

## Comparative Adjuvant HIV Vaccine Trial Begins in Kenya

In February, MHRP and partners will launch a Phase 1 comparative adjuvant study in Kericho, Kenya, to evaluate experimental HIV-1 Env DNA and gp145 vaccines combined with different adjuvants, including an Army-developed Army Liposome Formulation (ALF) adjuvant.

An adjuvant is a substance added to vaccines that can help to make the vaccine more effective by improving the immune response or causing the immune response to last longer than without the adjuvant. The goal of the Kericho trial, RV460, is to find whether an adjuvant can improve immunogenicity of the candidate vaccines. It will also help characterize the differences between the adjuvants and the role of adjuvants in priming versus boosting.

One of the adjuvants to be evaluated in RV460 is ALFA, one of the ALF family of adjuvants developed by MHRP (see sidebar). The gp145 protein vaccine was also developed by MHRP researchers, led by Dr. Victoria Polonis.

Dr. Gary Matyas is the Principal Investigator of RV460, which is funded by the DoD. It is a randomized, double blind trial with a target enrollment of 126 healthy adult participants. MHRP is conducting RV460 at the KEMRI/WRP Clinical Research Centre in Kericho, in collaboration with the United States Army Medical Research Directorate-Africa and NIAID Division of AIDS.



(From left) RV460 investigators Dr. Gary Matyas, Dr. Fred Sawe and Dr. Sandhya Vasan.

## ALF Adjuvant to be Evaluated in Three Clinical Trials in 2021



The Army Liposome Formulation (ALF) adjuvant developed by MHRP scientists will enter into three human clinical trials in 2021, two of which will be MHRP protocols to test the novel adjuvant in HIV vaccine formulations.

In a 2020 preclinical study conducted by MHRP, an HIV vaccine formulated with AFLA elicited stronger immune responses than a vaccine with a more commonly used alum adjuvant. Findings from the study were published in [PLOS Pathogens](#). ALFA will be used in the Phase 1 comparative adjuvant study in Kericho, Kenya in 2021.

ALFQ, which was awarded a patent in late 2019, was strongly potent as a vaccine adjuvant in preclinical studies. ALFQ is already in humans in two Phase 1 trials of candidate malaria vaccines at WRAIR and will enter its first HIV-related human clinical trial as part of an HIV vaccine formulation in Thailand in 2021.

ALFQ will also be tested as part of the SARS-CoV-2 vaccine developed at WRAIR. The Phase 1 trial is expected to begin in Spring 2021.

Watch a brief [video](#) for more information about the ALF adjuvants.

## COVID-19 and MHRP

In 2020, MHRP scientists joined forces with colleagues from the Emerging Infectious Diseases Branch at WRAIR to combat the latest infectious disease threat, COVID-19. MHRP provides expertise, honed through years of HIV research, to help develop and test a vaccine and discover monoclonal antibodies that may be used to prevent or treat COVID-19.

Visit [MHRP's website](#) for more details about how MHRP scientists are contributing to COVID research.

MHRP partner laboratories in Africa and Asia also pivoted to help detect and track the COVID pandemic. MHRP has helped develop research infrastructure at more than a dozen sites in African countries, and also supports multiple PEPFAR sites in Africa. Many of these MHRP-supported research laboratories are being leveraged for COVID-19 testing, substantially expanding testing capabilities within these African countries. Additionally, our collaborators at AFRIMS in Bangkok quickly stood up diagnostic testing capabilities to support the US embassy community and local partners, for which they received an award from the US Ambassador.

Many of our clinical studies were paused during the year, and all have now safely resumed. Our U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program adapted its implementation during COVID-19, successfully adjusting its prevention, testing and treatment in order to sustain gains made prior to the pandemic.

For more information on WRAIR's efforts to combat COVID-19, please visit [www.eidresearch.org](http://www.eidresearch.org).

## MHRP Selected as Clinical Trial Unit for NIAID Research Networks

MHRP, with WRAIR and the Henry M. Jackson Foundation (HJF), was selected by the (NIAID) at the National Institutes of Health as a Clinical Trials Unit (CTU) for their HIV research networks for the next seven years.

