

FEBRUARY 2021

# NEWSLETTER

Office of HIV/AIDS Network Coordination



## **Land, Labor, and Justice Acknowledgements**

We acknowledge the land we occupy today as the traditional home of the Duwamish, Tulalip, Muckleshoot, and Suquamish 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

*Join us in observing National Black HIV/AIDS Awareness Day on February 7.*

### **"We're in This Together"**

[National Black HIV/AIDS Awareness Day](#) (NBHAAD) is a day to increase

awareness, spark conversations, and highlight the work being done to reduce HIV in Black communities in the United

States. Even though we are physically apart, we all have a role to play in ending HIV.

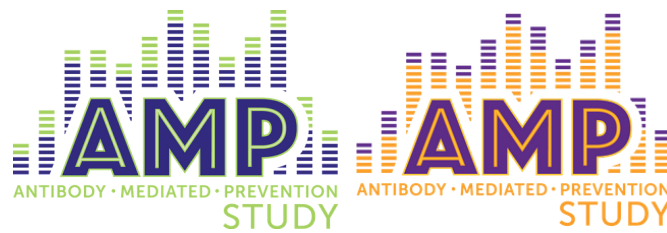


As part of National Black HIV/AIDS Awareness Day and Black History Month, the Legacy Project will be hosting a webinar focused on HIV & Aging: Resilience & Research – stay tuned for the announcement and registration details.

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



## ***Most advanced clinical trials testing broadly neutralizing antibody against HIV demonstrate efficacy against sensitive strains***

First opened in April 2016, the data of the two proof-of-concept Antibody Mediated Prevention (AMP) studies was first presented at the official press conference of the 4th HIV Research for Prevention (HIV R4P) Conference on January 26, 2021. AMP demonstrated that a broadly neutralizing antibody (bnAb) called VRC01 was effective at preventing the acquisition of HIV strains that were sensitive to the bnAb. The two studies (HVTN 704/HPTN 085 and HVTN 703/HPTN 081) successfully enrolled 4,623 participants. Men and transgender persons who have sex with men were enrolled from communities in Brazil, Peru, Switzerland, and the United States in HVTN 704/HPTN 085. Women were enrolled from communities in Botswana, Kenya, Malawi, Mozambique, South Africa, Tanzania, and Zimbabwe in HVTN 703/HPTN 081.

The AMP data show that VRC01 can prevent some strains of HIV, but not others. In the AMP studies, people who got VRC01 were less likely to get HIV if they were exposed to “sensitive strains” and were not protected from getting HIV if they were exposed to resistant HIV strains. AMP data suggest that combinations of bnAbs will be needed to effectively prevent HIV, similar to how combination ART is needed to effectively treat HIV. Also, the AMP data indicate the broad potential of antibody-based HIV prevention methods for people in diverse geographical areas where different HIV subtypes predominate.

Data from the AMP studies are informing the design of future studies with newer, highly potent and long-lasting HIV bnAbs. Several of these next-generation bnAbs are currently being evaluated in early-stage studies, particularly in bnAb combinations. NIAID, HPTN, and HVTN are pursuing multiple approaches toward the goal of delivering a range of HIV prevention options that are safe, effective, desirable to diverse populations, and scalable worldwide. This includes development of long-acting antiretroviral drugs for HIV prevention, antibody-based HIV prevention methods, and an HIV vaccine.

“The AMP trials were designed to determine whether long-term administration of a bnAb could reduce HIV acquisition, if susceptibility of circulating viruses in the community to the bnAb would influence prevention efficacy, and if measuring this susceptibility would be a biomarker of prevention efficacy. All three of these questions were answered by these two trials,” said [Larry Corey, M.D.](#), AMP Protocol Chair and Principal Investigator, HVTN Leadership Operations Center, which is based at the Fred Hutchinson Cancer Research Center.

