NEWSLETTER







Pictured: Fred Hutch campus, home of HANC offices and staff in Seattle, WA

HANC ANNOUNCEMENTS

Hot off the Press: Addressing Ethical Challenges in US-based HIV Phylogenetics Research

HIV phylogenetics research can help determine the relatedness of one person's HIV to another's, as in HPTN 052 and other partner studies. In 2018, the NIH convened a working group led by Dr. Liza Dawson to develop recommendations for ethical considerations in HIV phylogenetics research. The working group has now published its recommendations in JID. The JID editorial commentary notes:

"Researchers have a duty not to proceed with studies that will endanger their participants, and only guidance from such multidisciplinary groups can lower the risk of this happening accidentally."

HANC's Brian Minalga is one of the authors of this multidisciplinary paper that will help guide future HIV research.

Addressing Ethical Challenges in US-based HIV Phylogenetics Research

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Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at mhvu@fredhutch.org



PROTOCOL QUICK SUMMARY TOOL

Located on the HANC Portal

What is it?

The "Protocol Quick Summary" on the HANC portal is a resource that allows you to search information on DAIDS-funded protocols.

How do I use it?

Users can search for study information including study design, investigational products, status history, end points, team members, affiliated sites, and all protocol documents.

Enter your terms into a search field to display all related items. Click on the "Protocol No" to review an individual entry.

To access approved protocol documents (protocol, clarification memos, and letters of amendment), select "*Click here to view documents associated with this protocol*" under the "*Protocol Documents*" heading.

Please Note: Protocol documents are considered confidential, for reference only, and are not to be circulated.

The data displayed on this site is pulled from the NIAID Clinical Research Management System. NIAID CRMS is the database of record and should be referred to for real-time protocol information.



How can I access it?

Visit <u>https://portal.hanc.info/pm/SitePages/Home.aspx</u> and sign in with your HANC Portal username and password. If you forgot your HANC Portal log in information, you can reset your password and get help <u>here</u>.

The HANC Portal is a members-only, restricted site for use by members of committees and working groups coordinated by HANC.



Several of the NIH HIV/AIDS networks will have a presence at the 23rd International AIDS Conference (<u>AIDS 2020: Virtual</u>) held between July 6 to July 10, 2020. A summary listing of accepted sessions by network can be found <u>here</u> on the HANC website.

Updates from the COVID-19 Prevention Trials Network (CoVPN)



The HVTN and HPTN join the NIAID-funded Infectious Disease Clinical Research Consortium and sites affiliated with the ACTG in the COVID-19 Prevention Trials Network (CoVPN), a collaborative network that will be involved in implementing COVID-19 vaccine and monoclonal antibody efficacy trials in the coming months.

CoVPN 5001

The COVID-19 Prevention Network (CoVPN) begins its CoVPN 5001 study designed as a "dry run" for future trials that will test the efficacy of COVID vaccine candidates. CoVPN 5001 is designed to develop the clinical and laboratory pipelines for the rapid implementation of COVID vaccine efficacy trials while conducting groundbreaking scientific investigations. Approximately 800 study participants aged 18 years and older who have tested positive for SARS-CoV-2 infection will be enrolled at more than 60 participating trial sites in the United States, South America and sub-Saharan Africa. Interested individuals can email CoVPN.SBS-CEU@fredhutch.org for more information.



ACTG at AIDS 2020

The ACTG will make three presentations at <u>AIDS 2020: Virtual, the 23rd</u> <u>International AIDS Conference</u>, taking place July 6-10, 2020. ACTG investigators will highlight findings in an oral presentation regarding the efficacy and safety of third-line treatment regimens in resource-limited settings, a poster discussion on viral rebound rates after treatment interruption of modern ART, and a poster presentation assessing whether a standardized frailty score can improve clinicians' ability to estimate cardiovascular risk among people living with HIV who are aging.