Four MHRP partners sites in Thailand and Africa will conduct HIV research with support from the HIV Vaccine Trial Network (HVTN) and the AIDS Clinical Trials Group (ACTG). The new MHRP CTU includes:

### HVTN Clinical Research Sites:

- National Institute for Medical Research (NIMR) - Mbeya Medical Research Center (MMRC) in Mbeya, Tanzania
- Mahidol University in Bangkok, Thailand
- KEMRI/WRP Clinical Research Centre in Kericho, Kenya

### ACTG Clinical Research Sites:

- KEMRI/WRP Clinical Research Centre in Kericho, Kenya
- Moi University in Eldoret, Kenya

MHRP has worked with the NIAID networks since 2008, beginning in Kenya as part of the ACTG. The collaboration expanded into Tanzania and Mozambique with the HVTN in 2013. The co-principal investigators for the new award are Dr. Merlin Robb and COL Julie Ake.

This new award allows MHRP to continue to contribute to the global effort to improve the prevention and treatment of HIV through these clinical trial networks. This award is a reflection of the program's outstanding clinical research partners in Africa and Thailand.



*Team members at the National Institute for Medical Research - Mbeya Medical Research Center (MMRC) in Mbeya, Tanzania, including director Dr. Nyanda Elias Ntinginya (center). MMRC was selected once again as a partner for HVTN studies.*

# Operation Triple Zero Empowers Adolescents and Young People Living with HIV to Take Control of Their Health

In Kenya, the HIV epidemic among adolescents and young people between the ages of 10 and 24 is characterized by relatively high HIV incidence and sub-optimal treatment outcomes, including a high loss to follow-up, low adherence to treatment and low viral suppression. MHRP and local partners initiated Operation Triple Zero (OTZ) in its Kisumu West program, with the goal to have zero missed clinic visits, zero missed pills/medications, and zero viral load.

Weekend clinic hours were established to help adolescents keep up with appointment visits, as previous weekday hours conflicted with the school day. These clinic hours have led to increased attendance, thereby significantly improving retention, viral load monitoring and timely dose adjustment and ART optimization among this age group.

The Kisumu West program has also enrolled more than 540 adolescents into OTZ clubs, where adolescents receive peer support and share best practices for adhering to treatment.

“OTZ clubs have instilled positive behavior change among our adolescents as they get opportunity to interact with one another and with health worker mentors in a constructive way,” said Christine Magak, pediatric lead for the program. “This has greatly enhanced their adherence habits, reduced stigma and improved their performance in school.”

These activities are improving treatment outcomes among this age group. In a recent quarter, 60% of participants who began with high viral loads achieved re-suppression.

“Before I joined OTZ, I constantly had high viral load and, at one point, had lost hope in life,” said one participant named Rachel. “I made a commitment never to miss my medication... Today, I am virally suppressed and able to educate my fellow youths on the importance of good adherence for improved quality of life.”

Operation Triple Zero is an initiative of the President’s Emergency Plan for AIDS Relief (PEPFAR). MHRP has implemented PEPFAR in Kenya since 2004.



*Participants attend a learning session during a monthly OTZ club meeting at Bodi Health Center in Kenya.*

## STI/HIV Behavioral Intervention Study Opens at Joint Base Lewis-McChord

In late 2020 MHRP began enrollment at Joint Base Lewis-McChord for the KISS study, which stands for Knocking out Infections through Safer sex and Screening.

The study is a prospective trial to assess the acceptability and efficacy of a sexually transmitted infection (STI)/HIV behavioral intervention program in a population of Army personnel and other beneficiaries of the military health system. In addition to standard STI prevention counseling routinely provided by military medical treatment facilities,

the intervention arm will receive an evidence-based, gender-specific, interactive educational program and follow-up communications via text and telephone to reinforce concepts learned during the in-person educational session. Changes in sexual behaviors are evaluated via behavioral surveys at enrollment, six, and twelve months.

MHRP research physician Dr. Donn Colby is protocol chair for the study. It is expected to open at Fort Bragg later this year.

## MHRP in Nigeria to Help Develop National Key Population HIV and STI Guidelines



*Formal inauguration meeting of National Steering Technical Working Team for development of national HIV and STI KP service delivery guidelines*

MHRP/HJFMRI Ltd. Gte in Nigeria has been awarded funding to help develop national guidelines for key population (KP) services, funded by the Global Fund to Fight AIDS, Tuberculosis, and Malaria.

Although current guidelines are in place for general care in Nigeria, this initiative will modify the current minimum package of prevention intervention (MPPI) strategy to make it more inclusive and mindful of KPs, who comprise 40% of the HIV epidemic. The MPPI has not been updated since 2013 and serves as the backbone for HIV prevention guidelines.