### **Access AMP study results:**

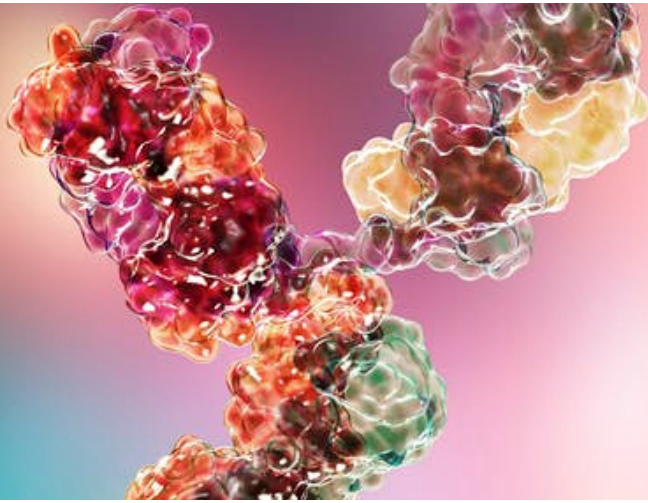
- [HVTN 704/HPTN 085](#)
- [HVTN 703/HPTN 081](#)

### **Press Releases:**

- [HPTN / HVTN](#)
- [NIAID](#)

### **News media coverage on AMP:**

- [Aidsmap](#)
- [Science](#)
- [The Independent](#)
- [Bhekisisa](#)
- [POZ](#)
- [TimesLIVE](#)
- [The News](#)
- [SCOOP](#)
- [Fred Hutch](#)
- [Healio](#)



## THE AMP STUDY: Sharing Results with Communities

AMP Study Results will be presented at four different webinars. Register for one or all of the sessions listed below.

### AMP Study Results Webinar - Africa

February 8 @ 6AM PT / 9AM ET / 4PM Botswana, Malawi, Mozambique, South Africa, Zimbabwe / 5PM Kenya

**Panelists:** Dr. Nyaradzo Mgodli, Dr. Margarita Gómez, Dr. David Burns, Dr. Simbarashe Takuva

**Moderator:** Kagisho Baepayne

**Zoom:** <https://bit.ly/2YIImLA>

**Or Telephone:**

**US:** 888 788 0099 (Toll Free) or 877 853 5247 (Toll Free)

**Zimbabwe:** +263 864 404 1086

**South Africa:** 0 800 064 584 (Toll Free) or 0 800 008 728 (Toll Free)

**Webinar ID:** 910 5942 1803

**Password:** 304141

### AMP Study Results Webinar - United States

February 10 @ 2PM PT / 5PM ET

**Panelists:** Dr. Margarita Gómez, Phil Andrew, Dr. Sri Edupuganti

**Moderators:** Gail Broder, Jonathan Lucas

**Zoom/Registration:**

<https://bit.ly/36pnsjo>

### Seminario Web sobre los Resultados del Estudio AMP - Perú

8 de Feb @ 3:00 - 4:30PM Perú & hora del este en EEUU / 12:00 - 1:30 hora del pacífico en EEUU

**Panelistas:** Dr. Jorge Sanchez; Dr. Robert De La Grecca; Dr. Margarita Gómez

**Moderadora:** Patricia Segura

**Zoom:** <https://zoom.us/s/91082198716>

**O únase por teléfono:**

+51 1 730 6777 (Peru) or +51 1 707 5788 (Peru) or +51 1 708 8312 (Peru) or 0 800 78743 (Toll Free) or 0 800 53089 (Toll Free) or 0 800 76930 (Toll Free)

**Seminario web ID:** 910 8219 8716

**Contraseña:** 732773

### Webinário: Resultados do Estudo AMP- Brasil

10 de fevereiro @ 12h - 13h30

**Palestrante:** Dr. Brenda Hoagland

**Moderadora:** Luciana Kamel

**Zoom:** <https://bit.ly/3acZWqE>

**Ou entre por telefone:**

**Estados Unidos da América:** 888 788 0099 (Gratuito) or 877 853 5247 (Gratuito)

**Brasil:** 0 800 878 3108 (Gratuito) or 0 800 282 5751 (Gratuito)

**ID do webinar:** 993 2471 8697

**Senha de acesso:** 976322



# DAIDS Applied Research Training 2.0

## Global Announcement

The Division of AIDS (DAIDS) is pleased to announce our second DAIDS Applied Research Training (DART) 2.0 event, which will be held virtually in Summer 2021 for our HIV/AIDS Network sites in the Latin American and Caribbean region.