Presentations at AIDS 2020 include the following:

Third-Line Antiretroviral Therapy including Raltegravir, Darunavir/Ritonavir and/or Etravirine Is Well Tolerated and Achieves Durable Virologic Suppression over 144+ Weeks in Resource Limited Settings (A5288; On-Demand Oral Abstracts & Poster Discussions OAB0404: Oral Abstract) Anchalee Avihingsanon, et al Topic: Antiretrovirals session 2



A5288 is a strategy trial that aimed to address challenges posed by second-line ART failures among people living with HIV in resource-limited settings. Participants with resistance to lopinavir and/or all NRTIs started third-line regimens based on their resistance profiles that included raltegravir, darunavir/ritonavir, and/or etravirine. This presentation reports on long-term outcomes over more than 144 weeks, showing good tolerability and durable virologic suppression.

Time to Viral Rebound After Interruption of Modern Antiretroviral Therapies (A5345; On-Demand Oral Abstracts & Poster Discussions PDB0102: Oral Poster) *Jonathan Z. Li, et al* Topic: Achieving virologic suppression

Strategies to achieve ART-free HIV remission will require treatment interruptions (TI). The time to viral rebound with older oral ART regimens is known, but it is unclear if it is the same, longer, or shorter after the interruption of more modern ART regimens. A5345 compares the timing at which viral rebound occurs when interrupting modern ART regimens to data from historic TI studies.

Comparison of the Frailty Score and the Pooled Cohort Equations in Predicting Cardiovascular Disease Among Persons with HIV (A5322; On-Demand E-Poster PEB0215: Poster room B) *Frank J. Palella et al* Topic: Comorbidities

The 2013 pooled cohort equations (PCE) for estimating 10-year atherosclerotic cardiovascular disease (CVD) risk has underestimated CVD events among people living with HIV. Frailty is associated with multiple adverse health consequences, including incident CVD, in both people living with HIV and the general population. This study evaluates whether adding the frailty score to the typical PCE improves its ability to estimate CVD risk among people living with HIV who are aging.



The 23rd International AIDS Conference (AIDS 2020) will take place virtually from 6-10 July. The conference will feature a combination of satellite sessions, community networking events, exhibitions, workshops and a Global Village.

HPTN researchers will present 17 abstracts covering <u>HPTN 068</u>, <u>HPTN 069</u>, <u>HPTN 071</u>, <u>HPTN 074</u>, <u>HPTN 078</u>, <u>HPTN 083</u>, <u>HPTN 084</u>, and the <u>Modeling</u> <u>Centre</u>. The HPTN <u>Scholars Program</u> will host a satellite session entitled "The Next Generation of Emerging Leaders of Color in the HIV Prevention Landscape," featuring three presentations from current and past scholars with a Q&A session to follow. A second satellite session, entitled "Spotlight on Zambia PopART (HPTN 071-2) Phylogenetics Study," includes presentations from four researchers discussing different study results aspects.



HPTN members will host two virtual booths: one in the exhibition space and the other in the Global Village. Each will feature information about the Network, our community engagement efforts, and current studies and those in development. The Global Village booth will also include frequently asked questions about our two long-acting injectable cabotegravir for PrEP studies (HPTN 083 and HPTN 084).

AIDS 2020 webcasts, e-posters and links to abstracts will be available online after their initial presentation at this link: <u>https://www.hptn.org/presentedresearch/AIDS2020</u>



Wakefield's Retirement

It is bittersweet that we announce the retirement of Wakefield from the HIV Vaccine Trials Network and Fred Hutch, with his last day on July 2nd. Wakefield has been a champion and trailblazer regarding community and stakeholder engagement with the HVTN for 20 years. His leadership, sage advice, guidance, and advocacy have helped propel the HVTN forward leaps and bounds over the years. Wakefield leaves behind a legacy of influence, vision, and impact that will forever be etched into the fabric and framework of our network. It is an understatement to say that he will truly be missed by all of us here at the Core Operations Center, our sites, our CABs, and our communities. We wish him the absolute best in retirement and look forward to celebrating him in person when physical distancing restrictions allow. We all hope that you take a moment to recognize and honor this living legend in whatever way you are able.

