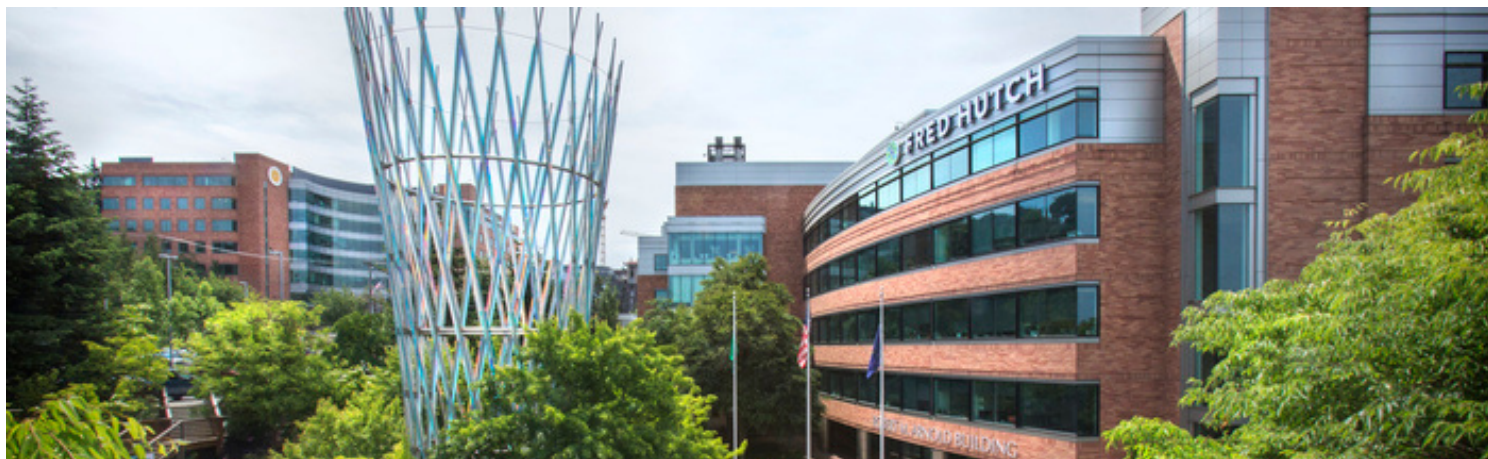


SEPTEMBER 2020

# NEWSLETTER

Office of HIV/AIDS Network Coordination



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

## IN MEMORIAM

On behalf of the Office of HIV/AIDS Network Coordination (HANC), we are deeply saddened that one of our dear colleagues and friends, David Hughes, passed away in early August. We want to express our condolences to his family, friends and colleagues.

David participated on numerous HANC working groups over the years, including Community Partners, the Cross-Network Evaluation Working Group, and he recently served as one of the Legacy Project Working Group co-chairs. David was kind, giving and always willing to help others. To honor David's memory and legacy, Community Partners and



the Legacy Project will strive to follow David's example of showing compassion, and recognizing that social justice is necessary in making this world a better place for all.

It was an honor to work alongside such an amazing and kind spirit!

## INSIDE THIS ISSUE:

|                                |     |
|--------------------------------|-----|
| <b>HANC Announcements</b>      | 2   |
| <b>Network Announcements</b>   | 3-5 |
| <b>Meeting Calendar</b>        | 6   |
| <b>Webinars &amp; Training</b> | 6   |
| <b>HANC Program Highlights</b> | 7-9 |
| <b>Resources</b>               | 10  |

*Do you have questions, comments, or content suggestions? Email the Editor, Milan Vu, at [mhvu@fredhutch.org](mailto:mhvu@fredhutch.org)*

# HANC ANNOUNCEMENTS

## *HANC Staffing Update*



It is with mixed emotions we announce that Legacy Project staff member Louis Shackelford will be transitioning to a new role at the HVTN. Louis accepted the position of Project Manager in External Relations at the HVTN, where he will continue his work building partnerships with community stakeholders to increase awareness and knowledge of HIV research. Legacy and HANC regret that Louis is leaving us, but we support his growth and development, and wish him success in this new role. Louis' last day at HANC/Legacy will be Friday, September 11, 2020.

