NEW Resource! Cross-Network Bill of Rights and Responsibilities for HIV Research

The new Cross-Network Bill of Rights and Responsibilities for HIV Research document provides a short list of the rights and responsibilities for participants in a clinical trial. The purpose of this document is to help research participants act on their own behalf and in partnership with study staff. Rights and responsibilities listed in the document are in no particular rank order. The document was developed by the Community Partners Bill of Rights and Responsibilities Working Group for use by sites, at their discretion, along with informed consent forms. Find it on the HANC website, Resources for Communities page and feel free to share with collaborators both within and outside the Networks.

Training and Webinar Preview

A new training module focused on Creating a Gender-Affirming HIV Research Environment is now available, plus webinars celebrating National Latinx AIDS Awareness Day, examining the effects of substance use/abuse on the adolescent brain, and exploring cure-related research in the ACTG are all coming up in the month of October. See the Webinars & Training page for more details!
The DAIDS Applied Research Training pilot took place 17-19 September at the Hyatt Regency in Johannesburg, South Africa. Over 110 attendees came together to focus on strengthening Good Clinical Practice (GCP) and International Council for Harmonization (ICH) compliance at clinical research sites and engage in small group, application-focused learning experiences.

Day one (17 Sept) kicked off with opening remarks from Manizhe Payton before quickly transitioning into the sessions for the day. Attendees split into one of four breakout rooms, collaborating in their assigned groups to work through case studies related to investigator responsibilities, study drug administration, IRB/EC, and informed consent. After a break, sessions resumed to tackle questions and scenarios around essential documents, source documents, safety oversight, and quality management.

Day two (18 Sept) featured a mix of breakout sessions and large group activity addressing good documentation practice, staying up-to-date with regulatory updates, monitoring, and part two of quality management focused on QA/QC (quality assurance/quality control) and CAPA (corrective and preventive action).

Day three (19 Sept) reconvened attendees as a large group to talk about audits, inspections, and expectations following the conclusion of DART. Susan Leister of DAIDS facilitated morning activities centered around audit readiness, and was followed by an expert panel discussion with representatives from PPD, sites, and DAIDS that addressed nuanced issues sites could encounter during a regulatory inspection.

Materials and resources from the training will be posted on the DART website, as well as testimonials, interviews and photos. As an additional resource, training kits will be posted on the 15th of each month. These kits are intended to facilitate training activities which sites may choose to conduct independently among their staff. Each kit builds on one another and emulates the applied style of training, which was used for this pilot event. To access the website, please request access by clicking the tab on the upper right corner of the webpage. Once access is granted, an email will be sent to you indicating how to enter the site. Any questions regarding the DART website can be sent to DARTsupportteam@niaid.nih.gov.
This month, the ACTG is highlighting two important studies:

**ACTG Study A5338 Raises Potential Concern about Standard DMPA Dosing Frequency among African Women Receiving HIV and TB Treatment**

Tuberculosis (TB) coinfection among pregnant women living with HIV is associated with poor outcomes so effective contraception to prevent unintended pregnancy is of paramount importance for young women with HIV and TB. However, hormonal contraceptives can fail as result of drug-drug interactions (DDI) between these agents and TB or antiretroviral treatments (ART). Depot medroxyprogesterone acetate (DMPA), provided as a shot every three months, is the most commonly used contraceptive among young African women, but has the potential to interact with both efavirenz (EFV) and rifampin (RIF). The A5338 study was designed to understand DDIs between DMPA and EFV and RIF, and, ultimately 1) identify the ideal dosing frequency for DMPA among women with HIV-TB coinfection; and 2) determine whether a 150 mg injection of DMPA was effective in preventing ovulation.

Of the 62 women enrolled in the study, 42 completed the pharmacokinetics study from five sites in Sub-Saharan African countries. Participants were on RIF-based TB treatment and EFV-based ART and given DMPA at study entry, with levels of the active metabolite of DMPA measured every 2 weeks. Their results were compared with those from women taking DMPA, but neither ART nor TB treatment, from the control arm of a separate study (A5093). The results of A5338 demonstrate that EFV-based ART in combination with RIF-based TB treatment reduced the amount of DMPA to a level associated with a risk of ovulation in 12 percent of women. Researchers also found that DMPA was cleared faster among women with HIV on ART and RIF-based TB treatment, suggesting that more frequent dosing might be necessary. ACTG is currently undertaking further analysis using data from this study and others to make a definitive recommendation about dosing of DMPA among HIV-TB infected women. ([Clinical Infectious Diseases](https://www.clinicalinfectious.org). 2019 Sep 5. pii: ciz863. doi: 10.1093/cid/ciz863; Mngqibisa R, et al)

