n 50 males/females) of the Academic Model for the Prevention & Treatment of HIV/AIDS (AMPATH®) to understand HIV and computer training needs. Conduct two staff focus groups (n~16) to assess positive prevention and ART adherence support practices, beliefs about patient computer use and training needs.<br>• 2.1.B. Using above, modify intervention content; translate and record audio files into local Kiswahili. Adapt skill-building videos on 'positive health' (prevention, disclosure, ART adherence, reproductive health, etc.).<br>• 2.1.C. Conduct iterative software usability testing with 10 urban and 10 rural patients (n=20) and n=8 staff. Perform 3-day test-retest reliability assessment to establish psychometric performance of measures.<br>Specific Aim 2: RCT. Establish biological and behavioral efficacy of a longitudinal HIV computerized counseling intervention in Kenya ('CARE+_Kenya') [Months 18-42]<br>• 2.2.A. Longitudinal RCT in an urban and a rural clinic. Randomly assign HIV-positive adults with missed ART doses on self-report, pharmacy refill or pill counts; or unprotected sex in last 6 months, >1 partner in last year, or sexually transmitted infection (STI) in last 3 years; to intervention (n=125) or risk-assessment control (n=125) for baseline, 3, 6, and 9 month sessions. HIV transmission risk will be measured by self-reported unprotected sex with HIV-negative/unknown partner, and trends in C. trachomatis, N. gonorrhoeae, T. vaginalis. ART adherence will be measured by HIV-1 viral load at 0, 6, 9 months, and at all time points, by electronic monitoring, pharmacy refill, self-report, and clinic attendance.<br>Specific Aim 3: Establish cost-effectiveness of computerized counseling in Kenya. [Months 1-48]<br>• 2.3.A. Follow patients at the two clinics to evaluate standard of care counseling messages and collect patient time-spent data (n=100, at baseline), to determine unmet patient counseling need.<br>• 2.3.B. Economically evaluate CARE+_Kenya. If RCT shows the intervention reduces viral load and transmission risks, we will use a Bernoulli transmission dynamics model to estimate number of secondary HIV infections prevented; then create a cost-effectiveness model to calculate 2 incremental cost-effectiveness ratios: 1) cost/HIV infection averted, and 2) cost/disability adjusted life year (DALY) saved.<br>• 2.3.C. If CARE+_Kenya is efficacious and efficient, we will develop a proposal for a cluster-randomized trial to assess translational effectiveness of CARE+_Kenya throughout the AMPATH system. | | |

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| **Update:** | Achievements:<br>1. LAUNCH OF THE RCT Module1 randomized controlled trials commenced on 1st September 2011 and Burnt Forest started on 23rd November 2011 (delays due ot equipment issues and lab staffing finalization).<br>2. AMENDMENTS: The IRBs of each institution in the study approved new support staff, the addition of Scott Braithwaite, informed consent forms, recruitment script and recruitment flyers, and a modification to the lab protocol for GC/CT using PCR and Trichomonas using in-pouch kits. A second amendment to add a pill count survey to further enhance data collection methods for the study was submitted to the IRBs of each institution and we anticipate approvals to be received soon.<br>3. SUPPORT VISITS: Care+ (Plus) Spanish Coordinator John Lizcano came to Kenya on August 21st for two weeks to assist the CARE Plus Kenya team during their start up RCT phase for both Module1 and Burnt Forest. Prof. Ann Kurth came to Kenya two months later in October to oversee trial progress and to ensure that the study protocols are being adhered to.<br>4. QA/QC One of the study investigators, Joyce Baliddawa, has been tasked with the role of assisting with Quality Assurance (QA) for the RCT procedures and documentation.<br>5. RECRUITMENT We have had tremendous success in recruitment of study participants in module1 study site. The same is expected for burnt forest over the coming months.<br>6. DATA COLLECTION We are currently using RCT appointment log, RCT recruitment script, RCT consent form, RCT participants tracking form, and RCT ID Number labels (that is being used on participants' paperwork and appointment and incentive logs). This helps us in ensuring we track our participants as they come on their monthly follow-up visits. All the data at the end of each day is stored electronically into the study database and uploaded on a weekly basis to NYU secure site while we another copy is stored to an external and password protected hard drive.<br>7. PSYCHOLOGICAL FINDINGS Some of the psychological findings we have documented for Module1 since recruitment began were as follows; a) Depression - 4 b) Intimate Partner Violence (IPVs) -29 c) Suicidal thoughts - 13 All participants were referred to AMPATH Psychosocial department for further intervention purposes by the study protocol (including following assessment with Psychiatry), especially for those with potentially suicidal thoughts.<br>8. LAB TESTING All Module1 lab results have been filed to the respective participant's files and another copy into their regular AMPATH file. All those with Trichomonas Vaginalis results turning positive, we recall them for further care. Soon we will have test result and treatment guideline sheets for reporting test results and suggested treatment back to the clinics.<br>9. STANDARD OPERATING PROCEDURES All SOPs were developed, revised and approved by the study team.<br>10. COMMUNICATIONS The study team has kept abreast with the study activities on a weekly basis via Skype conference calls. The study coordinator and NYUCN research scientists have provided weekly reports and study updates to the study team.<br>Plans:<br>1. RECRUITMENT We intend to finalize recruitment of participants for module1 study site by the end of 2011. We plan to finalize recruitment of participants for burnt forest by the end of March 2012. Based on this timeline, we expect to have last follow-up visits by the end of 2012.<br>Challenges:<br>1. HARDWARE One of the tablets for participants broke thus had to be shipped back to the US for repairs. It was repaired and is being configured for use in Burnt Forest. The server on the other hand experienced technical problems prior to the RCT and needed to be repaired.<br>2. ECAP A few eCAPs have been disabled due to breakage either when they were dropped or by water damage. The eCAPS that are disabled will be shipped back to the supplier for review and attempts to recover the data. New eCAPS have been provided to participants and additional ECAPS were requested in case of additional needs.<br>3. CARE+ APPLICATION PROGRAM We've had also to reschedule participants for follow up visits due to small computer bugs in the care tool but that was sorted out by the software |

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| | programming company in Seattle.<br>4. PERSONNEL It was necessary to request permission to employ the Phlebotomist at Burnt Forest for our study since he is well trained on the procedures we anticipate to carry out. Although this required extensive time, approval was obtained from AMPATH Program Managers Office, on 20th November 2011 and the Phlebotomist started working with the project on 23rd November 2011.<br>5. RECRUITMENT Due to the upcoming holidays, we have had to schedule next appointments of our participants to next year second week to match their regular AMPATH care. Most participants are travelling up country and will resume regular care the first and second week of January 2012. The CARE+ Kenya study team would like to thank AMPATH for their ongoing support and the opportunity to report our progress. | | |
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| **Project Name:** | Conceptual Model of Factors Sustaining Pediatric Adherence to Antiretroviral Therapy in Western Kenya (Qualitative Inquiry into Pediatric Adherence) | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, S. Ayaya, D. Marrero, E. Walumbe, T. Inui | | |
| **Start Date:** | 3/1/2007 | **Project End Date:** | 1/1/2010 |
| **Site(s):** | MTRH<br>Turbo<br>Burnt Forest<br>Chulaimbo | | |
| **Project Description:** | Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. The objective was to identify key factors sustaining children's adherence to ART in western Kenya. | | |
| **Update:** | From this study, we were able to develop a conceptual model to describe pediatric adherence to antiretroviral therapy in the setting of western Kenya. We continue to make use of the transcripts of the interviews and focus groups for grounded theory data analysis and in the development of our pediatric ART adherence measurement strategy and questionnaires. The conceptual model for pediatric ART adherence was published in Qualitative Health Research in December 2009 (Authors and title: Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. 'Factors sustaining pediatric adherence to antiretroviral therapy in Western Kenya') | | |
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| **Project Name:** | Descriptive Analysis of Patients Seen in an Emergency Department in Western Kenya | | |
| **Investigator(s):** | D. House, N. Ongaro, Nyabera, K. Yusi | | |
| **Start Date:** | 1/1/2011 | **Project End Date:** | 5/1/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | Capture a years worth of data regarding all the patients seen in the Accident & Emergency Department, including basic demographics, diagnoses, and disposition. | | |
| **Update:** | Continuing to collect data for all patients seen in 2011. | | |
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| **Project Name:** | Disclosure of HIV status to children: Evaluating the prevalence and impact of telling children about their HIV status in western Kenya | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, S. Ayaya, Marete, Tenge, Songok, Gisore, Nabakwe, Inui, Wiehe, Hartsell | | |
| **Start Date:** | 3/1/2011 | **Project End Date:** | 12/31/2012 |
| **Site(s):** | MTRH, Turbo, Webuye Hospital, Kitale | | |
| **Project** | HIV-infected children must eventually learn of their HIV status, but neither the prevalence of | | |