Dr. Stephaun Wallace

We are excited to announce that our very own Dr. Stephaun Wallace will be assuming the role of Director of External Relations. Dr. Wallace has been with us at HVTN Core for 4 years as part of the SBS/CEU team. He joined the HVTN in 2016 as a Senior Community Engagement Project Manager, and then was promoted to Community Engagement and Social Scientist. Dr. Wallace has actually been affiliated with the HVTN for over 10 years through his prior collaborations with the University of Rochester clinical research site, so he is no stranger to our organization. Dr. Wallace is a research epidemiologist by training, with more than 20 years of sexual/public health experience with diverse populations including LGBTQ and MSM populations, and more than 25 years of social justice/community mobilization experience. In addition to his role with the HVTN, Dr. Wallace is a Staff Scientist in Fred Hutch's Vaccine and Infectious Disease Divion, and a Clinical Assistant Professor in the Department of Global Health at the University of Washington. He's also a US Army veteran, and received his Master of Science in Management/Organizational Leadership from Colorado Technical University, and a PhD in Public Health-Epidemiology from Walden University.



Mosaico Study Pause Lifted

To ensure the health and safety of study participants and staff, the leadership of the Mosaico study team has developed a specific process allowing activity to resume on a site-by-site basis when deemed safe to do so based on a risk assessment and approval for each location. Previously there had been a hold on certain clinical trial activities (such as screening and new enrollments) until June 1st 2020. As the pandemic evolves, this delay has now been lifted. Janssen and its partners will continue to closely monitor the COVID-19 situation.

AIDS 2020

AIDS 2020 will be virtual and gets underway soon. Please <u>register</u> and join the global conversations under the theme: **Resilience**. Join us in wishing <u>Susan</u> <u>Buchbinder</u>, M.D., Director of Bridge HIV at the San Francisco Department of Public Health and <u>Stephaun E. Wallace</u>, Ph.D., HVTN's Director External Relations the best on their talks at the conference. <u>Rafael Gonzalez</u>, Community Programs Manager at Bridge HIV, San Francisco Department of Public Health will present a virtual poster presentation.

- Susan will deliver a <u>plenary</u> titled: *Biomedical HIV Prevention: Beyond* daily oral PrEP
- Stephaun's talk is titled: Vaccine trial enrollment considerations in an era of PrEP and will be part of the session: <u>SSO5- Trials, tribulations and</u> prevention.
- Rafael's poster is titled: HIV Prevention Product Preferences Among
 Participants Who Completed The AMP HVTN 704/HPTN 085 Clinical
 Trial.



The IMPAACT Network is delighted and proud that data from IMPAACT P1093 and the ODYSSEY (PENTA20) study have informed the United States (U.S.) Food and Drug Administration (FDA) decision to approve the first-ever dispersible tablet formulation of Tivicay PD (dolutegravir) tablets for children as young as four weeks of age and weighing at least 3 kg (or about 6.5 pounds). IMPAACT P1093 is an ongoing pharmacokinetic (PK), safety and dose-finding study of dolutegravir in combination antiretroviral treatment regimens in infants, children, and adolescents living with HIV. The study has enrolled more than 180 children at 34 research sites in Botswana, Brazil, Kenya, South Africa, Tanzania, Thailand, Uganda, the U.S., and Zimbabwe.

Read More ViiV Press Release



The IMPAACT Network will present seven abstracts from six studies at AIDS 2020: four as poster presentations and three as oral presentations. Of note, IMPAACT 2002 is presenting primary results, IMPAACT P1093 is presenting results related to the dolutegravir dispersible tablets in young children, and IMPAACT P1078 is presenting additional results related to risk factors for hepatotoxicity among women living with HIV receiving isoniazid during and after pregnancy.

All presentations are listed here: <u>https://impaactnetwork.org/publications/aids2020.html</u>



Results from MTN-041 (the MAMMA study) were published in <u>JIAS</u>. The MAMMA study explored community attitudes and perceptions about the use of two HIV prevention products – Truvada as daily oral PrEP and the monthly dapivirine vaginal ring – during pregnancy and breastfeeding. The study took place in Malawi, South Africa, Uganda and Zimbabwe, and involved group discussions with pregnant and breastfeeding women, as well as their male partners, mothers and mothers-in-law. The study team also conducted interviews with community leaders, health care providers, midwives and traditional birth attendants, among others. Study results indicated that pregnant and breastfeeding women welcome options for HIV prevention that recognize personal preference and autonomy. These findings – and others from the study – are helping to inform the implementation of the <u>DELIVER</u> (MTN-042) and <u>B-PROTECTED</u> (MTN-043) studies in pregnant women and breastfeeding women, respectively.

