Land, Labor, and Justice Acknowledgements
We acknowledge the land we occupy today as the traditional home of the Duwamish, Tulalip, Muckleshoot, and Suyamish tribal nations, the original caretakers of this land who are still here. Without them we would not have access to this working, teaching, and learning environment. We commit to conducting ourselves with dignity and treating this land and all the life it sustains with respect. We ask you to join us in this commitment, wherever you may reside. We also acknowledge exploited labor and ongoing struggles for justice on this land. We reflect on the ancestors of our various peoples, nations, tribes, and families; ancestors whose struggles, pain, power, privilege, and strivings we hold in our very bodies.

Pictured: Fred Hutch, home of HANC offices in Seattle, WA.

HANC ANNOUNCEMENTS

HANC commemorates World AIDS Day and this year’s theme: Global solidarity, shared responsibility.

Read the Legacy Project's statement in the latest issue of Be The Generation News.

Welcome Pedro Goicochea!
HANC is delighted to announce that Pedro Goicochea, MSc, MA will join our team as a Legacy Community Engagement Project Manager, effective December 1, 2020. Pedro brings a wealth of domestic and international experience in stakeholder engagement in the conduct of HIV clinical research. Pedro started his work in HIV/AIDS in the late ‘80s at the AIDS Control Program of the Peruvian Ministry of Health managing the first national prevention campaign. Since 2000, he has coordinated communications, community education and involvement in HIV prevention clinical studies funded by NIH’s Division of AIDS including the iPrEx study, the first to prove the efficacy of pre-exposure prophylaxis to prevent sexually acquired HIV in men and transgender women.

With a background in social communication, Pedro holds a master’s degree in Health Promotion Sciences from the London School of Hygiene and Tropical Medicine and another in Communication Strategies from Universidad de Lima. Please join us in welcoming Pedro!
HANC ANNOUNCEMENTS

HANC 2021 Work Plan Finalized

The Office of HIV/AIDS Network Coordination (HANC) is pleased to announce that the HANC 2021 Work Plan has been finalized. Thanks to all of the HANC collaborators and work groups for their ongoing contributions to the HANC cross-network coordination efforts. Click here to view the work plan.

Announcing the Legacy Project Working Group Co-Chairs

The Legacy Project Working Group is pleased to announce that Tyler Adamson will join Jorge Benitez as the new Legacy Project Working Group Co-Chair. We are delighted to have Tyler as a new co-chair and we are thrilled that Jorge has agreed to continue as co-chair for the next two years.

Tyler Adamson is currently a Congressional Fellow in Health Policy. In this capacity he works to support Federal policy development and advise on issues related to healthcare and public health. Previously, he worked with the Urban Indian Health Institute and Partnerships for Native Health conducting health improvement projects and research alongside Tribal communities, and as a previous Member of the Seattle/King County HIV Planning Council, he continued his advocacy for underserved communities at the city, county, and state levels. After completing a Bachelor of Science and Arts in Molecular Biology and Anthropology from the University of Washington, he received a Master of Public Health from Johns Hopkins University in policy, epidemiology, and human rights. Tyler joined the Legacy Project Working Group almost two years ago and has been honored to support further efforts to engage and collaborate with Tribal and other underrepresented groups around the United States. Working with these groups serves as a constant reminder that we go to communities not as experts, but as a catalyst towards the actualization of the knowledge and expertise they already possess.

Jorge Benitez is the Community Engagement Coordinator for the Columbia Research Unit (CRU) at Columbia University Medical Center. He has been employed in HIV-prevention research since 2002. Jorge currently leads community education and recruitment efforts to enroll HIV-negative people at low and at substantial risk of getting HIV, particularly Latinx and Black populations that are most affected by HIV. Jorge strongly feels that Latinx people need more education around biomedical research to gain a better understanding of research so more Latinx people feel empowered to join HIV biomedical studies.
COVID-19 Updates

COVID-19 CAB Coalition Update
COVID-19 Vaccine Efficacy Panel Discussion
December 11 at 10AM PT / 1PM ET

The HANC-facilitated COVID-19 CAB Coalition invites you to a panel discussion for the community on what COVID-19 vaccine efficacy means. HANC Director, Dr. Jeff Schouten will moderate a discussion with Dr. Larry Corey, principal investigator (PI) of the HVTN and CoVPN; Dr. Deborah Donnell, PI of the HPTN SDMC; and Neetha Morar, Senior Research Manager at South African Medical Research Council, on the challenges to assess the effectiveness of COVID-19 vaccines. Topics to be addressed include vaccine effectiveness, statistical challenges in the design, endpoints, and analysis of COVID-19 vaccine trials among other hot item issues. Click here to register.