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| **Description:** | disclosure to children nor the impact of disclosure on HIV-infected children have been clearly delineated within the AMPATH HIV care program in western Kenya. The objectives of this study are to measure the disclosure prevalence in the AMPATH clinics, with special attention to whether there are changes in disclosure after AMPATH pediatric disclosure training and protocols are implemented, and to assess how disclosure may impact children. We will assess what information about their HIV status is known by HIV-infected children enrolled in AMPATH. In addition, given the potential for disclosure to impact other areas of the child's life and medical care, we will gather information on the impact of disclosure on key areas in order to measure any changes after the implementation of the disclosure process. The factors that will be closely monitored include adherence to medication, experiences of stigma, and psychosocial issues related to disclosure. | | |
| **Update:** | IRB approval secured in 12/2010 and IREC approval secured in 06/2011. The project was implemented starting in 07/2011 and so far over 400 patients at the MTRH site have been evaluated. The study evaluations have also been implemented at the sites Turbo, Kitale and Webuye. The study's pilot results were submitted as an abstract to the Pediatric Academic Societies in 11/2011. An R01 submission to NICHD was made in 11/2011 to evaluate disclosure interventions in AMPATH clinics. | | |
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| **Project Name:** | EARNEST: A randomised controlled trial to evaluate options for second-line therapy in patients failing a first-line 2NRTI+ NNRTI regimen in Africa. Version 3.0, dated 06 September 2010. | | |
| **Investigator(s):** | K. Wools, A. M. Siika | | |
| **Start Date:** | 2/9/2011 | **Project End Date:** | 12/31/2014 |
| **Site(s):** | MTRH | | |
| **Project Description:** | EARNEST is a three arm parallel group, open-label, multi-centre, randomised controlled trial. 1200 patients will be included who are HIV-infected adults who have taken a first-line NNRTI-based regimen continuously for a total period of at least 12 months, and developed treatment failure defined by modified WHO 2010 criteria as one of the following: •New WHO Stage 4 event (with CD4 < 200 cells/mm3 and viral load (VL) > 400 copies/ml) •CD4 < 100 cells/mm3, or CD4 fall to pre-treatment baseline or below, or CD4 < 200 cells/mm3 X 2 with previous CD4 > 400 cells/mm3 (with VL > 400 copies/ml) •VL > 5,000 copies/ml ×2 The trial aims to determine whether, in patients failing a first-line NRTI and NNRTI-containing regimen 1. the use of bPI plus raltegravir (an integrase inhibitor) is superior to standard of care (bPI plus 2 new NRTIs) in achieving good HIV disease control at 96 weeks after randomisation. 2. the use of bPI monotherapy is non-inferior to standard of care in achieving good HIV disease control at 96 weeks after randomisation | | |
| **Update:** | The study closed to accrual in April 2011. Participants will be followed up for 144 weeks (approximately 3 years). One subject withdrew consent and one died; the 50 active ones are on follow up and are doing well. | | |
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| **Project Name:** | Electronic Medical Records to Improve Patient Care & Public Health in Rural Kenya | | |
| **Investigator(s):** | W. Tierney, L. Diero, S. Ayaya, B. Chemwolo, J. Songok, R. Spitzer, D. Caloia, J. Sidle, M. Were, K. Wools-Kaloustian, P. Braitstein, W. O'Meara, P. Biondich | | |
| **Start Date:** | 10/1/2007 | **Project End Date:** | 12/31/2011 |
| **Site(s):** | MTRH, Mosoriot, Turbo, Burnt Forest | | |
| **Project Description:** | Develop and implement a primary care module of the AMRS for Mosoriot, Turbo, Burnt Forest, and the ANC, Sick Child, and TB clinics at MTRH. Then use the system to implement computer-based decision support to improve coordination of care between AMPATH's HIV/AIDS clinics and these primary care clinics. | | |
| **Update:** | All aspects of the system have been implemented. Final asssessment of the reminders is to be | | |

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| | done before the end of December. Pre- and post-implementation time-motion studies have been done at Turbo and Burnt Forest. A pre-implementation time-motion study has been done at MTRH's sick child clinic; post-implementation study yet to be done. A pre-implementation quality assessment was done in the MTRH ANC clinic; post-implementation study is yet to be done. Implementation of the primary care module was slow and difficult. The model in the rural health centres had to be changed due to problems managing charts. MTRH TB clinicians never really embraced the system. It is being used well in the MTRH Sick Child and ANC clinics and at Turbo and Burnt Forest. Implementation at Mosoriot was spotty and difficult due to multiple changes in leadership and no commitment to the study by staff. Several publications are in the works; none published to date. Final report is being prepared. The system is to be taken over and maintained by the AMPATH Primary Healthcare Initiative. | | |
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| **Project Name:** | Engagement In Care Among HIV-Infected Patients In Resource Limited Settings: A Protocol For Assessing The Magnitude Of And Reasons For Failure To Engage In Care Among HIV-Infected Patients In The East Africa International Epidemiologic Databases To Evalua | | |
| **Investigator(s):** | C. Yiannoutsos, K. Wools-Kaloustian, E. Geng, P. Ayuo, L. Diero, B. Braitstein | | |
| **Start Date:** | 8/1/2011 | **Project End Date:** | 7/31/2012 |
| **Site(s):** | MTRH, Burnt Forest, Webuye Hospital | | |
| **Project Description:** | The effectiveness of the roll-out of antiretroviral therapy (ART) at President's Emergency Plan for AIDS Relief (PEPFAR)-funded sites in Africa most fundamentally depends on engaging HIV-infected patients to initiate ART followed by consistent retention in care. Failures of engagement in the form of failure to initiate ART (FTI) and failure to retain in care (FTR) may well represent the biggest limitation to the effectiveness of PEFPAR-funded ART services. Attempting to understand FTI and FTR brings a critical barrier into focus: in Africa, 25% of patients who start ART are lost to follow-up (i.e., have unknown outcomes) from their originating clinic by two years, and this percentage is likely as high among patients who are eligible but who have not yet started ART. For ART-eligible patients, losses to follow-up means that both deaths while awaiting ART initiation and ART initiation at other sites are systematically under ascertained, rendering the observed magnitude and impact of delays uninterruptable. For patients already on ART, losses to follow-up have been regarded as synonymous with disengagement from care. Yet emerging data suggests many 'lost' patients have simply started accessing care at newer sites as ART services decentralized. Furthermore, many lost patients have died, and unless these deaths are accounted for, existing estimates of outcomes and the effect of FTI and FTR are incomplete. Without generalizable and efficient strategies to manage the impact of losses to follow-up (i.e., unknown outcomes), the task of intelligently evaluating FTI and FTR is at a standstill. At a prototypical ART delivery site in Mbarara, Uganda, we have used a sampling-based approach to understand the effect of losses to follow-up on our clinic population's experience over time. We now propose to implement this approach at 11 sites in 3 countries in the East Africa IeDEA consortium in order to further understand the magnitude and determinants of FTI and FTR as well as the effects of FTR and FTI on survival and finally how to improve engagement in care for HIV-infected patients in Africa. Specifically, this process involves (1) enumerating an underlying cohort of patients from which engagement in care and loss to follow-up will be assessed, (2) identifying patients who become lost to follow-up and (3) identifying a representative sample of patients in whom outcomes obtained through contact in the community will be used to generalize to all lost patients and (4) ascertaining outcomes in this sample through patient contact in the community. | | |
| **Update:** | Update:<br>• The study received it's IREC approval on 1st of August 2011, and immediately commenced active follow- up.<br>• Outreach workers from all site were trained on the Patient follow-up and form | | |

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| | completion.<br>• IeDEA supplement hired additional staff for the 3 study site (2 for MTRH, 1 for Webuye and 1 for Burnt Forest)<br>• The study began with a sample of 1155 Patients inclusive for the 3 study sites namely MTRH, Webuye and Burnt Forest. Of the 1155 sampled, 953 lost to follow-up and are for tracking. We have so far tracked approximately 75% of the sampled to be tracked, 25% of the cases are either still pending revisits or being newly looked for.<br>• We also hired a full-time data entry clerk for data entry purposes. Data is entered into an online secure data tool called Quesgen.<br>• We cannot assertain the outcomes of these Lost-to-Follow-Up patients for now but until the close of the study when data will be analysed.<br>• Some of the challenges: -<br>o To date not about 10% of the patient charts/files have not been found<br>o Tracking patients in the rainy season was difficult for the trackers<br>o Looking for patients without locator information has also been a challenge to the trackers.<br>• Presentations and publications: NONE | | |
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| **Project Name:** | Enhancing Infant Feeding Options for HIV Infected Mothers | | |
| **Investigator(s):** | K. Wools-Kaloustain, W. Nyandiko,B. Nyunya, S. Bucher, C. Yiannoutsos, B. Musick | | |
| **Start Date:** | 1/10/2006 | **Project End Date:** | 1/31/2012 |
| **Site(s):** | MTRH, Burnt Forest, Chulaimbo | | |
| **Project Description:** | The purpose of this study is to determine if questionnaire administered within the clinic can be used to help decide which HIV (the virus that causes AIDS) infected women should be encouraged to breast feed and which should be educated about formula feeding their infants. In addition this study will help us to understand why some women choose to mix breast feeding with other types of foods. | | |
| **Update:** | Study complete, analysis complete, manuscript in progress | | |
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| **Project Name:** | Estimating the Weight of Children in Kenya: Do the Broselow Tape and Age-Based Formulas Measure Up? | | |
| **Investigator(s):** | D. House, E. Ngetich | | |
| **Start Date:** | 4/1/2011 | **Project End Date:** | 11/17/2011 |
| **Site(s):** | MTRH | | |
| **Project Description:** | Evaluating the accuracy and applicability of the Broselow tape (height based weight estimation) to commonly used age based formulas for estimating weight of sick children | | |
| **Update:** | Have completed the study and analysis which showed the Broselow tape to accurately predict weight of sick children and outperformed age-based formulas. The manuscript has been written and submitted for publication. | | |
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| **Project Name:** | Evaluation of a comprehensive strategy to measure pediatric adherence to antiretroviral therapy (CAMP study) | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, T. Inui, S. Ayaya, S. Downs, A. Carroll, W. Tu, W. Tierney, D. Marrero | | |
| **Start Date:** | 9/1/2009 | **Project End Date:** | 8/31/2014 |
| **Site(s):** | MTRH, Turbo | | |
| **Project Description:** | The objectives of this application are to develop and test a reliable, valid instrument to measure pediatric ART adherence for children ages 0 to 14 years in western Kenya and to evaluate which administration strategy yields the most accurate information about children's ART adherence. | | |

