

OCTOBER 2020

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.

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

HANC ANNOUNCEMENTS

COVID-19 Community Resources

In response to community voices who have expressed a need for timely and accurate information regarding COVID-19, the following [Public Health – Seattle and King County – Webinars](#) COVID-19 materials have been graciously made available to all global communities by Public Health – Seattle and King County.

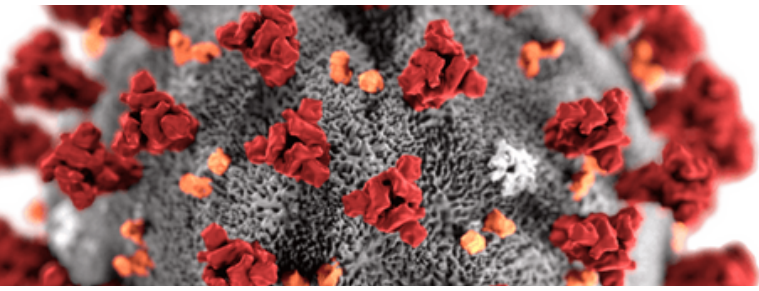
The expectation is that individuals, CABs, CAGs, community groups and or research sites can review these materials and modify them accordingly to address local needs so that they can be shared more broadly with respective communities. The ultimate goal is to ensure that all global communities have accurate knowledge regarding COVID-19 that they need to stay safe and healthy during this time.

Please check back in on the Google Drive periodically as new content will be added and feel free to share any modified materials that have been developed to [HANC – Materials and Webinars](#) so that those can be added to the resource library.

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



COVID-19 Updates

COVID-19 CAB Coalition

HANC has formed a new working group, the COVID-19 CAB Coalition to share information, facilitate resource sharing, advocate on the behalf of the overall COVID-19 research efforts, and to host COVID-19 related webinars. The coalition aims to create a COVID-19 CAB resource page to append resources already cataloged on the HANC website under the [interaction of COVID-19 and HIV](#). Current group members represent the CoVPN, ACTG, AVAC, the CFAR National CAB Coalition, the CAB at Stony Brook, DAIDS, and Community Partners.

Rise Above COVID and ACTIV-2



Rise Above COVID is a movement to find medicines for COVID-19 through the ACTIV-2 Study. This study is for people who have tested positive for COVID-19 in the last 5 days.

Launched in August, ACTIV-2 includes both phase 2 and phase 3 evaluations of multiple promising investigational agents for treating early COVID-19 in a single trial. Learn more about the ACTIV-2 study at RiseAboveCOVID.org



Upcoming COVID-19 Prevention Network (CoVPN) Events

COVID in Black: Black Women on COVID-19 (Episode 2)

October 6 @ 11:30AM PT / 2:30PM ET

This episode of the CoVPN *COVID in Black* discussion series will speak with Black women who work at the intersection of public health and social justice. The panelists will unpack the importance of raising awareness and knowledge about COVID-19 clinical trials, considerations when deciding to enroll in COVID-19 clinical trials, and what they believe is needed to support acceptability and uptake of an approved COVID-19 vaccine within Black communities. [Register here to attend via Zoom](#) or go to the [CoVPN Facebook page](#) to watch through Facebook Live.

Missed the first episode of *COVID in Black*? Watch the recording on the CoVPN YouTube page [here](#).

The Impact of COVID-19 on HIV Protection & Infection

October 6 @ 10:45AM PT / 1:45PM ET

This panel at the National Minority Quality Forum (NMQF) Summit will feature Guillermo Chacon (Latino Commission on AIDS), Dr. Stephaun Wallace (CoVPN/HVTN, Fred Hutch), and Cookab Hashemi (Gilead Sciences, Inc.). [Register here](#).

CoVPN Community & Stakeholder Engagement Strategic Plan

The CoVPN recently shared the [CoVPN Community & Stakeholder Engagement Strategic Plan](#). The plan is available in English, with Spanish translation forthcoming.