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MEETING CALENDAR

In light of the COVID-19 pandemic, numerous events have been postponed or made virtual. Please check each event's website for the latest details.

June-Sept 2020 Saving Ourselves Symposium Series (Virtual)

June-Oct 2020 HIV2020 Online (Virtual)

July 6-10 AIDS 2020 (Virtual)

July 10-11 IAS COVID-19 Conference (Virtual)

Aug 9-14 <u>2020 National Ryan</u> <u>White Conference on</u> <u>HIV Care &</u> <u>Treatment</u> (Virtual)

Oct 21-25 IDWeek 2020 (Philadelphia, PA)

Oct 24-28 APHA 2020 (Virtual)

Nov 1-4 Adherence 2020 (Orlando, FL)

Jan 17-21 2021 <u>HIVR4P</u> (Cape Town, ZA)

For details and other events, visit the HANC calendar



WEBINARS & TRAINING

Training

Transgender Training Resources Available on the DAIDS Learning Portal

Check out the all new <u>Transgender Training Resources Website</u> on the DAIDS Learning Portal (DLP)! There you will find the full Transgender Training Curriculum for HIV Research, related guidance documents, selected publications, and other useful tools.

All staff are encouraged to complete the full training curriculum, including our most recent addition, <u>Clinical Considerations for Transgender Participants in</u> <u>HIV Research</u>. This module, which is intended for staff with clinical responsibilities, focuses on the provision of clinical care to transgender research participants and addresses topics such as taking a transgender participant's history, conducting a physical exam, the interaction between hormones and antiretrovirals, and the potential impact of other gender-affirming interventions on HIV.

In addition, to the e-learning module, an in-person training tool is also available, including a PowerPoint presentation, facilitator's guide, and selected resources in <u>English</u>, <u>Spanish</u>, and <u>Portuguese</u>.

HANC Webinar Archives

Missed a webinar you wanted to attend? Visit the <u>HANC website</u> to view archived recordings of past webinars. Recent webinars of interest include:

 <u>COVID-19 Impact on Latinx Communities</u> featuring Dr. Carlos Rodriguez-Diaz and Dr. Audrey Harkness (aired June 24, 2020)



HANC PROGRAM HIGHLIGHTS

Need to contact a HANC staff member? <u>Click here</u> to go to the About the HANC Staff page.

HANC Staff Situation Update

In accordance with Fred Hutch policies in response to the novel coronavirus situation in Washington state, HANC staff are working remotely until further notice. Work with HANC collaborators will continue with as few disruptions as possible.



Behavioral & Social Sciences

Greg Davis, HANC Project Manager

The Behavioral Science Consultative Group (BSCG) has decided to delay Part Two of the webinar series, "Adherence Support Intervention Approaches Used in the NIH HIV/AIDS Clinical Trials Networks" until August/September. Once a date has been

selected, registration information will be shared with HANC collaborators. Part One can be viewed here.

The Financial Disclosure Working Group is in the process of finalizing the Financial Disclosure and Conflicts of Interest SOP for the upcoming annual solicitation. The annual solicitation is set to occur on Monday, September 21.



Community Partners

Russell Campbell, HANC Deputy Director

Community Partners will be working with global communities focusing on issues and concerns regarding COVID-19 and HIV Research efforts to determine if there are materials or resources needed to help support research efforts related to HIV and/or COVID-19



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Data Management Center Working Group (DMCWG) met to discuss exploration of electronic clinical outcome assessment (eCOA), electronic consent solutions, and DMC involvement in COVID-19 studies. In addition, the group discussed ongoing work related to protocol deviation reporting and safety data reconciliation.

HANC PROGRAM HIGHLIGHTS

(Cross-Network Coordination, continued) The Cross-Network Evaluation Working Group (EWG) addressed COVID-19 impacts to network evaluation committee activities and adjustments to site evaluations and metrics in light of the disruptions to site research operations.