**Antiretroviral Treatment Interruptions Look Different in Postpartum Women than in Men**

The short-term safety of treatment interruptions (a necessary part of cure studies) is not well-established, particularly in women and racially diverse populations. To address this gap in research and knowledge, PROMISE study (an international randomized controlled study, also supported by the IMPAACT network) explored the viral rebound kinetics and safety associated with treatment interruptions among women who underwent ART discontinuation postpartum as part of the international, randomized-controlled PROMISE trial. The team of researchers, led by a early stage investigator, Catherine Le, compared these results to those from men in historic ACTG interruption trials. *(continued on next page)*
The study evaluated 1,076 asymptomatic, virally suppressed women living with HIV with baseline CD4 ≥ 350 cells/uL who underwent ART discontinuation postpartum. In these women, the estimated median time to viral rebound was two weeks. An estimated 6 percent of women remained virally suppressed at 30 weeks. Among women who experienced viral rebound by 30 weeks (N=993), less than 4 percent experienced grade 3 or higher laboratory events, and 1 percent experienced a WHO stage 2 or higher clinical event. Less than 4 percent experienced a decline in CD4 count to < 350/uL.

The proportion of women with virologic suppression at weeks 4 and 12 was compared to that in the ACTG NWCS 371 analytic treatment interruption pooled analysis, which was 91 percent male. A significantly higher proportion of women in PROMISE (25.4 percent) were virologically suppressed (<400 copies/uL) at 12 weeks compared to ACTG NWCS 371 participants (6.5 percent, p < 0.01). While there were significant differences between participants in PROMISE and ACTG NWCS 371 beyond sex (including older age, longer duration on ART, higher proportion of NNRTI-based regimens, and initiation of ART during acute or early infection in the ACTG NWCS study), researchers found these data striking, as many characteristics of the participants in PROMISE favored more rapid rebound. This study demonstrates that inclusion of women in future cure studies is safe. Future studies of cure research should include both men and women in order to fully represent all people living with HIV. (AIDS. 2019 Aug 1. doi: 10.1097/QAD.0000000000002334; Le CN, et al)

Following concept review, the HPTN Executive Committee approved protocol development of HPTN 097 (submitted as HPTN 074 Plus): A Phase III Randomized Control Trial to Optimize HIV Viral Suppression Comparing the HPTN 074 Intervention as the Standard of Care with an Integrated Intervention of Immediate Antiretroviral Therapy and Medication Assisted Treatment Plus Enhanced Social Support and Mental Health Care Among HIV-Infected People Who Inject Drugs.

Recent results from the HVN 097 study published in Science Translational Medicine revealed that the RV144 vaccine regimen, designed to block the HIV strains B and E circulating in Thailand, also elicited vaccine induced immune responses among volunteers in South Africa, where a different strain of HIV predominates. “This breaks open the thought pattern that each region of the world needs a separate type of HIV vaccine based upon their circulating strains,” said Dr. Larry Corey, Principal Investigator of the HVN. (continued on next page)
The HVTN Social and Behavioral Sciences and Community Engagement Unit (SBS/CEU) would like to welcome two new amazing team members who joined to support the MOSAICO Study globally. Both of these dedicated professionals bring a wealth of experience, resources, and connections to various stakeholders, and we are fortunate to have them with us.

Patricia Segura officially joined the HVTN SBS/CEU team on August 1. She is the newest Community Engagement Project Manager focused on the MOSAICO Study. Patricia is based in Lima, Peru and will manage the HVTN Community Engagement Program for sites in Mexico and Peru.

Patricia joins our team with experience in community engagement, health education, and nursing that spans 30 years. She was previously at the IMPACT ACTU in Lima, Peru as the Head of Community Involvement and recently served as the Director of the HIV/STD National Program with the Peruvian Ministry of Health. She earned a Bachelor of Nursing degree from Universidad Nacional del Callao in 1988 and an MPH from University of Washington in 2004. She is excited to join the team in this capacity and looks forward to meeting those she has not met, and reconnecting with those she has. Patricia can be reached via email at: psegura@fredhutch.org.