In the three and a half years that Louis has served in his role at Legacy, he has remained steadfast to his commitment to increasing the representation of marginalized and medically underserved populations. Moving from New York City to Seattle, WA, Louis transitioned from his hometown for the first time believing he could have a greater impact at Legacy. While at Legacy, Louis established the New Investigators Working Group to enhance programs for early career researchers and developed partnerships with ballroom and kink communities. Louis participated in the development of HPTN 096, represented Legacy on several study protocols and the HPTN Black Caucus, and presented at numerous conferences and meetings. Additionally, Louis developed a passion for serving his country and enlisted in the US Air Force Reserve in 2019 as a medic.

Fortunately, Louis' new role at the HVTN will keep him actively involved in community engagement work in HIV research. As a result, we expect to still collaborate with Louis, and we look forward to his involvement with Legacy/HANC as dictated by his new role. We at Legacy and HANC are grateful for Louis' time at Legacy and wish him all the best moving forward.

Please join us in congratulating Senior Airman Louis Shackelford on his new role at the HVTN!

## ***Job Posting: HANC Legacy Community Engagement Project Manager***

The Legacy Project is seeking a Community Engagement Project Manager to support and ensure community engagement and collaborative integration of community engagement activities into the NIH-funded HIV clinical trials networks and related community mobilization efforts.

[HANC Legacy Community Engagement Project Manager Job Posting](#)

## ***New DAIDS Electronic Information Systems Policy***

The Office for Policy in Clinical Research Operations (OPCRO), DAIDS recently announced the availability of the new Electronic Information Systems Policy. This new policy has been developed to ensure consistency of Electronic Information Systems with 21 CFR part 11 and regulatory guidance. The Policy, associated Appendices, Frequently Asked Questions (FAQs) and the Implementation Memo can be found at <https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations>.

DAIDS plans for a phased implementation of this policy, as described in the [Implementation Memo](#). Please review the [FAQs](#) if you have questions regarding this policy. If your query is not addressed in the FAQs, email [DAIDSCRSSEISChecklist.sm@ppdi.com](mailto:DAIDSCRSSEISChecklist.sm@ppdi.com).

# NETWORK ANNOUNCEMENTS



## ACTG Announces Launch of ACTIV-2, Novel Clinical Trial Testing Multiple Therapeutics to Treat COVID-19

The ACTG recently announced the initiation of the ACTIV-2 Outpatient Monoclonal Antibodies and Other Therapies Trial. ACTIV-2 includes both phase 2 and phase 3 evaluations of multiple promising investigational agents for treating early COVID-19 in a single trial. ACTIV-2 will first evaluate the monoclonal antibody LY3819253.

ACTIV-2 will evaluate the safety and efficacy of investigational agents to treat adults who have COVID-19 illness but do not require hospitalization. The study will also enable researchers to assess the correlation between changes in viral shedding and clinical outcomes, leading to a better understanding of whether effective medications can reduce or halt the transmission of SARS-CoV-2 (the virus that causes COVID-19) to others. ACTIV-2 is a randomized, blinded, controlled adaptive platform that allows promising investigational agents to be added and removed over the course of the study, in order to efficiently test a variety of new agents against placebo within the same trial infrastructure.

“Early treatment of COVID-19 will be vital to help us prevent advanced illness, hospitalization, and transmission of SARS-CoV-2,” said ACTG Chair Judith Currier, M.D., M.Sc., University of California, Los Angeles. “ACTIV-2 is designed to help us rapidly identify treatments that have the potential to radically alter the current pandemic landscape. Individuals who have recently been diagnosed with COVID-19 and are not hospitalized have the opportunity to make a huge contribution by participating in this study.”