NETWORK ANNOUNCEMENTS



REPRIEVE Virtual Meeting: October 14, 2020

The 2nd REPRIEVE Virtual Meeting will take place on Wednesday, October 14th, 9:00 – 10:30 AM EDT! Anyone interested is welcome to join. The meeting will feature a keynote presentation from Dr. Esteban Martinez, PI of the REPRIEVE EU5332 protocol, entitled *Incidence and Severity of COVID-19 in People with HIV on ART: Findings from a Cohort Study in Spain*. There will also be presentations of articles recently featured in a Journal of Infectious Diseases supplement, *Critical Comorbidities in the Modern Antiretroviral Era: Baseline Demographics, Metabolic, and Immune Characteristics of the Global REPRIEVE Trial Population*. Join us to hear from Sara Looby, PhD and Markella Zanni, MD, *Correlates and Timing of Reproductive Aging Among Midlife Women with HIV in REPRIEVE*, Laura Smeaton, MS, *Characteristics of REPRIEVE Participants Identifying Across the Transgender Spectrum*, and Markella Zanni, MD and Tomas Neilan, MD, *Myocardial Steatosis Among ART-treated People with HIV in REPRIEVE*. Join the livestream by clicking [HERE](#).

ACTG Trials Reopening

In response to COVID-19, many ACTG trials temporarily closed to accrual to ensure the safety of our participants and staff. We are pleased to announce the following trials have reopened and are enrolling participants at sites that are able to safely conduct follow-up visits.

[A5300B: PHOENIX \(Protecting Households On Exposure to Newly Diagnosed Index Multidrug-Resistant Tuberculosis Participants\)](#) - Focuses on household contacts at high risk for developing multidrug resistant tuberculosis (MDR-TB), which is an infection that does not get better with standard treatment for TB.

[A5312: Early Bacteriocidal Activity of High-Dose Versus Standard Dose INH for INH-Resistant TB](#) - Determines if different doses of INH can fight INH-resistant TB.

[A5321: The ACTG HIV Reservoirs Cohort \(AHRC\) Study](#) - Studies differences and changes over time in HIV reservoirs (groups of HIV-infected cells that 'hide' from anti-HIV medications).

[A5375: Optimize LNG EC](#) - Determines if a higher dose of levonorgestrel Emergency Contraception (commonly called "Plan B" or the "Morning After Pill") is needed to achieve high enough drug levels in girls and women who are taking anti-HIV medications known to decrease the effectiveness of this form of birth control.

[A5377: Tri-Specific Antibody](#) - Studies a broadly neutralizing antibody called SAR441236 in humans to determine if an infusion is safe and tolerable and measures the amount of SAR441236 in the blood over time.

NETWORK ANNOUNCEMENTS



[A5381: Observational Cohort to Assess Therapeutic Efficacy and Emergence of HIV Drug Resistance Following Initiation of Tenofovir-Lamivudine-Dolutegravir \(TLD\) for First- or Second-Line ART](#) - Determines if people who have HIV qualify to switch to or receive dolutegravir-containing antiretroviral therapy.

Latest Opening:

[A5357: A Study of Long-Acting Cabotegravir Plus VRC01LS to Maintain Viral Suppression in HIV-1-Infected Adults](#) – Evaluates the safety and effectiveness of an combination of long-acting cabotegravir (CAB) and monoclonal antibody VRC-HIVMAB080-00-AB (VRC01LS).

[A5359: The LATITUDE Study](#) – Investigates whether long-acting injectable medications will be more successful for people who are non-adherent to their HIV medications than oral regimens.

[A5372: Drug-Drug Interactions Between Rifapentine and Dolutegravir in HIV/LTBI Co-Infected Individuals \(RPT-DTG PK Study\)](#) – Determines if taking medications to prevent TB affects the drug levels in blood of a the HIV medication dolutegravir (DTG) and if an extra dose of DTG is needed during this TB preventive treatment.