This panel discussion is part one of a two-part series to address efficacy assessments in COVID-19 therapeutic trials and products.

COVID-19 Vaccine Matters:
The Messenger RNA Vaccines & Masks

COVID-19 Vaccine Matters is a blog series discussing the evolving science and policy of COVID-19 vaccines, led by internationally renowned experts in vaccine development, Dr. Larry Corey and Dr. Chris Beyrer.

In a recent blog in this series, Dr. Larry Corey shares his thoughts on the interim results from the mRNA vaccine trials, the questions remaining that are important to find answers to, and the need to continue using appropriate COVID-19 prevention measures until we learn more. Read the blog here.

Upcoming CoVPN Webinars
Join the CoVPN and partners in conversation around COVID-19 vaccines, including how vaccines work, how they're developed, and what is the same or different about the COVID-19 vaccine.

December 8
10AM PT / 1PM ET
COVID-19 Clinical Trials in Communities of Color
Register here

December 9
6PM PT / 9PM ET
Iman & COVID: Reflections from the Muslim Community - Episode 5: COVID, Art, & Healing
Watch on Facebook Live

December 15
8PM PT / 5PM PT
Making Sense of Vaccines During COVID-19
Eventbrite registration

December 16
11AM PT / 2PM ET
"The World We Live in is a House on Fire": Latinx Health & COVID-19
Zoom registration
2020 ACTG Awards
On November 16, 2020, the ACTG virtually presented the 2020 ACTG Awards, including two new awards honoring ACTG investigators and leaders who recently passed away. Congratulations to all who were nominated and those who were selected! View the full virtual presentation here!

Kevin Robertson Memorial Award: Honoring his memory by recognizing ACTG investigators who exemplify his compassion, collegiality, and commitment to junior investigators and who have made significant contributions to interdisciplinary research within the ACTG. Congratulations Dr. Serena Spudich!

Charles Van Der Host Humanitarian Award: Honoring his memory recognizing ACTG members who exemplify the ideals that informed his life as an unwavering social justice advocate who dedicated his career to promoting universal access to HIV research, treatment, and care – regardless of setting, wealth, or privilege. Congratulations Dr. David Alain Wohl!

John Carey Award: Honoring his memory by recognizing junior investigators who best exemplify the ideals of the ACTG. Awardees have made significant contributions to the advancement of knowledge about HIV and its complications in the clinic or laboratory in ACTG-sponsored research. They have also demonstrated a cooperative spirit and shown intellectual promise and commitment to advance to a leadership position within the ACTG. Congratulations Dr. Kara Chew!

Constance B. Wofsy Award: Honoring her memory by recognizing investigators who have made significant contributions to research in women living with HIV. Awardees have demonstrated an ability to mentor junior investigators, on-going clinical involvement caring for women living with HIV, and addressed priority areas of the ACTG research agenda focused on women and girls. Congratulations Dr. Elizabeth Connick!

NIH Announces Restructured HIV Clinical Trials Networks
The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, recently announced the clinical investigators and institutions that will lead four NIH HIV clinical trials networks over the next seven years to conduct the innovative, efficient clinical research needed to accelerate progress against the HIV pandemic. NIAID also awarded grants to 35 U.S. and international institutions selected as HIV clinical trials units (CTUs). Read the full news release here. A complete list of awarded CTUs is also available here.
Identifying novel antiretroviral (ARV)-based methods and delivery systems for HIV prevention

Developing multi-purpose technologies for HIV prevention as well as for contraception and prevention of other sexually transmitted infections

Evaluating broadly neutralizing antibodies alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network

Designing and conducting population-specific integrated strategy studies that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness

Drs. Myron S. Cohen and Wafaa M. El-Sadr, principal investigators of the HIV Prevention Trials Network (HPTN), in collaboration with FHI 360, have received a seven-year award from the U.S. National Institutes of Health as part of the next funding cycle (2020-2027) for the Network. The core and protocol-specific funding will enable the HPTN to continue its HIV prevention research efforts focused on developing new biomedical prevention methods and optimizing the integration of proven biomedical, behavioral and structural interventions to achieve high-effectiveness and impact.