Please welcome Giulio Corbelli, the HVTN’s newest Community Engagement Project Manager who will be based in Roma, Italy as of September 1. Giulio will be focused on implementing the HVTN Community Engagement program in Italy, Poland, and Spain for the MOSAICO Study.

Giulio joins our team with more than a decade of experience in HIV work, and has additional professional experiences in journalism, theater/film-making, and the European AIDS Treatment Group (EATG) as a project advisor and member of their clinical trial management committee. Giulio has strong community and research roots in Italy and established relationships with key stakeholders in other areas of Europe. He earned a Master’s Degree in Civil Engineering from the University of Pisa. Giulio can be reached via email at: gcorbelli@fredhutch.org.

For more information about the MOSAICO Study’s community engagement efforts, please contact Stephaun Wallace, PhD, HVTN Social and Behavioral Sciences Junior Investigator Liaison at: sewallac@fredhutch.org.
The IMPAACT Network is proud to announce the launch of new social media channels and a newsletter for the Network. Visit the account at the links below and subscribe to the newsletter at impaactnetwork.org/news_/newsletters.html

facebook.com/IMPAACTNetwork
twitter.com/IMPAACTNetwork
linkedin.com/company/IMPAACTNetwork

The IMPAACT Network is also delighted to announce the publication of primary results from the IMPAACT P1078/TB APPRISE study in the 3 October 2019 issue of The New England Journal of Medicine. A NIAID news release related to the publication is available at http://j.mp/TB-px-in-pregnancy. Preliminary results from the study were previously announced and presented at the Conference on Retroviruses and Opportunistic Infections in March 2018.

**IMPAACT P1078** was a Phase IV, randomized, double-blind, placebo-controlled study designed to evaluate the safety of immediate versus deferred isoniazid preventive therapy (IPT) among pregnant and postpartum women with HIV in settings with high prevalence of tuberculosis (TB). The study concluded that antepartum IPT is as safe as postpartum IPT with respect to maternal safety events. There were more adverse pregnancy outcomes among mother-infant pairs randomized to IPT during pregnancy than among pairs randomized to IPT after delivery. Among pairs randomized to IPT during pregnancy, there was a higher number of infants who died before birth and a higher number of infants who had low birth weight, compared to pairs randomized to take IPT after delivery.

Based on these results, the study team concluded that the WHO recommendation to initiate IPT during pregnancy in women with HIV who are on antiretroviral therapy needs re-evaluation.

The 2019 MTN Regional Meeting took place September 9-12, 2019, in Cape Town, South Africa. Presentation slides and photos from the meeting can be viewed on MTN’s web site, including a music video developed by the MU-JHU Research Collaboration CRS to promote recruitment into the REACH study featuring Ugandan performer Joanita Muganga.

MTN is excited to report that the Chiang Mai, Thailand site for the MTN-035 rectal microbicide study has been activated. MTN-035, or DESIRE (Developing and Evaluating Short-acting Innovations for Rectal Use), is the first study to systematically examine placebo methods for delivering drugs to help prevent HIV from receptive anal sex. Study participants are using three placebo products rectally – a douche, suppository and insert (fast-dissolving tablet inserted into the rectum).
MEETING CALENDAR

Oct 2-6
IDWeek
(Washington, DC)

Oct 21-22
Inter-CFAR Women and HIV Symposium
(Chicago, IL)

Oct 30-Nov 2
Union World Conference on Lung Health
(Hyderabad, India)

Nov 6-8
17th European AIDS Conference
(Basel, Switzerland)

Dec 2-7
ICASA
(Kigali, Rwanda)

Dec 3-4
Biomedical HIV Prevention Summit
(Houston, TX)

Jan 9-12
MTN Annual Meeting
(Arlington, VA)

Mar 6-7
10th International Workshop on HIV & Women
(Boston, MA)

Mar 8-11
CROI 2020
(Boston, MA)

May 27-29
HVTN Full Group Meeting
(Washington, DC)

WEBINARS & TRAINING

Upcoming Webinars

National Latinx AIDS Awareness Day
October 15, 2019 @ 10 AM PST
In honor of National Latinx AIDS Awareness Day, Legacy will host a webinar discussing the impact of HIV in the Latinx community. Register here.