HPTN leadership will host an update webinar at 10 a.m. (EDT) on Tuesday, October 6, 2020. The 2.5-hour webinar will feature information about the state of the Network, critical study updates, and next steps for 2020 and beyond. Keynote speaker, Dr. Anthony S. Fauci, will discuss COVID-19 public health and scientific challenges.

To view the program schedule and access the webinar link, please visit:

<https://www.hptn.org/news-and-events/meetings/2020-hptn-update-webinar>

NETWORK ANNOUNCEMENTS



Recent publications on IMPAACT work have been released and include [IMPAACT P1076](#) in Clinical Infectious Diseases, [IMPAACT P1078](#) in Clinical Pharmacology & Therapeutics, and research on [Respiratory Syncytial Virus \(RSV\) vaccine development](#) in The American Journal of Respiratory and Critical Care Medicine.

In addition, the IMPAACT Network is excited to announce its rebrand, coming late this year. The rebrand will consist of a new logo, new colors, new website and new templates. Keep your eye out for emails from the Network (subscribe to our mailing list [here](#)) and follow IMPAACT on [Facebook](#), [Twitter](#) and [LinkedIn](#) to learn more about the upcoming rebrand.



MTN was excited to be part of a new episode from AVAC's podcast, *Px Pulse*, on the dapivirine vaginal ring.

The episode, [A leap forward for the dapivirine vaginal ring, the next steps are critical](#), aired on September 17 and featured five different perspectives on the ring, including Sharon Hillier, MTN PI. The presenters focused on how the ring expands HIV prevention options for cisgender women, and the most important next steps to bringing the ring to those who need it.

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 2-3

Adherence 2020
(Virtual)

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

Adolescent Trials Network's (ATN) iTech Studies and COVID-19: Adapting iTech During a Pandemic

October 8 @ 8AM PT / 11AM ET

The HANC-facilitated Youth Prevention Research Working Group (YPRWG) invites you to participate in a webinar about the ATN iTech studies featuring Dr. Lisa Hightow-Weidman (UNC) and Dr. Travis Sanchez (Emory). The UNC/Emory Center for Innovative Technology (iTech) aims to lower the burden of HIV infection by developing and evaluating innovative, interdisciplinary research on technology-based interventions across the HIV prevention and care continuum for at-risk or infected youth aged 15-24 years in the United States.

Dr. Hightow-Weidman will provide an overview of ATN's iTech and a summary of the included studies. She will present preliminary data from iTech and discuss changes made in response to COVID-19. Dr. Sanchez will discuss COVID-19 data collection and preliminary findings from the COVID-19 measures. [Register here.](#)

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.



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.

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 finalizing 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 8am PT/11am ET. [Register here](#).

The HANC-facilitated annual solicitation was sent out on September 21, 2020. If you have any questions, contact findisclosure@hanc.info.



Cross-Network Coordination

Milan Vu, HANC Project Manager

The Data Management Center Working Group (DMCWG) shared lessons learned from piloting Rave eCOA Clinical Outcome Assessments, discussed updates on the safety data reconciliation policy, and discussed activity related to protocol deviation reporting.

The Cross-Network Site Coordinators Working Group (SCWG) met to discuss updates related to site stressors and constraints due to the pandemic, recent release of the Electronic Information Systems (EIS) policy, and co-enrollment prevention in COVID-19 trials.

HANC PROGRAM HIGHLIGHTS



Laboratory Coordination

Tyler Brown, HANC Project Manager

The Laboratory Technologists Committee (LTC) held two conference calls to discuss experiences participating in virtual lab audits, study startup procedures for A5401, and validation of SARS-CoV2 assays.

The Lab Focus Group (LFG) held a conference call to discuss the group's annual work plan objectives and the ongoing review of cross-network SOPs.