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| | We will pursue the following four specific aims: Aim 1: Develop a reliable, valid comprehensive pediatric ART adherence measurement questionnaire (CAMP - Comprehensive ART Measure for Pediatrics); Aim 2: Develop a reliable, valid, short-form version of the pediatric ART adherence measurement tool (SF-CAMP) for use as an adherence screening measure in busy clinical care environments; Aim 3: Evaluate the field- readiness, implementation feasibility, and clinical utility of CAMP and SF-CAMP within the AMPATH HIV clinical care system in western Kenya; Aim 4: Evaluate the reliability and validity of this measurement tool in a clinic-based care setting compared to a home-based care setting. | | |
| **Update:** | Received funding for Aims 1, 2 and 3 via K23 career development to Rachel Vreeman via NIH-NIMH. IRB and IREC approvals secured. Approved IRB/IREC accrual target is 770. Completed cognitive interviews with 20 participants from urban and rural clinics to develop and modify the questionnaire. Project staff were hired and trained. For the adherence validation study, we have enrolled 211 patients (with 8 withdrawals). 193 children have completed the adherence validation study. With funding from a PEPFAR Public Health Evaluation, we have begun to carry out Aim 4, recruiting patients from the Turbo clinic site in addition to MTRH and evaluating the adherence measurement in a home-based vs. clinic-based care setting. All 40 children have been recruited for evaluation under Aim 4. Data entry for the validation study is underway. | | |
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| **Project Name:** | Impact of Disclosure on Pediatric ART Adherence (Qualitative Inquiry into Pediatric Adherence) | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, S. Ayaya, E. Walumbe, D. Marrero, T. Inui | | |
| **Start Date:** | 3/1/2007 | **Project End Date:** | 12/31/2011 |
| **Site(s):** | MTRH, Turbo, Burnt Forest, Chulaimbo | | |
| **Project Description:** | Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. Primary objective was to identify key factors sustaining children's adherence to ART in western Kenya. Disclosure to children of their own HIV status and disclosure of a child's status to others emerged as key factors for sustaining adherence; additional analyses of how caregivers perceive pediatric disclosure and its effects were then carried out. | | |
| **Update:** | We were able to describe the influence of disclosure of a child's HIV status (both to the child and to other people) on pediatric adherence. These data were presented in oral and poster presentations at the AIDS 2008 meeting in Mexico City. Manuscript was published in AIDS Patient Care and STDs in October of 2010. (Authors and title: Vreeman RC, Nyandiko WM, Ayaya SO, Walumbe EG, Marrero DG, Inui TS. The perceived impact of disclosure of pediatric HIV status on pediatric antiretroviral therapy adherence, child well-being, and social relationships in a resource-limited setting). | | |
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| **Project Name:** | Impact of Integrated Family Planning and HIV Care Services on Contraceptive Use and Pregnancy Outcomes: A Retrospective Cohort Study | | |
| **Investigator(s):** | K. Wools-Kaloustian, R. Kosgei, K. Lubano, C. Shen, B. Musick, A. M. Siika, H. Mabeya, J.Carter, A.Mwangi, J. Kiarie | | |
| **Start Date:** | 11/1/2009 | **Project End Date:** | 10/1/2011 |
| **Site(s):** | N/A | | |
| **Project Description:** | published | | |
| **Update:** | R. J. Kosgei, P. Muia Ndavi , J. O. Ong'ech, J. M. Abuya , A. M. Siika, K. Wools-Kaloustian, H. Mabeya, T. Fojo, A. Mwangi,T. Reid, M. E. Edginton, E. Jane Carter : Symptom screening: diagnostic usefulness to detect pulmonary tuberculosis in HIV-infected pregnant women in Kenya- Public Health Action 2011: Advance release doi: http://dx.doi.org/10.5588/pha.11.0004 | | |
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| **Project Name:** | Increasing Animal Source Foods in Diets of HIV-Infected Kenyan Women and Their Children | | |
| **Investigator(s):** | J. Ernst, G. Ettyang, C. Neumann, W. Nyandiko, A. Siika | | |
| **Start Date:** | 10/1/2006 | **Project End Date:** | 7/31/2012 |
| **Site(s):** | Turbo, Soy, Mautuma | | |
| **Project Description:** | The study is a three arm randomized, blinded and controlled nutrition intervention trial that tests the effect of iso-caloric biscuit supplements of meat, soy or wheat protein added to the diets of drug naive HIV-infected Kenyan women and their children-8 years and younger and who live in the Turbo environs and who receive care at one of the AMPATH clinics (Turbo, Soy, Mautuma and MTRH). The women are of reproductive age and at enrollment WHO stage I or II. The biscuits are provided five days a week (Monday to Friday) to subject mother and child, using directly observed therapy (DOT) for 18 months. The outcome variables include estimates of lean and fat mass, quality of life, strength measures, biochemical indicators of nutritional status, indicators of immune function, measures of inflammation, nutrient intake, food security, measures of growth and development in children and activities of daily living. | | |
| **Update:** | Follow up assessments at 15, 18 and 24 months continued. Biscuit distribution continues through December 2011 at which time all the subjects will have completed their intervention.<br>Challenges: 1) Inflated fuel costs has significantly affected the project budget.<br>Presentations/Publications: T wo abstracts submitted to the Experimental Biology meeting to be held in San Diego, California in April, 2012. One abstract submitted to a meeting to be held in Rio de Janeiro, Brazil in April, 2012. One presentation was given to Indiana University, School of Health and Rehabilitation Sciences Faculty, Students and Alumni in November, 2011<br>Research progress presentation given to AMPATH partners- Eldoret-Kenya in December, 2011 | | |
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| **Project Name:** | Indiana University - Moi University Academic Research Ethics Partnership | | |
| **Investigator(s):** | E. Meslin, D. Ayuku, J. Eberl | | |
| **Start Date:** | 5/31/2008 | **Project End Date:** | 5/31/2012 |
| **Site(s):** | MTRH, Moi University | | |
| **Project Description:** | The Indiana University - Moi University Academic Research Ethics partnership (IU-Moi AREP) is funded by a $940,000 four-year grant from the Fogarty International Center at the National Institutes of Health to establish a new research ethics training partnership with colleagues at Moi University in Eldoret, Kenya. IU-Moi AREP is a curriculum development and training initiative that builds on longstanding partnerships and collaborations in East Africa. IU-Moi AREP has developed two Master's degree programs: one at Indiana University - Purdue University Indianapolis and one at Moi University in Eldoret, Kenya. These graduate programs have common overlapping components, joint advisory committees, shared dissemination plans and harmonized evaluation strategies. Both programs include a curriculum involving required core courses and electives and a practicum experience, part of which is taken at the counterpart university. In addition, each IU-Moi AREP partner convenes an annual Teaching Skills in International Research Ethics (TaSkR) workshop to provide training to approximately 40 faculty and students each year. | | |
| **Update:** | Practicum: From September 12th to October 20th of 2011, seven MSc in International Health Research Ethics Students from Moi University in Eldoret, Kenya, participated in the first ever Indianapolis-based, six week intensive practicum exchange program. The students participated in group classes, presentations, meetings, and lectures. They also engaged in qualitative research on specific topics in international health research by conducting individual interviews with members of the IRB, IU researchers, and IRB staff members. The practicum consisted of two parts, core experiences and specialized research activities. The core experiences introduced students to research ethics and international relationships at IU and also provided cursory training on basic research skills. The specialized experience gave students the opportunity to | | |