During this new funding cycle, the HPTN will focus on the following four priority areas:

1. Identifying novel antiretroviral (ARV)-based methods and delivery systems for HIV prevention
2. Developing multi-purpose technologies for HIV prevention as well as for contraception and prevention of other sexually transmitted infections
3. Evaluating broadly neutralizing antibodies alone or in a combination that prevent HIV acquisition, in collaboration with the HIV Vaccine Trials Network
4. Designing and conducting population-specific integrated strategy studies that combine biomedical, socio-behavioral, and structural interventions for HIV prevention to maximize their effectiveness

Click here to view the press release.

The HVTN RAMP Scholars Program has released its latest request for applications which are due January 4, 2021. This program is focused on African American/Black and Latinx medical students interested in HIV vaccine research. The HIV Vaccine Trials Network, in collaboration with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, is investing in a young generation of HIV prevention researchers by providing African-American and Latinx medical students with opportunities to conduct independent research while receiving mentoring, project and salary funding, training, and professional development opportunities. The complete Request for Applications can be found at http://www.hvtn.org/ramp.
This year scholars are welcome to apply to the following projects, now posted on the RAMP website:

**Short-term Projects (8-10 weeks)**
- Get2PrEP3.0: An Initiative to Reduce Missed Opportunities for the Provision of HIV Prevention Services for Patients Testing Positive for STIs. *(Location: NEW YORK, US)*
- Stick2PrEP 3.0 – Understanding Engagement in PrEP Care Among Individuals Receiving Sexual Health Services Before, During, and After the COVID-19 Pandemic. *(Location: NEW YORK, US)*
- Clinical profile of COVID-19 in people living with HIV (PLHIV) in Lusaka – A retrospective observational study. *(Location: LUSAKA, ZAMBIA)*
- Mobile health (mHealth) interventions for improving HIV prevention knowledge and clinical research literacy among youth communities in Zimbabwe. *(Location: HARARE, ZIMBABWE)*

**Long-term Project (9-12 months)**
- Patterns of daily pre-exposure HIV prophylaxis use, and barriers and facilitators to its access and use in men who have sex with men and in transgender men and transgender women. *(Location: SOSHANGUVE, SOUTH AFRICA)*

**IMPAACT Network Awarded Funding for Another Seven Years**
We are delighted to announce the IMPAACT Network has been awarded the grant for another seven years by the National Institutes of Health. We look forward to another productive seven years of collaboration on IMPAACT’s important research agenda focused on infants, children, adolescents, and pregnant and postpartum women! Read the NIH news release here.

**2020 International Workshop on HIV Pediatrics**
Four IMPAACT abstracts were presented at the 2020 International Workshop on HIV Pediatrics, rescheduled from July to November 2020. All presentations can be found on the IMPAACT website here.

**IMPAACT Rebrand and New Website**
The launch of the new IMPAACT website and rebrand is tentatively scheduled for mid-December or January. Sign up for our mailing list to stay up to date on communications regarding the launch.
MTN is excited to share the welcome news that the monthly dapivirine vaginal ring has taken another big step toward potential introduction to cisgender women. The International Partnership for Microbicides (IPM), developer of the ring, announced on November 30 that the ring has received prequalification from the World Health Organization (WHO). The designation from the WHO confirms that the ring meets global standards for quality, safety and efficacy. The product’s addition to the WHO’s list of prequalified medicines will help guide national and global procurement decisions, pending country regulatory approvals for its use. IPM plans to make the ring available first in sub-Saharan Africa, where cisgender women’s HIV prevention needs are immense. MTN is continuing its studies of the monthly ring in adolescent women (MTN-034), pregnant women (MTN-042) and breastfeeding women (MTN-043).
HANC PROGRAM HIGHLIGHTS
Need to contact a HANC staff member? Click here to go to the About the HANC Staff page.

HANC Staff Situation Update
In accordance with Fred Hutch policies in response to the 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) continues to meet regularly. The BSCG has submitted a paper for publication and is waiting to hear if it has been accepted. The paper will be made available to the Behavioral Science Interest Group (BSIG) members via the BSIG Digest.

The Youth Prevention Research Working Group (YPRWG) will meet again in January 2021. The YPRWG will review the updated network clinical research site list and discuss the possibility of conducting a survey for the new sites on site familiarity/experience with adolescent research. The YPRWG will also begin discussing possible webinar topics for 2021.