Exploring and Disrupting Pathways to Risky Behaviors
October 16, 2019 @ 10 AM PST
The Youth Prevention Research Working Group invites you to a webinar on the adolescent brain and substance use/abuse. The webinar will review what we do and don't know about child development and implications for their pathways to risky behavior. Register here.

HIV Cure Research: An Overview of ACTG’s Cure-related Research and the Socio-behavioral Aspects of Cure-related Research (Part 3)
October 31, 2019 @ 11 AM PST
Please join the Behavioral Science Working Group (BSWG) for the third and final part of HANC’s Cure Research Webinar Series. In Part Three, Dr. Rajesh Gandhi and Dr. Karine Dubé will discuss the cure-related research being conducted by the AIDS Clinical Trials Group (ACTG) and the socio-behavioral aspects of cure-related research. Register here.

Training

Creating a Gender-Affirming HIV Research Environment
Available on the DAIDS Learning Portal
This module is designed to facilitate transgender inclusion in HIV research by creating more gender-affirming spaces through staff understanding and responsiveness, the physical environment, and research study design. This is the third of the five-module Transgender Training Curriculum for HIV Research created by the Division of AIDS (DAIDS) Cross-Network Transgender Working Group. Access the course here.

To supplement the eLearning course, an in-person training tool is also available so you can provide in-person training at your site or in the community. It includes a PowerPoint presentation, facilitator’s guide, scenarios for an exercise, and selected resources all in English, Spanish, and Portuguese.

For details and other events, visit the HANC calendar.
HANC PROGRAM HIGHLIGHTS

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

Behavioral & Social Sciences

Greg Davis, HANC Project Manager

The Behavioral Science Working Group will host the third and final part of HANC’s Cure Research webinar series on October 31 at 11am PT/2pm ET with Dr. Rajesh Ghandi and Dr. Karine Dubé. Part One provided an overview of the state of HIV cure-related science. Part Two discussed community perspectives of HIV cure-related research. In Part Three, we will discuss the cure-related research being conducted by the AIDS Clinical Trials Group (ACTG) and the socio-behavioral aspects of cure-related research.

The YPRWG will host the “Exploring and Disrupting Pathways to Risk Behaviors” webinar on the adolescent brain and substance use/abuse on October 16, 2019 at 10am PT/1pm ET. Dr. Kevin Haggerty and Dr. Diane Fishbein will focus on three key areas where science can be our guide. First, how do social conditions, such as toxic stress associated with adverse childhood experiences, impact brain development and the consequences for future health and behavior? Second, what remedies have been developed that move us upstream to “turn off the trauma tap” and, in effect, prevent pathways to substance abuse, sexual risk behaviors, and HIV infection? And third, how does the use of substances impact the brain and behavior to further entrench negative pathways; such knowledge can be instructive in helping us to more effectively target interventions. In closing, we will discuss some promising trends and ongoing concerns that can be addressed via further investments in prevention.

Registration links for both webinars can be found on the Webinars & Training page.

Community Partners

Russell Campbell, HANC Deputy Director

Community Partners will be holding its 2019 Face-to-Face Meeting October 26-27 in Washington, D.C.

The Community Partners Bill of Rights and Responsibilities Working Group is pleased to share the Bill of Rights and Responsibilities for HIV Research document. This cross-network document provides a short list of the rights and responsibilities for participants in a clinical trial. (continued on next page)
The Site Coordinators Working Group (SCWG) discussed updates on several DAIDS policies, including the recently released CQMP policy and associated memo. In addition, the group reviewed updates on the DAIDS protocol funding (PF) pilots that were implemented in the past year, discussing some of the challenges faced by sites in regards to transferring funds and excess/shortage of funds.

The Data Management Center Working Group (DMCWG) discussed a new cross-network working group proposal centered around data standards, common data elements, and collection of pregnancy outcome data. The group also touched on trial master file (TMF) implementation and the DMCWG 2020 workplan.

Regarding the Clinical Trials Unit (CTU) funding opportunity announcement: individual networks have elected to publicly share the scientific aims of their Leadership and Operations Center (LOC) applications on their websites in an effort to provide information to investigators in a transparent way. This information can be found on the following network websites:

- ACTG
- HPTN
- HVTN

The Lab Technologists Committee (LTC) held two conference calls to discuss the upcoming LTC membership elections, lab technologist (LT) solicitations for six new protocols, and accessing LTC resources on the HANC websites. The LTC’s SOP Working Group held four additional conference calls to continue revising the Lab Processing Chart Standard Wording Documents.