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| | work on a specific project under the guidance of a mentor. Students attended group lectures, including: 'Introduction to Research Ethics, Education, and Policy (REEP)' by John Baumann, Executive Director of REEP; 'An AMPATH Update' by April Bell, AMPATH Research Manager; 'An Introduction to the Office of International Affairs and the Confucius Institute of IUPUI' by Ian McIntosh, Director of the Office of International Affairs; 'Conflict of Interest' by Sherry Oswalt-Smith, Conflict of Interest Manager; 'Research Compliance: Privacy and HIV Studies' by Marcia Gonzales, Assistant Vice President for Research Compliance; 'An Introduction to the Human Subjects Office' by Sarah Crabtree, Senior Research Compliance Consultant; 'Cultural Differences and Logistical Challenges of the IU-Kenya Partnership' by Ron Pettigrew, Manager of the IU-Kenya Partnership; and 'An Introduction to Library Services' by Jere Odell, the Academic Literature Specialist at the IU Center for Bioethics. Students attended classes, including: a two day course on 'How to Conduct Qualitative Research'; a weekly class, 'Introduction to Research Ethics'; one 'African Health and Culture' class; and a two day 'Research Coordinator Education Program.' They attended informal meetings with David Wilkes, Executive Associate Dean for Research Affairs; Patrick Loehrer, Director of IU Simon Cancer Center; Joe Scodro, Associate General Counsel; and Tom Inui, Director of Research for the Indiana University Kenya Program. Students also observed a monthly IRB meeting as well as a monthly Conflict of Interest meeting. The group visited the Eli Lilly Bioethics Program in Indianapolis. They also visited the Poynter Center for the Study of Ethics and American Institutions and Swahili Language Institute at the Indiana University campus in Bloomington, Indiana. In addition to the core experiences, the practicum included specialized research activities. Students were required to developed research proposals prior to their arrival in Indianapolis. The research proposals were used to match each student with at least one primary mentor (some students had 2 co-mentors). The student worked with his or her mentor to clarify key concepts in the literature, further develop the student's interview guide, and arrange additional interviews.<br>Short Courses:From November 21st through December 9th, the IU-Moi AREP Partnership conducted a three week short course on International Health Research Ethics. This course was intended to build capacity in the area of International Research Ethics in order to maintain the ethical and scientific quality of research protocols developed by local and international scientists. Course content focused on the responsible design and conduct of scientific research. Topics covered included: Ethical Theories and African Ethics, Good Clinical Practices in International Research Ethics, Emerging Issues in International Research Ethics, Ethics and Gender in Research, and Public Health Research and Policy.<br>TaSkR IV: TaSkR IV will take place February 1-3 in Eldoret, Kenya. It will follow the two and a half day format used in previous years and will be welcoming Dr. Ross Upshur from the University of Toronto and Dr. Jeremy Sugarman from Johns Hopkins University as TaSkR faculty. Just prior to TaSkR IV, IU-Moi AREP will be collaborating with the University of Manitoba and the University of Nairobi. From January 29 - 31, TaSkR faculty will be teaching a Research Ethics Course as part of the International Infectious Disease and Global Health Training Program. |

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| **Project Name:** | International epidemiologic Databases to Evaluate AIDS (IeDEA) | | |
| **Investigator(s):** | C. Yianoutsos, K. Wools- Kaloustian, S. Ayaya, L. Diero, J. Otieno, G.R. Somi, R. Swai , K. Ngonyani, R. Lyamuya, H.B Mtiro, J. Sidle, P. Braitstein, J. Martin, D. Bangsberg, D. Glidden, S. Deeks, P. Hunt, L. Diero, S. Ayaya, D. Nash, E. Abrams, B. Elu | | |
| **Start Date:** | 6/20/2006 | **Project End Date:** | 7/31/2016 |
| **Site(s):** | All Sites | | |
| **Project Description:** | IEDEA(International epidemiologic Databases to Evaluate AIDS) Initiative This initiative will establish international regional centers for the collection and harmonization of data and the establishment of an international research consortium to address unique and evolving research questions in HIV/AIDS currently unanswerable by single cohorts. High quality data is being | | |

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| | collected by researchers throughout the world. This initiative provides a means to establish and implement methodology to effectively pool the collected data—thus providing a cost effective means of generating large data sets to address the high priority research questions. Combination of data collected under various protocols is frequently very difficult and not as efficient as the collection of pre-determined and standardized data elements. By developing a pro-active mechanism for the collection of key variables, this initiative will enhance the quality cost effectiveness and speed of HIV/AIDS research. |
| **Update:** | As of August 31st 2011, IeDEA has a total of 149,719 AMPATH data of which 96299 are female and 53420 are male. Research EA IeDEA co-investigators are actively involved in both international and local working groups. The international Phamaco-vigilance committee is co-chaired by Dr. Braitstein, and the Pediatric working group is lead by Prof. Ayaya and Dr. Wool-Kaloustian,. Dr. Diero and Dr. Siika are actively involved with the TB working group. Dr. Martin leads the Oncology working group and Ms. Musick is actively involved in the Data harmonization working group.<br>On-going Studies within IeDEA, East Africa Regional Consortium:<br>1. 'International Epidemiologic Databases to Evaluate AIDS (IeDEA) East Africa Regional Consortium' - on going<br>2. 'International Epidemiologic Databases To Evaluate AIDS (IeDEA); Proposal for Data Extraction and Analysis for the Initial Projects (Version 1.0.25 October 2007)' - on-going<br>3. 'National Cancer Institute Supplement to East Africa IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as well as Assessing Sarcoma Incidence in Western Kenya' - on-going<br>4. 'Engagement in Care Among HIV-Infected Patients in Resource limited Settings' A supplement to IeDEA East Africa- on-going<br>Presentations:<br>• Wachira J, Middlestadt SE, Vreeman R, Braitstein P. Factors Underlying Taking a Child to HIV Care: Implications for Reducing Loss to Follow-up among HIV-Infected and Exposed Children. IN: XVIII International AIDS Conference, 17-20 July 2011.<br>• Nash D, Farr A, McKaig R, Ekouevi D, Wools-Kaloustian K, Egger M, Hemingway-Foday J, Cooper D, Moore R, Masys D.Characteristics of HIV care and treatment programs in the International Epidemiologic Databases to Evaluate AIDS (IeDEA) Collaboration. IN: XVIII International AIDS Conference, 17-20 July 2011.<br>• Ciaranello AL, Lu Z, Ayaya S, Losina E, Musick B, Vreeman R, Freedberg KA, Yiannoutsos C, Wools-Kaloustian K. Incidence of WHO Stage 3 and 4 events and tuberculosis in untreated, HIV-infected children enrolling in care before 1 year of age: An IeDEA East Africa regional analysis. IN: XVIII International AIDS Conference, 17-20 July 2011.<br>• The IeDEA Pediatric Working Group. Programmatic and clinical management practices in the International Epidemiologic Databases to Evaluate AIDS (IeDEA) Pediatric Group: Results from a multiregional site assessment. IN: XVIII International AIDS Conference, 17-20 July 2011.<br>Publications:<br>• Braitstein P, Songok J, Vreeman RC, Wools-Kaloustian KK, Koskei P, Walusuna L, Ayaya S, Nyandiko W, Yiannoutsos C. 'Wamepotea' (They have become lost): Outcomes of HIV-positive and HIV exposed children lost to follow-up from a large HIV treatment program in Western Kenya. J Acquir Immune Defic Syndr. 2011 Jul 1;57(3):e40-6.<br>• Braithwaite RS, Nucifora KA, Yiannoutsos CT, Musick B, Kimaiyo S, Diero L, Bacon MC, Wools-Kaloustian K. Alternative antiretroviral monitoring strategies for HIV-infected patients in east Africa: opportunities to save more lives? J Int AIDS Soc. 2011 Jul 30;14:38.<br>• Braitstein P, Katshcke A, Shen C, Sang E, Nyandiko W, Ochieng VO, Vreeman R, Yiannoutsos CT, Wools-Kaloustian K, Ayaya S. Retention of HIV-infected and HIV-exposed children in a comprehensive HIV clinical care programme in Western Kenya. Trop Med Int Health. 2010 Jul;15(7):833-41. Epub 2010 May 14. |