“It is a very exciting opportunity and a great honor for the program to be contributing to such a national process, in such a recognizable manner” said Dooshima Uganden-Onkonkwo, Prevention Program Manager of HJFMRI Ltd. Gte in Nigeria. “Our team has been very successful in reaching KPs through our PEPFAR-supported program, and now we can apply our expertise to benefit even more people through these new national guidelines.”

A crucial part of the initiative is creating an extensive network of one-stop shop (OSS) clinics across the country. Currently, OSS clinics are available in a few metropolitan areas such as Lagos and Port Harcourt.

The OSS clinics are community centers that serve as a safe place for prevention, testing and treatment options. This model has demonstrated an excellent performance and its expansion will ensure safe access to high quality services to a larger section of KPs across Nigeria.

## DREAMS Program Celebrates First Ever Graduation in Mbeya, Tanzania

Thousands of voices joined together in song as MHRP partners in Mbeya City, Tanzania, hosted the first ever DREAMS program graduation, where 1,804 adolescent girls and young women (AGYW) celebrated their completion of the core DREAMS training.

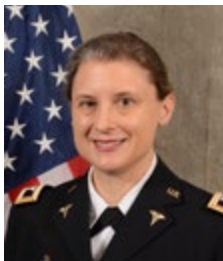
The DREAMS initiative, funded by PEPFAR, is conducted with HJFMRI and many local partners and aims to help young women become Determined, Resilient, Empowered, AIDS-free, Mentored and Safe through education, vocational training and other evidence-based interventions.

Since MHRP launched DREAMS in Tanzania 2016, the program has reached 22,103 AGYW and has 241 DREAMS ambassadors. The program offers various methods of family planning and teaches girls entrepreneurial skills including electronic technician training, tailoring, hair dressing, soap making, tie-dyeing and more. Beyond learning entrepreneurial skills, the AGYWs participate in money saving and economic strengthening groups.



*In September 2020, DREAMS in Mbeya Region celebrated the first ever DREAMS graduation for 1,804 adolescent girls and young women (AGYW) who completed the core training program.*

## MHRP Leadership Update: New Roles



[COL Julie Ake](#) was selected as the Director of MHRP at WRAIR in July 2020. COL Ake has been with MHRP since 2010 and has served as WRAIR's Deputy Principal for the President's Emergency Plan for AIDS Relief (PEPFAR) program as well as the Principal Deputy Director for MHRP.

[Dr. Rasmi Thomas](#) is now the Chief of MHRP's new Laboratory of Integrative Multiomics (LIM). Dr. Thomas has led the Host Genetics Section (HGS) where she's built an impressive omics repertoire that she has applied across multiple significant HIV vaccine, therapy, and pathogenesis questions. In addition, she recently launched the Advanced Sequencing Core which will be paired with HGS to make up LIM. Dr. Thomas is also MHRP's newest Department of the Army civilian.

In July 2020, [Dr. Trevor Crowell](#) became the Associate Director of the Department of Epidemiology and Threat Assessment (DETA) at MHRP. In his new role, he oversees cohorts and other epidemiologic studies of HIV, sexually transmitted infectious (STIs), and other infectious disease threats to global public health and U.S. military force readiness.

[Dr. Denise Hsu](#) assumed the role of Associate Director of Therapeutics in 2020 where she will be taking over the HIV remission portfolio. Dr. Hsu previously was the head of the nonhuman primate lab, Department of Retrovirology, at the Armed Forces Research Institute of Medical Sciences (AFRIMS) in Thailand.

See [website](#) for more information on MHRP leadership and scientists.

## More Stories on the new MHRP website: [hivresearch.org](http://hivresearch.org)



### [A Life Transformed by PEPFAR](#)

Few stories exemplify the purpose and the promise of PEPFAR as clearly as that of Joyline, whose 16-year experience with the Walter Reed Program-Kenya has caused ripples through her life that have grown to touch her family and community.

"It used to be that an HIV diagnosis was a death sentence that created a lot of despair," said Dr. Fred Sawe, the HJFMRI director for MHRP in Kericho, Kenya. "PEPFAR has been able to turn that problem upside down, so now a positive diagnosis is a mark of life, enabling people to get help and treatment. It's transformed lives and communities in Africa."



### [A Key Member of our Thailand Team: A Speedy Motorcycle Courier](#)

MHRP's researchers at the AFRIMS in Bangkok, Thailand have the unique capability to interrogate the impact of HIV in mucosal and lymphoid tissues. This research directly translates into supporting MHRP's product development in the context of prophylactic vaccines as well as in cure studies.