The Virology Quality Assurance Advisory Board (VQAAB) held a conference call to discuss and wrap up the VQA contract transition and review new panel analysis reports from RNA036, DNA222-BS, and HCV001-002. Duke University took full control of the VQA contract on September 20, 2019.

The CPQA Advisory Board (CPQAA) held a conference call to discuss CPQA program updates on proficiency testing, CPQA sub-working groups, and the AVR/SOP Peer Review Program. The group also discussed establishing a sub-working group aimed at harmonizing the bNAb-focused work that is taking place among both network and non-network laboratories. (continued on next page)
(Laboratory, continued) The Lab Focus Group (LFG) held a conference call to discuss the new Harmonized Lab ID System, changes to the DAIDS Guidelines for Good Clinical Laboratory Practice Standards (GCLP), and the ongoing efforts to improve network-EQA communications. The group also discussed efforts to draft a new SOP that outlines the development and approval process for new Protocol Analyte Lists (PALs).

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

The Legacy Project and the DAIDS Cross-Network Transgender Working Group had three abstracts accepted to the Biomedical HIV Prevention Summit (December 3-4 in Houston, TX):
- Be the Generation: Mobilizing Communities to End the HIV/AIDS Epidemic
- HIV Prevention for Historically Black Colleges and Universities
- Fostering Transgender Awareness and Inclusion in HIV Research

Russell Campbell, Brian Minalga, and Louis Shackelford will attend the Summit to manage these sessions among several others that are pending confirmation from NMAC.

October 15: In recognition of National Latinx AIDS Awareness Day, Legacy will be hosting a webinar discussing the impact of HIV in the Latinx community. Our speakers will be Dr. Manuel Ocasio, Director of Behavioral Research and Community Engagement for Adolescent Medicine, Tulane University School of Medicine; and Moises Agosto-Rosario, Director of Treatment, National Minority AIDS Council (NMAC).

October 23: Legacy and the Women’s HIV Research Collaborative recognize the Day to End Violence Against Women Living with HIV.

WWW.HANC.INFO/LEGACY
BE THE GENERATION
FOLLOW THE LEGACY PROJECT ON

Financial Disclosure
Greg Davis, HANC Project Manager

The HANC-facilitated annual solicitation was sent out on September 20. Investigators receiving the solicitation have until October 20 to submit their statements.
WORKING GROUP MEMBER SPOTLIGHT

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

Belinda Ameterra
Meet Belinda Ameterra, a current member of Community Partners. About Belinda:
I hail from Worcester, a rural town 100 km from Cape Town. I joined the CAB in 2008 and became the first female chairperson in 2014. Whilst the CAB is autonomous, it has a long-standing relationship with the South African Tuberculosis Vaccine Initiative (SATVI), at its Worcester field site.

As a Community activist and a survivor of the Worcester Bomb blast in 1996, I also work in the prison with the youth. I am in the process of starting community advice office that will offer the following services resources to Healthcare Facilities, Restoration and Restorative Justice, Victim Offender Dialogue, prison inmates, young pregnant moms, veterans etc.

Moisés Agosto
Meet Moisés Agosto, a member of the Legacy Project Working Group.

Moisés is a longtime treatment advocate and educator for people living with HIV/AIDS. A frequent public speaker and writer in both English and Spanish, Moisés has played a crucial role in ensuring that communities of color have equal access to care, treatment, and lifesaving information and has won numerous awards for his work with the HIV community. He is currently the Director of Treatment for NMAC (formerly known as the National Minority AIDS Council).

Before joining NMAC, he worked at the International Treatment Preparedness Coalition (ITPC) with the HIV Collaborative Fund for HIV Treatment Preparedness, a project of the Tides Foundation. Previous to ITPC he served as the Vice President and Managing Director for Community Access, a Nelson Communications Company and member of the Publicis Healthcare Group. Moisés served as the editor of SIDA Ahora, the Spanish publication of the People with AIDS Coalition of New York, and was an active member of ACT UP. Moisés graduated from the University of Puerto Rico in Rio Piedras with a B.A. in Literature and Education.
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.

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.

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.

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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