Given the current situation with the global pandemic, we have decided to conduct a completely virtual event that will incorporate applied clinical GCP/ICH compliance at our clinical research sites, aligning with DAIDS efforts to strengthen regulatory compliance across the HIV/AIDS Network enterprise. In addition, we will incorporate content to include communication and quality management skills on a systems level, with an emphasis on implementation and process improvement.

We will be limiting overall attendance of the event to ensure that we maintain the small group atmosphere for effective virtual learning experiences.

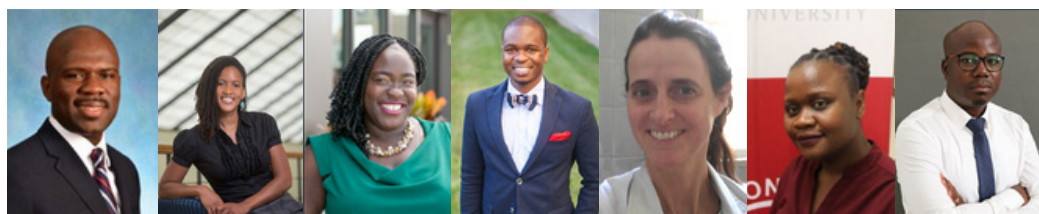
We will be reaching out to potential DART 2.0 participants shortly. For more information contact the DART support team at [DAIDS\\_CRSS\\_DART\\_2.0@mail.nih.gov](mailto:DAIDS_CRSS_DART_2.0@mail.nih.gov).



## NETWORK ANNOUNCEMENTS



In January, the ACTG announced the addition of a new agent to our ACTIV-2 study, an adaptive platform that includes both phase 2 and phase 3 evaluations of multiple promising investigational agents for treating early, symptomatic COVID-19 in a single trial. This phase 2 study will evaluate the combination of the two monoclonal antibodies BR11-196 and BR11-198 to treat early COVID-19. To read more, see the press release [here](#).



The HPTN Scholars Program is pleased to announce the next group of talented scholars. During the next 18 months, they will conduct secondary analyses of HPTN study data, working alongside leading HIV prevention researchers affiliated with the Network. More than fifty (50) scholars have participated in the program since it started in 2010. The U.S. National Institute of Allergy and Infectious Diseases, U.S. National Institute on Drug Abuse, and the U.S. National Institute for Mental Health fund the HPTN Scholars program. Click [here](#) to meet the Scholars.

# NETWORK ANNOUNCEMENTS



## NMAC Biomedical HIV Prevention Summit

Black AIDS Institute, Treatment Action Group, and HIV Vaccine Trials Network submitted a joint abstract focused on the development and implementation of the a 4-module curriculum-based training program called "We the People Research Cohort". This training program aims to increase the knowledge and capacity of community advocates to engage in the critical conversations and activities occurring regarding innovation in HIV biomedical prevention research and the evolving conversations around HIV prevention efficacy trial designs. For more information on the NMAC Biomedical HIV Prevention Summit, go to:

<https://www.biomedicalhivsummit.org/>



## CoVPN/HVTN Welcomes Terrell Jackson

Terrell Jackson (He/Him/They/Them) has joined the COVID-19 Prevention Network and HIV Vaccine Trials Network and his first day is Monday, February 1st. As External Relations Project Manager, Terrell is the newest member of the External Relations Unit in the HVTN Leadership and Operations Center (Core) at Fred

Hutchinson Cancer Research Center in Seattle, WA. As the External Relations Project Manager, Terrell's primary focus will be implementing stakeholder engagement strategies domestically. These strategies create opportunities for consultation with key stakeholders and communities to inform the design and implementation of Network studies. Consultations optimize the inclusion and participation of populations and communities who bear the greatest burden of HIV.

Terrell grew up in the nation's oldest city of Saint Augustine, FL. They received their bachelor's degree in biological sciences from Florida Atlantic University (FAU), a Translational Research Certificate in Behavioral Health from the University of South Florida, and is finishing up their Masters of Healthcare Administration from New York University (NYU). They have had professional opportunities in programming, coordination, and health policy through their work lobbying for LGBTQ+ biomedical rights at the Florida State Capital, community engagement experience piloting and expanding preventative programs at social and clinical organizations in North Florida, and through their research conducted with the top behavioral health clinic in the United States. On off days you can find them playing with their dachshund/chihuahua mix puppy (Luna), indulging in French pastries, or making their own natural body products like soap, lotions, and oils.