The Cross-Network Site Coordinators Working group (SCWG) discussed impacts of COVID-19 restrictions on site operations and site status with regards to resuming in-person clinical trials operations.

Opportunity Available: Infectious Diseases Research Manager

The Terry Beirn CPCRA CTU is hiring an Infectious Diseases Research Manager to support multiple domestic and international clinical research sites involved in COVID-19, Influenza, HIV prevention and therapeutics, and other infectious diseases within selected NIH-funded networks. More information about this position can be found <u>here</u> and by contacting Adriana Sanchez at Adriana.Sanchez@va.gov.



Laboratory Coordination

Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee held two conference calls to discuss lab site preparedness for the numerous COVID-19 therapeutic and vaccine trials schedule to open this summer. The group also discussed procedural changes for reopening ACTG

and IMPAACT HIV protocols, including changes to managing specimens in LDMS.

The Lab Focus Group held a conference call to discuss ongoing specimen shipment challenges, resuming DAIDS GCLP audits, and plans for resuming network protocols.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss CPQA proficiency testing updates, new network study compounds, including new COVID-19 treatments, and new guidance for labs on reagent vendors.

The Virology Quality Assurance Advisory Board held a conference call to discuss plans to resume VQA proficiency testing operations, and the scope of the new COVID-19 work taking place in the Duke VQA Program.

COVID-19 Laboratory Resources Webpage: HANC continues to share the latest lab-focused announcements and resources related to COVID-19 on the HANC Laboratory Resources webpage, located <u>here</u>.

HANC PROGRAM HIGHLIGHTS



The Legacy Project Brian Minalga and Louis Shackelford HANC Legacy Project Team

On July 2, Brian Minalga and Rona Siskind present, "Improving Gender Inclusion in HIV Research" to the ACTG Underrepresented

Populations Committee at 10 a.m. Pacific. Join the Zoom meeting here.

The DAIDS Cross-Network Transgender Working Group has completed its 5-part training curriculum, the Transgender Training Curriculum for HIV Research. The training is available on the new <u>DAIDS</u> <u>Transgender Training Resources page</u> along with several other resources from the working group.

<u>Addressing Ethical Challenges in US-based HIV Phylogenetics Research</u> was published in the Journal of Infectious Diseases. Brian Minalga is one of the authors on this multidisciplinary project convened by the NIH.

The Be the Generation <u>HIV Prevention Research training module</u> and the <u>Women's HIV Research</u> <u>Collaborative training</u> on biomedical HIV prevention have both been updated to reflect the results of HVTN 702 and HPTN 083.

ABOUT COMMUNITY PARTNERS

Community Partners

(CP) is a crossnetwork body charged by the Network Leadership and the Division of AIDS (DAIDS) with promoting representation of the communities within which the National Institutes of Health (NIH) HIV/AIDS clinical trials networks conduct research.

ABOUT THE LEGACY PROJECT

The Legacy Project works nationally to increase awareness and support for HIV prevention and treatment clinical and behavioral research by addressing factors that influence participation of historically underrepresented communities.

The Legacy Project Work Group (LPWG) is comprised of members from HANC, CP, network operations centers, clinical research sites, community members, and DAIDS. The LPWG works to increase representation and engagement of African-Americans, Latinos and Native Americans in HIV prevention and therapeutic research in the U.S.

WORKING GROUP MEMBER SPOTLIGHT

In an effort to highlight the work of HANC and members involved in HANC working groups, we would like to introduce you to a few of our members from Community Partners and the Legacy Project Working Group:



Raymond Allmond

Raymond is a member of Community Partners, active member of the Case Western Reserve University / University Hospitals unit's CAB, an ACTG-GCAB representative, and member of the Women's, Ethics, Data, CAB-HIV Aging ad hoc working groups and Community Scientific Sub-Committee HIV Aging working group. He is also the chair for the CAB-HIV Aging working group.

From Raymond: I am a 64-year-old PLWHIV Advocate/Activist diagnosed in July of 2000. I have been advocating for my community and people with HIV for 20+ years. My biggest challenge is finding enough time and resources to do all the work that is needed to fully serve the HIV community's needs in HIV research while still earning enough to make a reasonable living. I am especially impassioned in giving voice to the needs of underserved HIV populations including the aging HIV populations, women living with HIV, and historically underserved communities of color.