Community Partners
Russell Campbell, HANC Deputy Director

Community Partners and the TBTC (Tuberculosis Trials Consortium) Community Research Advisors Group (CRAG) hosted the Study 31/A5349: Four-Month Regimen TB Treatment Game Changer webinar on November 23rd highlighting the findings of Study 31/A5349, which was led by the U.S. Centers for Disease Control and Prevention's (CDC) Tuberculosis Trials Consortium (TBTC) in collaboration with the AIDS Clinical Trials Group (ACTG). Dr. Richard Chaisson, Dr. Sue Swindells and Mike Frick discussed how the game changing findings from this study have the potential to complement current options for the treatment of drug-susceptible TB with a new effective and safe 4-month regimen.

CP is pleased to share the updated Recommendations for Community Engagement document. The world of clinical trials research is highly regulated, with an array of documents guiding the conduct of clinical trials research. Policy documents and procedural guidelines, such as Good Clinical Practice (GCP) and Good Clinical Laboratory Practice (GCLP), cover most aspects of clinical research but none of these documents discuss standards for engaging community in the research process.
(Community Partners, continued) Community representatives working with the National Institute of Allergy and Infectious Diseases (NIAID) at the NIH increasingly felt that this type of guidance was essential and in 2009 sought to develop recommendations as a way to address good community practice. These recommendations are intended as a tool to help research staff and community representatives expand and deepen existing partnerships, and forge new ones, with the ultimate goal of facilitating effective community engagement in all aspects of clinical trials research.

Cross-Network Coordination
Milan Vu, HANC Project Manager

The Cross-Network Communications Working Group (CWG) discussed coverage and release of the results from HPTN 084. In addition, the group discussed the recent news surrounding efficacy of the COVID-19 vaccine product from Pfizer and implications for the rest of the CoVPN vaccine and prevention research agenda.

The HPTN 084 study press release, study update press briefing, and public webinar can be found on the HPTN website [here](#).

The network [CTU and CRS List](#) has been updated on the HANC website. This list includes active clinical research sites and their affiliated clinical trials unit for the ACTG, HPTN, HVTN, IMPAACT, MTN, and NICHD-IMPAACT.

Laboratory Coordination
Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held two conference calls to discuss LT experiences with ACTG protocol A5401, specimen barcode scanning requirements and LTC member workload and protocol assignments.

The LTC is seeking new applicants for the upcoming membership term that begins 01 March. Committee membership solicitation begins on 21 December with a deadline of 15 January. Please contact Rose Lagattuta ([rlagattuta@milabcentral.org](mailto:rlagattuta@milabcentral.org)) if you or someone from your lab would like to apply.

The Lab Focus Group met to discuss the potential impact related to de-funded/newly funded sites as part of the site-recompetition, site related issues with GCLP rollout, specifically around GCLP site training, SMILE’s electronic Investigation Report platform, and further review of the Audit Checklist. The next call is scheduled for December 21st.

Frontier Science released a guidance document that describes LDMS tools for generating reports for inspections and audits. That document can be accessed on the LDMS website or by clicking [here](#).
This month, the Legacy Project is delivering trainings for the HPTN 091 study team on affirming transgender women as participants in HIV research.

The Legacy Project is delighted to announce that Jessy Dame has joined the Legacy Project Working Group. Jessy Dame is a very proud self-identified Two-Spirit, gay, Métis Registered Nurse doing his Masters of Science in Nursing at UBC. His parents are from Manitoba, both Treaty 1 and 2 Territory. Jessy did his undergraduate degree at Thompson Rivers University and has been as an RN for 5 years, working within Neonatal/Postpartum health, as well as, within remote communities on the coast and within northern BC. He currently works as the Two-Spirit program manager at the Community Based Research Center and as a community health nurse at a queer sexual health clinic.

Brian Minalga will be out of the office for a much-needed break, December 21 - January 1.
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.

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. Click here for more information.

OCSEO 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 (OCSEO). Click here to find newsletter archives.

NIH Corner
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. Click here 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. Click here 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. Click here to visit the site and request specimens.

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. Click here to learn more or email c3pno.info@fstrf.org to request data or specimens.

ClinRegs
ClinRegs is an online database of country-specific clinical research regulatory information designed to assist in planning and implementing international clinical research. Click here 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. Click here to explore DASH.