To read more, please see the complete press release [here](#).



HPTN researchers recently initiated the first HPTN study to enroll U.S. adolescents under the age of 18 exclusively.

# NETWORK ANNOUNCEMENTS



HPTN 083-01 is evaluating safety, acceptability, and tolerability of a pre-exposure prophylaxis (PrEP) regimen containing long-acting injectable cabotegravir (CAB LA) for adolescents assigned male at birth. A companion study, HPTN 084-01, is expected to start soon and will examine whether injectable CAB LA for PrEP is safe, acceptable and tolerable for adolescents assigned female at birth in South Africa, Uganda, and Zimbabwe. HPTN 083-01 and HPTN 084-01, collectively known as 'the Twins' studies, will also provide an ideal opportunity for study participants to balance the perceived risks and benefits of HIV prevention options.

Read more at: <https://www.hptn.org/news-and-events/featurestories/Teens-Taking-Charge-for-HIV-Prevention>



HIV VACCINE  
TRIALS NETWORK

There is no update from the HVTN this month. For the latest news, visit the HVTN website at [www.hvtn.org](http://www.hvtn.org).



[IMPAACT P1090](#), a Phase I/II trial to evaluate the pharmacokinetics (PK), safety and tolerability of etravirine among ARV treatment-experienced children living with HIV, is now closed to follow-up. IMPAACT P1090 enrolled 26 participants in Brazil, South Africa and the United States. The study also informed the Committee for Medicinal Products for Human Use (CHMP) positive opinion to lower the age limit for etravirine for children in Europe in May 2020 and the U.S. FDA's labeling expansion [approval](#) in July 2018.

In addition, some IMPAACT studies are now allowed to resume accrual including [IMPAACT P1108](#), [IMPAACT P1115](#), [IMPAACT 2005](#) and [IMPAACT 2019](#). Continue to check the IMPAACT [COVID-19 resource webpage](#) for updates and guidance.



MTN is pleased to announce the launch of the [B-PROTECTED study](#) (MTN-043). The final study to be initiated by the MTN as a NIAID-funded network, B-PROTECTED will enroll cisgender women who are breastfeeding, as well as their babies, at trial sites in Malawi, South Africa, Uganda and Zimbabwe. A similar study involving pregnant women, called [DELIVER \(MTN-042\)](#), is ongoing.





# NETWORK ANNOUNCEMENTS



Both B-PROTECTED and DELIVER are open-label Phase IIIb studies designed to evaluate the safety of two HIV prevention methods – Truvada as oral PrEP and the monthly dapivirine vaginal ring, which in late July received a positive opinion by the European Medicines Agency, a significant step toward its potential approval in African countries. B-PROTECTED will enroll up to 200 HIV-negative breastfeeding mothers and their 6- to 12-week-old babies. Participants will be randomly assigned to use either the monthly dapivirine ring or Truvada. Women will use their assigned product for three months and be followed by the study team for an additional two weeks. Researchers will assess how much drug from Truvada and the dapivirine ring passes into breast milk and how much passes to the baby after breastfeeding, and will measure the effects, if any, this may have on the health and safety of both mother and child.

In an earlier study called MTN-029/IPM 039, MTN researchers found dapivirine was absorbed at very low levels in breast milk and noted no safety concerns. That study enrolled 16 women in the United States who were no longer nursing their babies, but still producing milk. One of the participants who volunteered for MTN-029/IPM 039 was the subject of a recent piece by the MTN – [Pumped up for HIV Prevention](#) – as we take a look back at the people who have made important contributions to the network over the last 14 years.