# NETWORK ANNOUNCEMENTS



## Rebrand and Website

As of January 2021, the IMPAACT Network has a new look! The network rebrand consists of a new logo, new colors, new templates, and a redesigned mobile-friendly website. Learn more about the rebrand and new website [here](#).

## Study Results

Primary results from [IMPAACT P1092](#) have been published in [Pediatric Infectious Diseases](#). The PK and safety findings for zidovudine (ZDV), lamivudine (3TC), and lopinavir/ritonavir (LPV/r) support the current WHO weight band dosing of syrup formulations in children with severe acute malnutrition.

[IMPAACT P1112](#) Dose Group 5 safety and PK results were the focus of a presentation at HIVR4P's Clinical March of bNAbs oral abstract session. Results showed that VRC07-523LS administered subcutaneously at birth (and at 12 weeks old if still breastfeeding) is safe and well-tolerated, is rapidly absorbed, and maintains concentrations. This suggests that VRC07-523LS, with its enhanced potency and extended half-life, could achieve target levels for the duration of breastfeeding with dosing every three months.

The [IMPAACT 2009](#) study team also presented a poster that complimented the primary [PK Component findings](#) in Clinical Infectious Diseases by describing site experiences with successful implementation of Directly Observed Therapy.

See the HIVR4P presentations at <https://www.impaactnetwork.org/impaact-r4p-2021>.

## IMPAACT at CROI 2021

Following receipt of the CROI 2021 general abstract submission outcomes, the IMPAACT Network will present research in one oral presentation and six Science Spotlight™ presentations across six studies.

More information will be shared on the IMPAACT website closer to the meeting.



MTN presented the results of several studies at the HIV Research for Prevention (HIVR4P) Virtual Conference, Jan. 27-28 and Feb. 3-4.

One of the studies, [MTN-044/IPM 053/CCN019](#), evaluated a vaginal ring containing the antiretroviral drug dapivirine and the contraceptive hormone levonorgestrel. Results showed that sustained levels of each drug were delivered when the ring was used continuously for 90 days – levels likely sufficient to serve its dual purpose of protecting against HIV and unintended pregnancy.

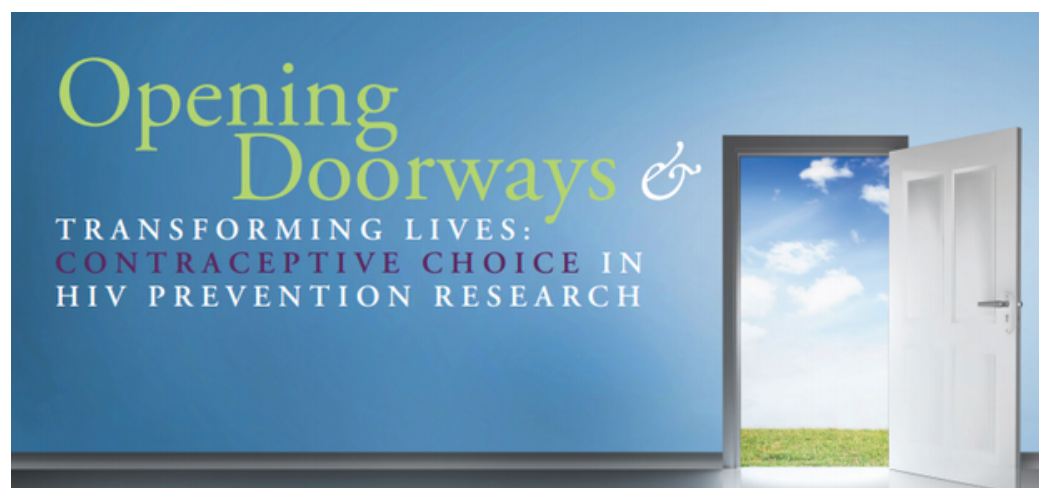
# NETWORK ANNOUNCEMENTS



A reformulated version of the ring will be evaluated in an upcoming trial by the ring's developer, the International Partnership for Microbicides, in collaboration with NIH's Contraceptive Clinical Trials Network, to improve on its ability to stay in place. In the same HIVR4P session, preliminary results of MTN-045, or the CUPID Study, were also presented. In [MTN-045](#), 400 couples in Uganda and Zimbabwe were interviewed about their views and preferences for potential dual-purpose products. More than 90 percent of the couples liked the idea of a two-in-one product, especially if it was framed first and foremost as a contraceptive rather than a method for HIV prevention.