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| | • Brinkhof MW, Spycher BD, Yiannoutsos C, Weigel R, Wood R, Messou E, Boulle A, Egger M, Sterne JA; International epidemiological Database to Evaluate AIDS (IeDEA). Adjusting Mortality for Loss to Follow-Up: Analysis of Five ART Programmes in Sub-Saharan Africa. PLoS One. 2010 Nov 30;5(11):e14149.<br>• Egger M, Ekouevi DK, Williams C, Lyamuya RE, Mukumbi H, Braitstein P, Hartwell T, Graber C, Chi BH, Boulle A, Dabis F, Wools-Kaloustian K. Cohort Profile: The international epidemiological databases to evaluate AIDS (IeDEA) in sub-Saharan Arfica. Int J Epidemiol. 2011 May 18. [Epub ahead of print] | | |
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| **Project Name:** | Joint Moi University-Indiana University International Ethics Review Committee | | |
| **Investigator(s):** | E. Meslin, D. Ayuku | | |
| **Start Date:** | 9/15/2011 | **Project End Date:** | 9/14/2011 |
| **Site(s):** | MTRH, Moi University | | |
| **Project Description:** | The intent of the project was to create and operate a Joint Ethics Review Committee between Indiana University and Moi University (Eldoret, Kenya) that would be responsible for reviewing and approving research proposals undertaken jointly by these two universities, to provide training (in person and online) for committee members and reviewers, and to assess its capacity for ongoing success and sustainability. This project endeavored to establish the structural, ethical, and legal framework for a Joint Moi University-Indiana University International Ethics Review Committee (IU-Moi ERC) to provide timely and high quality ethical review of international collaborative research proposals. In particular we wanted to understand any regulatory or institutional impediments to establishing this first-ever committee. In addition, the project aimed to develop and provide specific training to prospective committee members, administrators, and staff to ensure competency in the assessment and review of collaborative international protocols. | | |
| **Update:** | Specific Aim 1. Establish the administrative structure and ethical/legal framework for a Joint Moi University-Indiana University International Ethics Review Committee (Moi-IU ERC) to provide timely and high quality ethical review of international collaborative research proposals.<br>• Sub Aim 1.1 Obtain the requisite regulatory and institutional authorization to establish this committee, including the National Council for Science and Technology in Kenya, the relevant U.S. regulatory authorities, and from both academic partners. This authorization would be confirmed in a Memorandum of Understanding involving relevant parties. Progress: Regarding Kenya, while regulatory and institutional authorization has not yet been forthcoming, we did acquire key information about the process by which such authorization would occur. In particular: (1) the NCST oversees all the research within the country and sets ethical guidelines on research involving human subjects; in this capacity is delegates authority to Kenyan ethics committees, and would therefore be the source to delegate authority to the proposed joint committee; (2) the legal framework for NCST is mandated under the Science and Technology Act of 1979. Moi's Institutional Research Ethics Committee (IREC) operates under delegated authority of NCST established under Cap 250, but is also supervised by the National Bioethics Committee (this was new information to us). Moreover, Kenyan ethics committees undergoes external audit both by the NCST and also other certifying bodies such as the Kenya Bureau of Standards (KBS). Discussions about the Joint ERC project are under active discussion at the NCST (Dr. Simon Langat), the National Bioethics Commission of Kenya (Dr. Karina Bhatt), and with Moi University. We expect that this process will take some months. Regarding USA, inquiries with OHRP's Office of International Affairs provided valuable insight for understanding the necessary regulatory steps for establishing a Joint IRB. We were assured that no specific regulatory barriers exist; indeed, one accepted view of the current Common Rule is that it anticipates new institutional arrangements for undertaking ethics review. On the other hand there are key | | |

institutional decisions must be made that do have regulatory implications. Two of them are: (1) whether the new committee wishes to be considered a separate entity from either university, which would require taking certain steps to achieve 'business' status; and (2) determining whether to amend/revise the existing Federal-wide Assurances (FWA) that IU and Moi currently have or to negotiate a new FWA. In our view, these decisions are not technically difficult or hard to implement from the perspective of a US institution.

- Sub Aim 1.2 Construct a nimble and efficient administrative structure to coordinate all aspects of the Joint ERC including: hire a program manager, appoint co-chairs and members from both universities, and develop Standard Operating Procedures (SOP) to guide the actions of the Moi-IU ERC that satisfy best practices in international research ethics

Progress: Much progress has been made towards development of the administrative structure for the joint committee

- Hired a part-time Program Manager for the duration of the grant to coordinate all aspects of the IU component of the Joint ERC
- Established membership criteria
- Identified the IU-based members of the Joint ERC who were willing to serve, the identified the IU Co-Chair (Dr. Matt Johnson) and IU-Vice Chairs (Dr. Ken Fife, Dr. Ed Liechty)
- Conducted regular teleconferences of project team, staff and project investigators
- Liaised with counterparts at Moi to establish collaborative mechanisms for communication
- Identified the Moi Co-Chair (Dr. Edwin Were)
- Confirmed the necessity for seamless real time communication using teleconference
- Provided a briefing to the Chair of the Kenya National Bioethics Committee (not identified in initial Aim).

We were not able to complete some of the other components of the administrative structure including:

- Update the Federal-Wide Assurances (FWAs) at both IU and Moi to include new ERC as appropriate (this requires more progress as described above)
- Drafting of applicable SOPs it was determined that until the Moi members of the committee had been identified, and Moi institutional approval granted it would be premature to develop a novel SOP.

Specific Aim 2. Develop and Provide Specific Training to Ensure Competency in the Administration, Assessment and Review of International Protocols

- Sub Aim 2.1 Develop ethics competency standards that will be required as a condition of membership on the new Moi-IU ERC and the training program to meet these standards. We will extend our existing R25-funded training workshops on 'Teaching Skills in International Research Ethics' to include specific components for committee members, reviewers and administrators.

Progress: Research ethics competency standards were established for prospective committee members via several methods:

- The existing R25-funded training workshop provided by the IU-Moi Academic Research Ethics Partnership, called 'Teaching Skills in International Research Ethics' (TaSkR) was extended to prospective committee members and included specific components for committee members, reviewers, and administrators. The TaSkR workshop offered in Indianapolis in April 12-14, 2011 had over 50 faculty, staff, students, as well as collaborative partners in attendance.
- An additional fourth day was convened April 15, 2011 designed as a specific training session for the Joint IU-Moi ERC. The format was geared towards developing competency in both substantive and procedural aspects of international research ethics review. A representative from OHRP was also in attendance. Sessions

focused on substantive issues were conducted with an emphasis on the background and history of international research ethics; the ethical foundations of international research ethics; Kenyan and U.S. laws, policies, and regulations; and customs, norms, and local values of indigenous populations. Procedural sessions were included to understand IU and Moi University's standard operating procedures; informed consent forms and processes; mechanisms for collaborative review, mechanisms for achieving consensus within the new IU-Moi ERC; and evaluating the committee. The session also featured a mock IU-Moi ERC review.

- In addition to the mock review undertaken at the April 15 training session, an additional 'mock' committee meeting/review was conducted from Eldoret. This and the prior review experience demonstrated the need for ongoing training, efficient communication mechanisms, and a clear assurance of procedural rules for convening the first-ever committee.

- Sub Aim 2.2. Develop an online training module that would be included within the suite of modules offered by the Collaborative Institutional Training Initiative (CITI) designed specifically for the IU-Kenya environment, to be used by IRB members, reviewers, administrators, and investigators at both institutions.

Progress:It was determined that a full module could not be developed and tested within our time period.

Significant Results

A. Obtained a comprehensive understanding of the regulatory processes and procedures necessary for developing the IU-Moi Joint ERC. In the case of Kenya, we now understand better the nuanced mix of policy, custom and process between the NCST, the National Bioethics Committee, and Moi University that will need to be coordinated and harmonized before they can reach a decision about whether to delegate authority to a new/separate committee; or whether a different arrangement is necessary. In the case of the US, we now understand better the policy choices and decisions that face a US university that seeks to develop a new IRB in partnership with a foreign institution. As noted above. US regulations anticipate new institutional arrangements for undertaking ethics review, but that key institutional decisions are still required such as whether to amend vs. construct a new FWA; and whether the new joint committee ought to be a separate business entity with a new IORG code. To our knowledge this information had never been collected before. This analysis is now being prepared as a manuscript.

B. Identified Members, Co-Chairs, Staff, Preliminary Procedures. We undertook several tasks to begin the process of constructing the joint committee including: agreeing to a committee of equal membership from each institution (8 + 8); identifying a 'pool' of willing faculty and staff at IU to sit on the committee, undertake reviews on its behalf and generally support the principle we were striving to accomplish; agreeing to a structure of two co-chairs (one from each institution) and at least one vice-chair from each institution; discussing a process for review/approval of protocols that minimizes the risks from a failure to appreciate the challenges of representation, majority/minority voting (e.g., protocols approved only with a minimum of 50% approval of 8 reps from each institution); and hiring a part-time Program Manager who undertook to facilitate regular teleconference communication between the teams and coordinated all activities during the course of the grant.