Quest Diagnostics in Baltimore (Quest) has relocated to a new facility and are now receiving specimen shipments at a new address. Their new address and fax number can be accessed on the HANC website by clicking [here](#).

A new CDC Import Permit has been issued for shipping specimens to the Biomedical Research Institute (BRI) Biorepository from outside of the US. The new permit can be accessed on the HANC website by clicking [here](#).



The Legacy Project

Brian Minalga, HANC Legacy Project Community Engagement Officer

Thursday, October 15: Legacy recognizes [National Latinx AIDS Awareness Day](#).

October 19-21: [United States Conference on HIV/AIDS \(USCHA\)](#). Legacy is involved with the following virtual sessions:

- TRANSforming HIV Research: Systemic Change to Advance Transgender Inclusion
- Words Matter: Using Non-stigmatizing Language in the HIV Field
- The Impact of COVID-19 on NIH HIV/AIDS Research
- Voices from Stolen Land in the Time of COVID-19
- Long-Acting Antiretroviral Injectables (LAIs) and Broadly Neutralizing Antibodies (bNAbs) Messaging/Considerations for Women and POC
- Historical Distrust Impact on Research Community Engagement

October 25-28: [American Public Health Association Annual Meeting \(APHA\)](#). The Women's HIV Research Collaborative and Legacy Project will present the following live, virtual sessions:

- Monday, 10/26 at 7:30 a.m. Pacific: "Okay Ladies Let's Get Information: Women & Biomedical HIV Prevention"
- Monday, 10/26 at 9:30 a.m. Pacific: "Addressing the Intersection of Intimate Partner Violence and HIV in Women"
- Tuesday, 10/27 at 12 p.m. Pacific: "Fostering Transgender Inclusion in Research"

COMMUNITY PARTNERS SPOTLIGHT

Community Partners members are sharing some of the HIV study activities that are resuming at sites. We invite others to share updates of HIV study activities by sending photos to rcampbel@fredhutch.org with the subject line: Resuming HIV Study Activities.



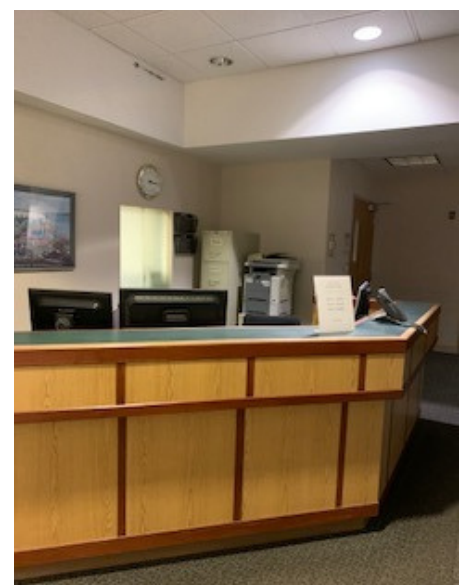
Site interviewers at Makerere University – John Hopkins University Research Collaboration in Mulago Hospital Complex in Uganda demonstrate how social distancing looks following the risk mitigation plan that was submitted to the IRBs.



Photos from Case Western Reserve University CRS in Cleveland, Ohio of changes in work locations as the site resumes HIV study activities. Two self-contained pods the size of shipping containers were installed outside of the site's clinic building for trial visits by people with active COVID-19, alongside two designated parking spots. Participants stay in their car until staff indicate they can proceed to the pod.

The site also found space for the large volume of new HIV and COVID-19 prevention vaccine clinical trial participants by acquiring the hospital's Medical Access Clinic. The space has a reception room and several exam rooms to hold the hundreds of clinical trial visits required by this pandemic.

Expanding to new locations, even outside of your front door, requires countless institutional meetings, new equipment and supplies, new SOPs and emergency procedures, and different staffing levels and duties. It's so much more than just different rooms.



ABOUT COMMUNITY PARTNERS

[Community Partners](#) (CP) is a cross-network 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.

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 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. [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 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