[Another set of MTN studies presented at HIVR4P](#) focused on the evaluation of on-demand and behaviorally congruent rectal microbicides as HIV prevention options for people who practice anal sex. MTN researchers reported the results of three Phase I studies ([MTN-026](#), [MTN-033](#) and [MTN-037](#)) that found both of two gel-based products tested – dapivirine gel and PC-1005 – to be well-tolerated, with higher doses of the active drugs likely required to provide protection from HIV and other sexually transmitted infections.

MTN's Behavioral Research Working Group developed the [MTN Social and Behavioral Compendium](#), a PowerPoint presentation that encompasses the entire history of social and behavioral research at the network. This document covers lessons learned and best practices from 2006 through 2020.



MTN has completed the latest installment in its "A Look Back..." series. The story, [Opening Doorways & Transforming Lives: Contraceptive choice in HIV Prevention Research](#) focuses on the work of the Contraceptive Action Team in expanding choice of pregnancy prevention options for participants in HIV research.



## 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.*

**Jan 27-28 & Feb 3-4**  
HIVR4P  
(Virtual)

**Feb 2**  
IAS COVID-19  
Conference:  
Prevention  
(Virtual)

**Mar 6-10**  
CROI 2021  
(Virtual)

**Mar 30-31**  
Biomedical HIV  
Prevention Summit  
(Virtual)

**May 20-22**  
ACTHIV 2021  
(Virtual)

**July 18-21**  
IAS 2021  
(Virtual)

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

## WEBINARS & TRAINING

### Upcoming Webinars

#### DAIDS SCORE Manual Launch Sessions

The Division of AIDS (DAIDS) invites you to the launch of our [Site Clinical Operations and Research Essentials \(SCORE\) Manual](#). The SCORE Manual is a new site-facing resource which consolidates DAIDS operational and procedural requirements to support implementation of DAIDS sponsored clinical research within the DAIDS Clinical Trials Networks. During this session, DAIDS will provide an overview of the SCORE Manual, followed by Q&A. Please join us for one of the launch sessions to learn more!

*Note: The same presentation is being offered on two separate dates. Please register for one of the events to attend. A recording of the presentation will be made available following both sessions.*

#### SCORE Manual Session A

Tuesday, 9 February 2021

12pm PST / 2pm CST / 3pm EST / 5pm BRT, ART / 10pm SAST, CAT / 11pm EAT (Wednesday, 10 February at 3am ICT)

[Register here for Session A](#)

#### SCORE Manual Session B

Thursday, 11 February 2021

5am PST / 7am CST / 8am EST / 10am BRT, ART / 3pm SAST, CAT / 4pm EAT / 8pm ICT

[Register here for Session B](#)

### Training

#### DAIDS Learning Portal Updates

New and updated trainings on the DAIDS Learning Portal (DLP) have been added to improve adherence to and understanding of DAIDS policies and procedures and current ICH GCP guidelines. Check out the new and updated trainings on the [DLP](#).





# 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 Financial Disclosure/Conflicts of Interest (FDCOI) Working Group has started editing the FDCOI SOP for the 2021 annual solicitation.

The Youth Prevention Research Working Group (YPRWG) is currently editing a site survey to send to the new NIH HIV/AIDS Clinical Trials Networks sites to assess site experience with adolescent research.

The COVID-19 CAB Coalition (CCC) met in late January for its first call of 2021. The CCC discussed potential webinar topics for upcoming webinars/panel discussions. The group also discussed creating short videos for the various CABs that make up the CCC to share CAB and study information. Once created, the videos will be shared via the [COVID-19 Community Resources Page](#) and social media.

The Behavioral Science Consultative Group (BSCG) met in January to discuss plans for the upcoming year. The BSCG provided updates for ongoing Network HIV studies and COVID-19 trials. The BSCG is waiting to hear back from a journal on a recently submitted paper; the BSCG hopes to hear from the journal soon regarding publication.