C. Confirmed that the Challenges of Developing a Joint Ethics Review Mechanism are Unequally Allocated Between the Two Institutions. At IU, the challenges relate more to staffing, coordination, and decisions about the status of its FWA than to policy or US regulatory hurdles. Moi faces the same challenges as IU, but in addition must also address the university's relationship to the NCST and National Bioethics Committee, where concerns about national sovereignty and control over health research are more profound. Articulating the types of challenges that each institution faces - and recognizing that the burden at one institution may be different at another is a critical component for any successful partnership

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| | - especially those that depend on trust and collaboration like this one does.<br>D. Clear Identification of Similarities and Differences Between IU IRB and Moi IREC. For the most part, Indiana University and Moi University share many similarities in scope, authority and activity regarding their respective review processes. Of particular relevance to this proposal is that IU and Moi each have FWAs. However, our analysis revealed a number of relevant institutional/process differences which distinguish the committee activities throughout the life cycle of ethics review that require harmonization. These topics include: pre-review process, membership issues, minutes, forms, internal office tracking/ database, meeting layout/format, terminology, and expedited review. On top of this, there are many logistics issues that also require attention (e.g., meeting by teleconference, time zones, quality of phone lines). Training and Ongoing Education. Although a final decision to establish this committee was not achieved during the grant period, we did make significant progress towards training prospective members and preparing the landscape the committee once it was approved. The following are examples of specific training activities we undertook during this project:<br>1. Utilized our successful R25-funded Teaching Skills in International Research Ethics (TaSkR) workshop (trained 100+ individuals to date)<br>2. Dedicated an entire day to training members of the Joint ERC. This meeting followed the 2011 Indianapolis TaSkR III Workshop that included 50+ attendees from IU and Moi, including OHRP representative)<br>3. IU provided separate training sessions (4 hours total, supplemented by CITI) for its IU-based members and staff<br>4. Moi provided (and continues to offer) 'short courses' on research ethics to provide competency experiences for Moi faculty, many of whom will be approached to participate in the ethics review process<br>5. Facilitated 'mock reviews' of existing protocols to provide real time review experiences |

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| **Project Name:** | Low Risk Express Care | | |
| **Investigator(s):** | K. Wools-Kaloustain, A. M. Siika, R. Kosgei, C. Yiannoutsos, B. Musick, E. Sang | | |
| **Start Date:** | 11/1/2009 | **Project End Date:** | 1/31/2012 |
| **Site(s):** | All Sites | | |
| **Project Description:** | An assessment of the impact on patient outcomes of introducing the low risk express care model into the clinics. | | |
| **Update:** | Working on a revision of the analysis. | | |

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| **Project Name:** | Modified Directly Observed Antiretroviral Therapy (M-DART): An intensive, nurse-directed, home-centered, treatment strategy to reduce mortality and loss to follow-up in high-risk HIV-infected patients initiating antiretroviral therapy. | | |
| **Investigator(s):** | K.Wools, A.Siika, T.Murage, H.Thirumurthy, S.Goodrich | | |
| **Start Date:** | 5/2/2011 | **Project End Date:** | 11/26/2011 |
| **Site(s):** | Port Victoria, Khunyangu | | |
| **Project Description:** | M-DART is a randomized clinical trial comparing the effectiveness of a home-based modified directly observed antiretroviral (ART) treatment strategy to clinic-based standard of care in patients with HIV/AIDS in Port Victoria and Khunyangu, Kenya. The aim is to reduce both mortality and the number of patients lost to follow-up after ART therapy is initiated. | | |
| **Update:** | IREC approved amendments to the protocol version 1.2 in August,2011.The amendments included addition of objective number 3 which seeks to determine patients' perception of quality of life and stigma following implementation of M-DART and addition of Co-Investigator(Suzanne Goodrich) in view of objective number 3. Enrollment of patients started in August,2011. | | |

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| **Project Name:** | National Cancer Institute Supplement to East African IeDEA: Improving Kaposi's Sarcoma and Lymphoma Diagnostics as Well as Assessing Kaposi's Sarcoma Incidence in Western Kenya. | | |
| **Investigator(s):** | C. Yiannoutsos, K. Wools-Kaloustian,N. Busakhala, L. Diero, N. Buziba, T. Maurer, P. Loehrer, M. Strother, M. Czader, P. Leboit, T. McCalmont | | |
| **Start Date:** | 8/20/2009 | **Project End Date:** | 7/31/2016 |
| **Site(s):** | All Sites | | |
| **Project Description:** | The toxicity and potential side effects of therapy for malignancy justify a standard of care in cancer medicine of tissue-biopsy. Further, an accurate assessment of the epidemiology of HIV-related malignancy requires reliable pathologic diagnosis. This study will help validate local pathology for the diagnosis of KS. The limited resources available to local pathology mandate that most diagnoses are made via H&E staining and immunohistochemistry which are techniques, like many pathology diagnostic tools, open to inter-observer variability in interpretation - thus the experience of the pathologist is a major determinant in diagnostic accuracy. Quality assurance efforts and continuing evaluation of diagnostic skills are routine practices in the United States to help ensure ongoing reproducibility between pathologists. The present effort will facilitate similar ongoing quality checks and thus increase the reliability of a biopsy-based diagnosis of Kaposi's sarcoma and lymphoma at the selected sites. | | |
| **Update:** | Punch Biopsies are continually been done at the Oncology clinic, AMPATH Centre. Visiting clinicians continue to go to the Oncology sites namely, Busia, Chulaimbo, Kitale, and Webuye and Port Victoria. Currently 945 punch biopsies have been done both AMPATH and Non-AMPATH patients. Of These 851 are AMPATH patients'. 901 samples have been read and results available, 436(48.4%) turned positive for KS, 349(38.7) turned negative, and 116(12.9%) are indeterminate. Specimen samples are shipped to UCSF for a re-reads every 2-3 months. Data collection and entry continues. We now enter KS data on a secure online system called Quesgen. | | |
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| **Project Name:** | Novel drug formulations for pediatric TB | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, G. Knipp, C. Kissinger, T. Blaschke, S. Ayaya | | |
| **Start Date:** | 1/1/2009 | **Project End Date:** | 6/30/2011 |
| **Site(s):** | MTRH | | |
| **Project Description:** | The aim of this study is to utilize the porcine model as a surrogate for human pediatric patient PK studies in order to develop a novel, fast-melt pediatric formulation of rifampicin that can be safely and efficaciously used to treat children diagnosed with tuberculosis. The primary objectives were: A) To develop novel orally disintegrating films (ODF) and tablets (ODT) formulations of rifampicin for the treatment of TB in infants and young children; and B) To compare the pharmacokinetic properties of rifampicin in juvenile pigs with those reported in the literature for human pediatric patients in an attempt to validate the juvenile porcine model as a human pediatric surrogate for preclinical pharmacokinetic and pharmacodynamic studies. Fast-melt film formulations were developed and tested according to the USP methodology. Dissolution and assay experiments were carried out according to the USP monograph for rifampicin capsules and selected film formulations. To determine the PK parameters of the dosage form, pigs were modified with a jugular catheter, externalized in the dorsal scapular region. Whole blood samples were collected using the Culex-L large animal automated blood sampling system, and plasma samples were analyzed by LC-MS/MS for rifampicin content. | | |
| **Update:** | ODFs and ODTs of rifampicin have been developed for pediatric administration and are currently undergoing characterization and optimization. Long term chemical and physical stability tests are currently underway at various temperature and relative humidity conditions to determine if these dosage forms are viable for remote areas and developing countries. Differences in rifampicin exposure have been observed between adult and juvenile pigs when dosed with the | | |

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| | same formulation. Similarities in pharmacokinetic parameters of rifampicin between juvenile pigs and human pediatric patients suggest that the pig may be a more predictive model for performing PK studies. A poster presentation of the results of this study was made to the AAPS Indiana/Ohio Discussion Group (I/ODG) on August 9, 2011. | | |
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| **Project Name:** | Optimal Combination Therapy After Nevirapine Exposure | | |
| **Investigator(s):** | K. Wools Kaloustian, A. M. Siika, S. N. Kimaiyo, W. D. Owino Ong'or, J. Sidle | | |
| **Start Date:** | 11/13/2006 | **Project End Date:** | 2/26/2010 |
| **Site(s):** | MTRH | | |
| **Project Description:** | A5208/OCTANE is a phase III study comprising two randomized clinical trials (RCT) to be conducted concurrently. Both trials will compare the virologic response to non-nucleoside reverse transcriptase inhibitor (NNRTI)-based (Arm 1A) versus protease inhibitor (PI)-based (Arm 1B) antiretroviral treatment (ART) in HIV-infected treatment-naïve women. Trial 1 will evaluate the superiority of PI-based ART over NNRTI-based ART in women with prior single dose (SD) nevirapine (NVP) prophylaxis for mother-to-child-transmission (MTCT) of HIV. Trial 2 will evaluate the equivalence of PI- and NNRTI-based ART in women with no prior NVP exposure. | | |
| **Update:** | The study is closed to follow up. There have been several publications and presentations:<br>1. S. Lockman et al: Antiretroviral therapies in women after single-dose nevirapine exposure. N. Engl. J. Med, 1533-4406, Vol 363,issue 16, pages 1499-509, Oct/14/2010<br>2. AL Ciaranello et al: First-line antiretroviral therapy after single-dose nevirapine exposure in South Africa: a cost-effectiveness analysis of the OCTANE trial. AIDS,1473-5571, Vol 25, Issue 4, Pages 479-92, Feb/20/2011<br>3. VF Boltz et al; Role of low-frequency HIV-1 variants in failure of nevirapine-containing antiviral therapy in women previously exposed to single-dose nevirapine. Proc. Natl. Acad. Sci. U.S.A., 1091-6490, Vol 108, issue 22, pages 9202-7, May/31/2011 | | |
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| **Project Name:** | Patient-Reported Outcomes of Cancer Care in Eldoret, Kenya | | |
| **Investigator(s):** | L. Hess, V. Naanyu, C. Asirwa | | |
| **Start Date:** | 10/14/2010 | **Project End Date:** | 7/1/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This project is designed to validate and subsequently implement a standardized questionnaire to obtain patient perspectives of their physical and psychosocial well-being (quality of life) during and following cancer treatment. First, the instrument will be tested for validity in a cancer patient population in Eldoret in a two-phase study. Second, it will be implemented into standard data collection practices for routine clinical care for the validation study. Knowledge about the quality of life of cancer patients in Eldoret will help us to understand the broader context of wellness among cancer patients and will help guide future strategies to improve comprehensive cancer patient care. | | |
| **Update:** | Accrual to this study is ongoing. The only barrier has been lack of return for subsequent chemotherapy, thus the inability to obtain all needed follow up assessments. We will have to enroll additional participants to reach our goal of 120 patients with complete assessments for the validation portion of the study. | | |
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| **Project Name:** | Pediatric ART Pharmacokinetics and Adherence Feasibility Study (also titled, Development and Evaluation of a Tool to Measure Pediatric Adherence to Antiretroviral Therapy - Phase 1 - Feasibility) | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, N. Busakhala, S. Ayaya, L. Labbe, E. Liechty, T. Blaschke | | |
| **Start Date:** | 4/1/2008 | **Project End Date:** | 6/30/2012 |