## 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.*

### July-Oct 2020

Saving Ourselves  
Symposium Series  
(Virtual)

### June-Oct 2020

HIV2020 Online  
(Virtual)

### Oct 19-21

USCHA  
(Virtual)

### Oct 21-25

IDWeek 2020  
(Virtual)

### Oct 24-28

APHA 2020  
(Virtual)

### Nov 1-4

Adherence 2020  
(Orlando, FL)

### Jan 15-16, 2021

NAESM Conference  
(Virtual)

### Jan 27-28 & Feb 3-4, 2021

HIVR4P  
(Virtual)

### Mar 6-10, 2021

CROI 2021  
(Virtual)

For details and other events, visit the [HANC calendar](#)



## WEBINARS & TRAINING

### Upcoming Webinars

#### Youth Prevention Research Working Group webinar

October 8 @ 10AM PT / 1PM ET

Save the date for a webinar on the Adolescent Trials Network's (ATN) iTech protocols. Presents will include Dr. Lisa Hightow-Weidman and Dr. Travis Sanchez. Learn more about iTech [here](#), and for a current list of ATN studies, including iTech protocols, [click here](#). Stay tuned for more details, including the official webinar announcement, description, and registration link.

### Training

#### Transgender Training Resources

Available on the DAIDS Learning Portal

The [Transgender Training Resources Website](#) on the DAIDS Learning Portal (DLP) contains 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,

### Webinar Archives

Missed a webinar you wanted to attend? Visit the [HANC website](#) to view archived recordings of past webinars. Recent webinars of interest include:

- [Clinical and Community Perspectives on the Use of Hair Samples in HIV Research](#) featuring Dr. Monica Gandhi, Morénike Giwa Onaiwu, and Charles Chasakara (aired August 14, 2020)

Additional webinars conducted in collaboration with the COVID-19 Prevention Network are available here:

- [A 'We the People' Research Discussion on Medical Mistrust](#) (with Black AIDS Institute)
- [Uniting to End COVID-19](#) (with the Urban Indian Health Institute)
- [7 mil millones de razones: Unidos para poner fin a COVID-19](#)
- [7 Billion Reasons Why: United to End COVID-19](#) (with the Latino Commission on AIDS)



## 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.

As noted under the **HANC Announcements** on page 2, the Legacy Project is seeking a Community Engagement Project Manager to support and ensure community engagement and collaborative integration of community engagement activities into the NIH-funded HIV clinical trials networks and related community mobilization efforts. Find the job posting [here](#).



### Behavioral & Social Sciences

*Greg Davis, HANC Project Manager*

The Behavioral Science Consultative Group (BSCG) continues to meet monthly. The group has been providing updates on ongoing HIV trials and COVID-19 studies. A subgroup of the BSCG is drafting a paper (details on the topic will be provided later) to submit for publication.

The Youth Prevention Research Working Group (YPRWG) is hosting a webinar with Dr. Lisa Hightow-Weidman and Dr. Travis Sanchez on the Adolescent Trials Networks iTech studies. The webinar will be on Thursday, October 8 at 10am PT/1pm ET. A registration link will be shared with HANC collaborators once it is available. To learn more about iTech, follow this link: <https://itechnetwork.org/>

The HANC-facilitated annual solicitation will occur on September 21, 2020.



### Community Partners

*Russell Campbell, HANC Deputy Director*

Community Partners would like to welcome Francisco Rentas as the new HVTN representative. Francisco is a HVTN/CoVPN Social & Behavioral Sciences and Community Engagement Project Manager, Seattle, WA.

# HANC PROGRAM HIGHLIGHTS

“The most incredible thing about working in community engagement is getting to see and interact with the people on the ground who are really doing the work of building relationships within their communities and bringing our heroes in to volunteer for studies with the goal of moving science forward. I learn so much more from these field workers and advocates when I get to visit them in their home communities than I do sitting in my office. With every trip I take, I am further empowered and inspired to do what I can to support their efforts and bridge that gap between our scientific community and the people whose lives it seeks to improve.”



Welcome Francisco!