### Community Partners

*Russell Campbell, HANC Deputy Director*

Community Partners is in the process of soliciting representatives to serve on the Strategic Working Group (SWG). Two Community Partners Executive Committee members are selected to serve as members of the National Institutes of Health (NIH)

HIV/AIDS Clinical Trials Networks SWG. Participation in these groups involves communicating Cross-Network community perspectives to the Network leadership and advancing appropriate issues related to community involvement within the NIH HIV/AIDS Clinical Trials Networks. Community Partners is also in the process of soliciting a new CP Co-Chair.

# HANC PROGRAM HIGHLIGHTS



## Cross-Network Coordination

*Milan Vu, HANC Project Manager*

The Cross-Network Site Coordinators Working Group met to share updates on various DAIDS initiatives and discuss site approaches to remote source document verification.

The group also reviewed the [Cross-Network IT Best Practice Standards](#) for sites and laboratories, which is due to be updated in 2021.

The DAIDS Site Clinical Operations and Research Essentials (SCORE) manual recently launched. The SCORE Manual consolidates DAIDS operational and procedural requirements needed to support implementation of DAIDS-sponsored clinical research. The manual serves as a reference describing DAIDS requirements and may be a resource for current site staff as well as for onboarding new research staff. View the SCORE Manual [here](#).

Two launch sessions will be held in February to provide an overview of the SCORE Manual and address questions. The same presentation is being offered on two separate dates. See the **Webinars & Training** section for more event details and registration.



## Laboratory Coordination

*Tyler Brown, HANC Project Manager*

The Laboratory Technologists Committee (LTC) held two conference calls in January to discuss laboratory updates to A5401, standard processes for Lab Processing Chart preparation, and new Protocol LT assignments. The LTC SOP WG met separately in

January to continue revising the ACTG/IMPAACT Laboratory Shipment Evaluation Procedure.

The CPQA Advisory Board (CPQAAB) met in January to discuss CPQA program updates on proficiency testing (PT), including approaches to PT for COVID-19 related activities. The meeting featured a presentation from Dr. Anthony DeStefano on emerging technologies for bioanalytical method validation of large molecules.

The Lab Focus Group (LFG) met with the DAIDS Clinical Laboratory Oversight Team (DCLOT) in January to discuss the Patient Safety Monitoring in International Laboratories group (pSMILE) contract outage. The LFG met again later in January to discuss the role of the Network Laboratory Centers in providing interim continuity of operations for pSMILE contract services.

The Virology Quality Assurance Advisory Board (VQAAB) met in January to review new proficiency testing data for HIV RNA panels and revise the list of VQA participating labs.

# HANC PROGRAM HIGHLIGHTS



## The Legacy Project

*Brian Minalga and Pedro Goicochea, HANC Legacy Project Community Engagement Officers*

HIV research news abounds! We at the Legacy Project have updated our handy resources to help you navigate what's new in HIV prevention

research:

- [Be the Generation](#) website on microbicides, PrEP, Treatment as Prevention, and HIV vaccine research (also [en español](#))
- The [Women's HIV Research Collaborative's comprehensive training](#) on biomedical HIV prevention for cis and trans women

Please welcome Dazon Dixon Diallo as the new co-chair of the Women's HIV Research Collaborative (WHRC)! Many thanks to Clare Collins for her 4 years of leadership to the WHRC--the maximum time allowed. Dazon will lead the WHRC with Morénike Giwa Onaiwu, who is beginning her second 2-year term as WHRC co-chair.

**February 7:** Legacy recognizes [National Black HIV/AIDS Awareness Day](#). As part of National Black HIV/AIDS Awareness Day and Black History Month, Legacy will be hosting a webinar focused on HIV & Aging: Resilience & Research – stay tuned for the announcement.

Please join us in welcoming Eddie Givens as a new Legacy Project Working Group member. Eddie is a longtime advocate and a CAB member who resides in Houston, Texas. Eddie has been volunteering his time and energy in the Houston HIV community since 2006. Currently, he is a member of the [HART](#) Houston HIV Cross-Network CAB since 2017. Eddie shared that he has unique energy and creativity with endless bounds.

# 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.

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[WWW.HANC.INFO](http://WWW.HANC.INFO)