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| **Site(s):** | MTRH | | |
| **Project Description:** | The primary objective of this study was to establish feasibility of pediatric pharmacokinetics (PK) modeling, body water assessment, and comprehensive adherence assessment in a resource-limited setting. The secondary objectives were to model the PK parameters of nevirapine (NVP) in children in western Kenya, including oral clearance, apparent volume of distribution, and half-life, and to use mixed-effects modeling to assess sources of variation in NVP pharmacokinetic parameters, focusing on body composition. | | |
| **Update:** | 20 children were enrolled in the study and have completed all of the study procedures. Participants underwent two inpatient assessments, one at ART initiation and one 3-4 months later. At each of these inpatient assessments, timed blood samples were drawn at 0, 1, 3, 8, and 12 hours after an observed nevirapine (NVP) dose. Plasma NVP was measured by a rapid enzyme immunoassay (ARK Diagnostics, Sunnyvale, CA, USA), which was successfully introduced and implemented using the existing chemistry analyzer in the AMPATH reference lab in Eldoret, Kenya. The participants also received deuterium-labeled water, allowing body water composition assessment from the timed plasma samples. Serum proteins, anthropometrics, and saliva for CYP2B6 genotype analysis were also collected. Participants also underwent 3-4 months of adherence monitoring, using Medication Event Monitors (MEMS®), pill counts or volume measures, and questionnaires. Preliminary pharmacokinetics modeling based on these data were completed. Population pharmacokinetics parameters for nevirapine were determined. %H2O explained 7.4% of the variability of CL/F. Participants' TBW% affected CL/F ($p<0.05$): a 30% lower value increased CL/F by 12%. Lower weight-for-age Z scores also tended to reduce CL/F. These findings suggest that, as weight increases, total body water percentage decreases and this increases the clearance. Abstract was presented at the National Clinical & Translational Research Education Annual Meeting, April 2009; 2nd International Workshop of HIV Pediatrics, Vienna, Austria. July 2010; and AIDS 2010 Conference, Vienna, Austria. July 2010. Manuscript development underway and awaiting revised pharmacokinetics modeling. | | |
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| **Project Name:** | Post-Crisis Evaluation | | |
| **Investigator(s):** | K. Wools-Kaloustain, S. Ndege, S. Goodrich, Somi, J. Sidle and others | | |
| **Start Date:** | 1/1/2009 | **Project End Date:** | 2/29/2012 |
| **Site(s):** | All Sites | | |
| **Project Description:** | Retrospective look at how AMPATH dealt with the post Election violence, including a look at how soon patients returned to clinic and a case study of how the Burnt Forest Clinic dealt with the Crisis. | | |
| **Update:** | Collecting additional information and the response process. Requested additional data to the dataset as two sites were not represented in the patient level data Mosoriot and Burnt Forest. | | |
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| **Project Name:** | Qualitative Assessment of Barriers to Antiretroviral Therapy Adherence among Adolescents (Qualitative Inquiry into Pediatric Adherence) | | |
| **Investigator(s):** | R. Vreeman, W. Nyandiko, C. Zeunik, S. Ayaya, D. Marrero, T. Inui | | |
| **Start Date:** | 3/1/2007 | **Project End Date:** | 6/30/2012 |
| **Site(s):** | MTRH, Turbo, Burnt Forest, Chulaimbo | | |
| **Project Description:** | Qualitative research project involving focus groups and individual key informant interviews with parents and caregivers of HIV-infected children taking ART, older children on ART, and healthcare providers of children with ART. Objective was to identify key factors sustaining children's adherence to ART in western Kenya. This analysis focuses on adolescent-identified factors impacting the experience of medication-taking and creating barriers and facilitators to adherence. | | |
| **Update:** | In western Kenya, the need to maintain secrecy about ART emerged as a key theme related to | | |

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| | adolescent ART adherence. We presented ''I can't be free to tell them': A qualitative assessment of barriers to antiretroviral therapy adherence among adolescents in western Kenya' as a poster presentation at the 2009 International AIDS Society meeting in Cape Town, South Africa. The manuscript is under review at SAHARA-J. | | |
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| **Project Name:** | Rationing of Combination Antiretroviral Therapy (cART): Impact on Morbidity, Mortality, and Loss To Follow-Up in a Large HIV Treatment Program in Western Kenya | | |
| **Investigator(s):** | A. Bell, S. Kimaiyo, K. Wools-Kaloustian, A. Katschke, C. Shen, H. Liu, C. Duefield, G. Simiyu, B. Musick, J. Sidle, A. Siika, P. Braitstein | | |
| **Start Date:** | 9/1/2006 | **Project End Date:** | 3/31/2011 |
| **Site(s):** | All Sites | | |
| **Project Description:** | From March 12 - August 31, 2007 (approximately 6 months), Kenya experienced a shortage of HIV-related medications. The United States Agency for International Development (USAID) funded Academic Model Providing Access to Healthcare (AMPATH) was asked by the Kenyan government to limit new cART initiation. The program agreed to limit the new cART starts to 1000 patients per month. For the 6 month period, AMPATH continued to start new patients with CD4<100 cells per cubic millimeter, but limited the number started with the usual criteria, effectively 'capping' new cART initiations. The objective of this retrospective analysis was to determine the impact of the restriction on morbidity, mortality, and loss-to-follow-up. We conducted an analysis of all patients who were (i) non-pregnant adults (age 14 or older); (ii) enrolled either during the six-month period with restricted cART (the 'cap' period) or the six months prior (the 'pre-cap' period); and (iii) eligible for cART at enrollment by the pre-cap standard, that is, (1) CD4 < 200; (2) WHO stage 4 illness; or (3) WHO stage 3 AND CD4 < 350. Primary endpoints are compared between the cap and pre-cap cohorts. Descriptive statistics are used to summarize key variables. Kaplan-Meier estimators are used to estimate survival probabilities. Cox proportional hazard model is used to adjust for potential confounders. | | |
| **Update:** | The analysis has been completed. The manuscript is under review at AIDS Research and Treatment. | | |
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| **Project Name:** | REACH Informatics Center of Excellence | | |
| **Investigator(s):** | P. Biondich, A. Siika, P. Braitstein, L. Diero, J. Sidle, S. Downs, J. Hogan, K. Kroenke, B. Mamlin, E. Meslin, D. Ngare, W. Nyandiko, W. O'Meara, M. Overhage, M. Palakal, J. Rotich, C. Shen, R. Vreeman, M. Were, K. Wools-Kaloustian, C. Yiannoutsos | | |
| **Start Date:** | 6/1/2009 | **Project End Date:** | 6/30/2014 |
| **Site(s):** | MTRH | | |
| **Project Description:** | The project is a collaboration between Indiana and Moi Universities and the global leadership of the Regenstrief Institute. The project/program is mandated to;<br>1. Provide post-doctoral informatics training to faculty at Moi University and Moi Teaching and Referral Hospital to implement and use health information technology to enhance research and improve health care quality, efficiency and outcomes.<br>2. Support the training of East Africans so as to support the development, implementation, maintenance, evolution and use EHRs in low-income countries through didatic and mentored practicum training programs. | | |
| **Update:** | Events:<br>• OpenMRS Implementers workshop was held in June and attended by 18 participants largely from KEMRI programmes in Kenya. 12 AMPATH staff were engaged in the workshop<br>• Data Management training focusing on Data Quality and Assurance was held in July and attended by 19 participants.<br>• Developers beginners training was held in the months of September and October. Attended | | |