## Cross-Network Coordination

*Milan Vu, HANC Project Manager*

The Data Management Center Working Group (DMCWG) shared updates on COVID-19 studies, reviewed and approved publication of the Cross-Network Pregnancy Data Standards, discussed updates on safety data reconciliation, and discussed the ongoing protocol deviation reporting pilot.

The Cross-Network Evaluation Working Group (EWG) held its quarterly call to share network evaluation committee updates, discuss annual evaluation reports, and review the 2021 work plan for the committee.

The Cross-Network Site Coordinators Working Group (SCWG) met to discuss ongoing site activities in HIV and COVID-19 studies as well as site limitations due to the pandemic, efforts to prevent disallowed participant co-enrollment in trials, and implementation of the DAIDS remote source document verification strategy at sites.

The Pregnancy Outcomes Data Working Group (PODWG) recently published the [Cross-Network Pregnancy Data Standards](#) as a harmonized approach for capturing pregnancy outcome data variables in the clinical database through common identifiers and naming, question text, SDTM annotations, data type, and response options. These standards will be implemented by SCHARP and Frontier Science and are available to others as a resource and reference tool.



## Laboratory Coordination

*Tyler Brown, HANC Project Manager*

The Laboratory Technologists Committee (LTC) held two conference calls to discuss lab site preparedness for ACTG protocol A5401, including unique procedures for specimen collection, shipping and tracking in LDMS. The group also discussed lab operations and issues related to the recent resumption of several ACTG and IMPAACT HIV protocols.



# HANC PROGRAM HIGHLIGHTS

The Lab Focus Group (LFG) held a conference call to discuss Lab Center updates, planned changes to laboratory site monitoring procedures, and updating the Cross-Network Guidelines for Diagnosis of HIV Infection.

The CPQA Cross-Network Clinical Pharmacology Forum (CNCPL Forum) held a conference call to discuss updates on validating methods in support of COVID-19 treatment studies, CPQA proficiency testing program updates, and updates to CPQA technical guidance documents.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to discuss updates on current and upcoming VQA proficiency testing rounds, deployment of the HIV-1 Drug Resistance Program web application, and review new proficiency testing data for HIV RNA and HIV Drug Resistance panels.

On August 14th HANC held a webinar presentation on the use of hair samples in HIV research featuring presenters Monica Gandhi, Morénike Giwa Onaiwu and Charles Z. Chasakara. Click [here](#) to watch a recording of this webinar.



## The Legacy Project

*Brian Minalga and Louis Shackelford*  
HANC Legacy Project Team

The Women's HIV Research Collaborative has released a sign-on document calling for a commitment to scientific accuracy and cultural sensitivity when communicating about clinical research study populations. Read the statement and sign on [here](#).

The latest issue of the Be the Generation newsletter is now available, bringing you the latest information and resources in biomedical HIV prevention research by the HPTN, HVTN, MTN, and HANC. Available in [English](#) and [en español](#).

Legacy Project staff have been conducting a lot of webinars with the COVID-19 Prevention Network with a focus on informing Black, Indigenous, and Latinx communities about the COVID-19 prevention research agenda. Check out some of our recent recordings:

- [A 'We the People' Research Discussion on Medical Mistrust](#) (with Black AIDS Institute)
- [Uniting to End COVID-19](#) (with the Urban Indian Health Institute)
- [7 mil millones de razones: Unidos para poner fin a COVID-19](#)
- [7 Billion Reasons Why: United to End COVID-19](#) (with the Latino Commission on AIDS)

# 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. [Click here](#) to view current and past newsletters. Email [btg@hanc.info](mailto: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](mailto: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. [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.

### 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.

### 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). [Click here](#) 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. [Click here](#) to learn more or email [c3pno.info@fstrf.org](mailto: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.

FOLLOW HANC ON



FIND MORE RESOURCES AT  
[WWW.HANC.INFO](http://WWW.HANC.INFO)