I am an artist in heart and spirit and believe that dedication, compassion and creativity are the keys to solving the ills of the world. I am an impassioned person living with HIV who believes that PLWHIV, like all of humanity, deserves the very best that life has to offer.



Harlan Pruden

Harlan Pruden (Nehiyô/First Nations Cree), whose mother is from the Beaver Lake Reservation and father from the Whitefish Lake Reservation, both located in northeastern Alberta – Treaty 6 territory, works with and for the Two-Spirit community locally, nationally and internationally. Currently, Harlan is a Ph.D. student at UBC and an Educator at Chee

Mamuk, an Indigenous public health program at BC Centre for Disease Control. Harlan is also the Managing Editor of the TwoSpiritJournal.com, a member of the Board of Trustees for the Vancouver Public Library and an Advisory Member for the Canadian Institutes of Health Research's Institute of Gender and Health. In August 2014, Harlan was appointed by President Obama to the US Presidential Advisory Council on HIV/AIDS (PACHA) and provided advice, information, and recommendations to the Secretary of Health & Human Services and the White House. (In December 2018, Harlan was (happily) fired/dismissed from PACHA by Mr. Trump via Fedex.)

RESOURCES

Newsletters

Be the Generation Newsletter

The Be the Generation (BTG) project builds scientific literacy and community capacity to engage with biomedical HIV prevention research. *BTG News* is its quarterly newsletter publication on biomedical HIV prevention research, geared for community audiences who are interested in the HIV prevention research field. <u>Click here</u> to view current and past newsletters. Email btg@hanc.info to subscribe.

Behavioral Science Interest Group Newsletter

Interested in behavioral science? Join the Behavioral Science Interest Group (BSIG) and subscribe to the BSIG Newsletter. Email Greg Davis at gpdavis@fredhutch.org for more details.

Laboratory

CNICS Research Network

The CFAR Network of Integrated Clinical Systems (CNICS) provides peer-reviewed-open access to a rapidly evolving clinical research platform that prospectively collects patient data, including validated outcomes, longitudinal resistance data, and detailed PROs with readily available biological specimens. <u>Click here</u> for more information.

EQAPOL

The goal of the External Quality Assurance Program Oversight Laboratory (EQAPOL) is to establish a panel of fully characterized viruses from acute/early and chronic HIV infections. Viral Diversity samples are available to NIAID-approved laboratories, and products created for the EQAPOL Viral Diversity Program are available to order. <u>Click here</u> for more information.

Specimen Repository

The specimen repository is a collaboration between the ACTG, IMPAACT, and HVTN clinical trial networks to make available to investigators the large body of specimens collected for HIV research. <u>Click here</u> to visit the site and request specimens.

Network Publications

Several of the HIV/AIDS clinical trials networks and collaborators publish their own newsletters, covering a range of topics from network-wide news to community level events. Links to various network publications are on the *Newsletters* page of the HANC website. <u>Click</u> <u>here</u> for more information.

OCSO MOB Newsletter

Looking for the latest on site monitoring and regulatory compliance? Check out the Monitoring Operations Branch (MOB) Newsletter, produced by the DAIDS Office of Clinical Site Oversight (OCSO). <u>Click here</u> to find newsletter archives.

NIH Corner

C3PNO Virtual Data Repository

The C3PNO Virtual Data Repository facilitates the sharing of HIV, substance use, clinical data, behavioral, and biospecimens collected by the NIDA longitudinal HIV cohorts with outside researchers. <u>Click here</u> to learn more or email c3pno.info@fstrf.org to request data or specimens.

ClinRegs

ClinRegs is an online database of countryspecific clinical research regulatory information designed to assist in planning and implementing international clinical research. <u>Click here</u> to explore ClinRegs.

NICHD Data and Specimen Hub (DASH)

NICHD DASH is a centralized resource for researchers to access data and biospecimens from NICHD-funded research studies for secondary analyses. <u>Click here</u> to explore DASH.

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