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| | by 8 participants from Kenya and Uganda. AMPATH & Regenstrief developers facilitated the training.<br>Updates:<br>• Fellowship selection for 2012 is ongoing. Candidates will be selected by the end of December 2011.<br>• There are currently two fellowship students at Indiana with one engaged in research work in Eldoret. –<br>• Sponsored 3 participants for the OpenMRS Implementers conference 2011. - Planning for short courses trainings for 2012.<br>Challenges: There areinadequate facilities for training (venues/rooms) at the AMPATH Centre. | | |
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| **Project Name:** | Reduce Alcohol First in Kenya Intervention (RAFIKI) | | |
| **Investigator(s):** | R. Papas, B.Gakinya, J.Baliddawa, J.Sidle | | |
| **Start Date:** | 4/1/2012 | **Project End Date:** | 3/31/2017 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This study will determine whether a group cognitive-behavioral therapy intervention that demonstrates preliminary evidence of reducing alcohol use among HIV-infected outpatients in western Kenya is effective when compared against a group health education intervention in a large sample over a longer period of time. It will be delivered by paraprofessionals, individuals with limited formal education and little or no relevant professional experience. This approach is consistent with successful cost-effective models of service delivery in resource-limited settings in which paraprofessionals (e.g., clinical officers, traditional birth attendants and peer counselors) are trained. | | |
| **Update:** | Interviews for RAs and counsellors were conducted in the month of October. Their contracts will be prepared in November and training of the new staff will be held in December. | | |
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| **Project Name:** | Renal Study | | |
| **Investigator(s):** | C. Wyatt, W. Owino Ong'or, K. Wools-Kaloustian, J. Abuya | | |
| **Start Date:** | 12/10/2007 | **Project End Date:** | 12/10/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This study is comparing the performance of equations to estimate kidney functions to a direct measure of kidney functions based on the plasma disappearance of iohexol, following an injection in HIV infected patients | | |
| **Update:** | The study has been permanently closed to accrual after achieving the target number of participants, and remains open for data analysis and manuscript preparation only. | | |
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| **Project Name:** | Screening for Cervical Cancer in HIV-Positive Kenyan Women: The Role of Human Papillomavirus Typing | | |
| **Investigator(s):** | E. Dainty, E. Omenge, D. Walmer, S. Cu-Uvin, J. Carter, D. Westreich | | |
| **Start Date:** | 10/11/2011 | **Project End Date:** | 7/1/2012 |
| **Site(s):** | MTRH, Mosoriot, Turbo | | |
| **Project Description:** | Among HIV positive women in Kenya, cervical cancer has the highest incidence of any malignancy. In order to effectively screen HIV-infected women for cervical cancer, an understanding of the natural history of human papillomavirus (HPV) and HIV co infection is critical, as HPV infection in the causative agent for cervical cancer. Emerging data supports the existence of geographically disparate types of HPV, particular those causing invasive cervical cancer in HIV positive women. This study will investigate HPV genotype distribution in HIV-infected Kenyan women with the following objectives: | | |

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| | • Objective #1: To describe the prevalence of HPV genotypes in HIV infected women with cervical dysplasia and invasive cervical cancer in Eldoret, Kenya.<br>• Objective #2: To determine how CD4 count relates to HPV genotype distribution between women with cervical dysplasia and cervical cancer. Samples for HPV genotyping will be collected as one-time cervical swabs from patient encounters. These samples will be sent to Innogenetics, a lab in Mombasa, Kenya that is owned by collaborators from Belgium. Study investigators are currently exploring the possibility of performing the HPV genotyping at the immunology lab at Moi Teaching and Referral Hospital. Our hope is that we will be able to introduce this test at Moi Teaching and Referral Hospital, and thus build the local capacity for diagnostics on site. | | |
| **Update:** | Enrollment started October 11. We expected full accrual by February. No major issues or concerns. | | |
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| **Project Name:** | Street Children & Substance Abuse: Knowledge, Attitudes & Practices in Kenya | | |
| **Investigator(s):** | L. Embleton, P. Braitstein, D. Ayuku | | |
| **Start Date:** | 5/22/2011 | **Project End Date:** | 1/1/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | Objectives: To a) describe the knowledge, attitudes, and practices (KAP) of street-involved children and youth aged 10 to 19 in Eldoret, Kenya; b) to describe the frequency of drug and alcohol use among this population; and c) describe factors associated with the use of all substances used by street-involved children and youth in Eldoret, Kenya. Data obtained from this study will inform policy, programs and services directed towards street-involved children and youth in resource-constrained settings. | | |
| **Update:** | Enrolling of subjects and data collection is complete. Data analysis is on going | | |
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| **Project Name:** | Symptom Screening: Diagnostic Usefulness to Detect Pulmonary Tuberculosis in HIV-Infected Pregnant Women in Kenya | | |
| **Investigator(s):** | E. J. Carter, R. J Kosgei, M. Ndavi, J. O. Ong'ech, J. M. Abuya, A. M. Siika, K. Wools-Kaloustian, H. Mabeya, T. Fojo, A. Mwangi, T. Reid, M. E. Edginton | | |
| **Start Date:** | 10/1/2009 | **Project End Date:** | 10/2/2011 |
| **Site(s):** | | | |
| **Project Description:** | Published | | |
| **Update:** | R. J. Kosgei, P. Muia Ndavi , J. O. Ong'ech, J. M. Abuya , A. M. Siika, K. Wools-Kaloustian, H. Mabeya, T. Fojo, A. Mwangi,T. Reid, M. E. Edginton, E. Jane Carter : Symptom screening: diagnostic usefulness to detect pulmonary tuberculosis in HIV-infected pregnant women in Kenya- Public Health Action 2011: Advance release doi: http://dx.doi.org/10.5588/pha.11.0004 | | |
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| **Project Name:** | The IU Simon Cancer Center (IUSCC) AMPATH-Oncology Institute (AOI): An Exemplar of Care for the Developing World and a Population-Based Research Environment for IUSCC | | |
| **Investigator(s):** | T. Inui, N. Busakhala, C. Asirwa, O. Omege | | |
| **Start Date:** | 7/1/2011 | **Project End Date:** | 6/30/2014 |
| **Site(s):** | Yet to be determined | | |
| **Project Description:** | Kenya, like much of the developing world, is rapidly undergoing an 'epidemiologic transition' from a health scene dominated by infectious diseases to one in which the major causes of death and disability are cancer and other chronic diseases. Under these circumstances, applying science to the management and control of cancer has become as relevant to Kenya as it is in the United States. Similarly, what is learned about the prevention and treatment of cancer in the | | |

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| | developing world literally has direct relevance to care in the United States. Cancer care and attendant research in Kenya, whose population is the most genetically diverse in the world, will catalyze the discovery of new genes of importance to our fight against cancer, new genomic predictors of cancer, and new genetic variants that predict response to therapy. Recognizing both emerging threats to population health and potential for advancing care and science, the IU Simon Cancer Center (IUSCC) and the IU-Kenya AMPATH Program have been actively pursuing resources to respond. The focus of the partnership is to develop a sustainable and comprehensive academic clinical care program that will serve the citizens of western Kenya, and in the process, create a unique program of international collaboration for patients with, or at risk for, malignancies. The mission of the AMPATH Oncology Institute (AOI) is to be the premier cancer program in Sub-Saharan Africa, noted for excellence in cancer prevention, treatment and palliative care. AOI activities will directly contribute to advances in cancer care, accelerate discoveries in the biology and treatment of cancer, and provide support for the IU Simon Cancer Center's quest to become a federally designated Comprehensive Care Center. | | |
| **Update:** | This project has been activated administratively. The leadership group is holding regular meetings. Pilot project protocols are in preparation. | | |
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| **Project Name:** | The Prevalence of Markers of Atherosclerosis Among Adult Patients with Congestive Cardiac (heart) Failure | | |
| **Investigator(s):** | E.Velazquez, S. Kimaiyo,G. S. Bloomfield, J. E. Carter, M. Maghasi, C. Akwanalo, J. Hogan | | |
| **Start Date:** | 5/24/2010 | **Project End Date:** | 5/31/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | Using a case-control research design in a Kenyan population with heart failure, this project will describe the range of etiologies of heart failure within this population. This project will collect pilot data on the burden of atherosclerosis and malnutrition among patients with heart failure at Moi Teaching and Referral Hospital (MTRH) Inpatient ward, Primary Care and Cardiology Clinics, through the collection of both echocardiographic and serologic studies coupled with clinical assessments; thereby informing hypotheses for larger prospective, regionally-relevant analyses in the future. | | |
| **Update:** | The study was amended in June 2011 to increase the number of participants by consenting and enrolling at least 40 more patients; to recontact study participants in order to collect blood samples for 4 (four) new blood tests in accordance with the study co-sponsor; and perform carotid ultrasonography. These amendments have been approved by all IRBs. We are waiting to receive final approval from the sponsor before recruitment continues. | | |
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| **Project Name:** | The Relationship of Indoor Air Pollution (IAP) Exposure to Isolated Right Heart Failure (IRHF) in Women in Western Kenya | | |
| **Investigator(s):** | C. Sherman, S. Kimaiyo, J. E. Carter, J. Hogan, D. Lagat, L. Diero | | |
| **Start Date:** | 11/22/2010 | **Project End Date:** | 1/31/2012 |
| **Site(s):** | MTRH | | |
| **Project Description:** | This pilot study aims to look at the association of Isolated Right Heart Failure (IRHF), pulmonary function abnormalities and Indoor Air Pollution in women in western Kenya. The information gained will be utilized for the preparation of a larger study as well as harm reduction strategies for the reduction of IAP. | | |
| **Update:** | This study was amended in February 2011 to exclude women who are current smokers only and to include women who live within an area reached by 60 minutes of driving from MTRH. Data entry and follow up of participants is currently ongoing. | | |
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