This critical work depends on a speedy motorcycle courier who safely, securely and quickly transports valuable specimens to the lab. The couriers ensure that specimen integrity is maintained while navigating busy Bangkok traffic.

# MHRP and Collaborators at HIVR4P 2021 | Jan 27-28 and Feb 3-4

MHRP at the HIV Research for Prevention Conference (HIVR4P // Virtual) that features the latest in biomedical HIV prevention research and implementation in a new virtual format

Presenter	(#) Title	Date	Time (EST)	Session
Carolyn Williamson*	(1409) Analysis of genetic diversity and VRC01 pressure on HIV-1 break-through viruses from the AMP trial (HVTN 703/HPTN 081 and HVTN 704/085)	Wednesday 27 January	12:30 - 1:30 pm	The clinical march of bNAbs
<b>COL Julie Ake†</b>	Session Co-Chair	Thursday 04 February	10:00 - 11:00 am	In vivo modulation of immune response to vaccination
<b>Sandhya Vasan*</b>	(33) Progress with delayed boosting vaccination	Thursday 04 February	11:15 - 12:15 pm	An ambitious and advancing pipeline: T-cell and non-neutralizing antibody-based vaccine strategies
<b>Alexandra Schuetz*</b>	(990) Dynamics of mucosal immune responses elicited by systemic prime/boost vaccination	Thursday 04 February	5:30 - 6:30 pm	Mucosal transmission and immune responses
<b>Thembi Mdluli</b>	(811) Impact of baseline variables on time to viral rebound after treatment interruption in acutely treated HIV-1 infected participants	on-demand		
<b>Alexandra Schuetz</b>	(991) Impact of gender affirmation surgery and exogenous hormones on mucosal immune responses and risk of HIV transmission in transgender women	on-demand		
<b>Nicole Dear</b>	(589) Factors associated with transactional sex in the African Cohort Study	on-demand		
<b>Samantha Townsley</b>	(660) Founder Env-specific IgM B cell responses during acute HIV-1 infection associate with the development of broadly neutralizing antibodies	on-demand		
<b>David Chang</b>	(623) Viral Suppression and CD4 counts with transition to TDF/3TC/DTG (TLD)	on-demand		
Nkechinyere Harrison	(1383) Effect of multi-month ARV dispensing on HIV clinic attendance at 68 Nigerian Army Reference Hospital Yaba, Lagos	on-demand		
Vincent Muturi-Kioi	(958) Recommendations and considerations for developing a biometric system to prevent co-enrollment in HIV and infectious disease clinical trials	on-demand		
Siriwat Akapirat	(1097) Vaccination with Ad26.ZEBOV, MVA-BN-Filo or MVA-BN-Filo, Ad26.ZEBOV induced predominantly IgG binding to Ebola glycoprotein in cervi-co-vaginal mucus in HIV-infected and uninfected participants	on-demand		

**bold** - MHRP

\* - oral abstract

† - Co-Chair

Thursday, January 28, 7:45-8:45am

## “Engaging Lake Victoria Fishing Communities in HIV Prevention Research: Lessons from Uganda, Kenya and Tanzania”

Four presenters will discuss unique challenges and novel approaches to enhance community engagement in fishing communities in East Africa. The satellite will draw from lessons learned in Uganda, Kenya, and Tanzania by the Lake Victoria Consortium for Health Research (LVCHR).

MHRP’s IT Director Matt Johnston will present on a technology developed to prevent co-enrollment in clinical studies.



Wednesday, February 3, 1:45-3:15pm

## “Engagement of African Men and Transgender Women Who Have Sex with Men in HIV Research”

The satellite, co-hosted by MHRP and IAVI and co-organized by MHRP’s Dr. Trevor Crowell, will address how to effectively engage key populations who are at especially high-risk of HIV infection in sub-Saharan Africa.

The first panel consists of five presentations which will explore characterizing gaps in engagement around PrEP, care and treatment and the HIV/STI syndemic. They will also discuss the spectrum of sexual and gender minorities affected by HIV, and community perspective around effective engagement.

The second panel will discuss how African MSM and TGW can be successfully engaged in planned HIV biomedical prevention trials, recruitment and retention strategies and best practices and tools to inform future research in Africa and other regions. Presentations will examine online strategies for engagement, mobilization to diagnose HIV earlier, and community perspective for new strategies.