



Office of HIV/AIDS Network Coordination

2022 Work Plan (Year 16)

December 1, 2021 – November 30, 2022

Table of Contents

Introduction	2
Major Cross-Network Projects.....	4
Infrastructure and Administrative Support	13
HANC Staff Role	13
The HANC Public Website.....	13
The HANC Collaborator Portal.....	13
Communications & Information Sharing.....	14
Clinical Research Support Contract	14
Objectives and Activities by Area of Coordination.....	15
Behavioral Science Coordination.....	15
Communications Working Group	17
Community Coordination	17
Data Management Center Coordination.....	22
Evaluation Coordination.....	23
Financial Disclosure Database	24
Laboratory Coordination	24
Legacy Project.....	28
Network Leadership	35
Site Management Coordination	36
Training Resources	37
Appendix I: Tangible Deliverables by Area of Coordination	38
Behavioral Science Coordination.....	38
Communications Coordination.....	38
Community Coordination	38
DAIDS.....	39
Data Management Center Coordination.....	39
Financial Disclosure Database	39
Laboratory Coordination	39
Legacy Project.....	40
American Indian/Alaska Native Working Group	40
New Investigators Working Group	41
Latinx Caucus.....	41
Site Management Coordination	41
Training Resources	41
Women’s HIV Research Collaborative (WHRC)	41
General Activities	42

Introduction

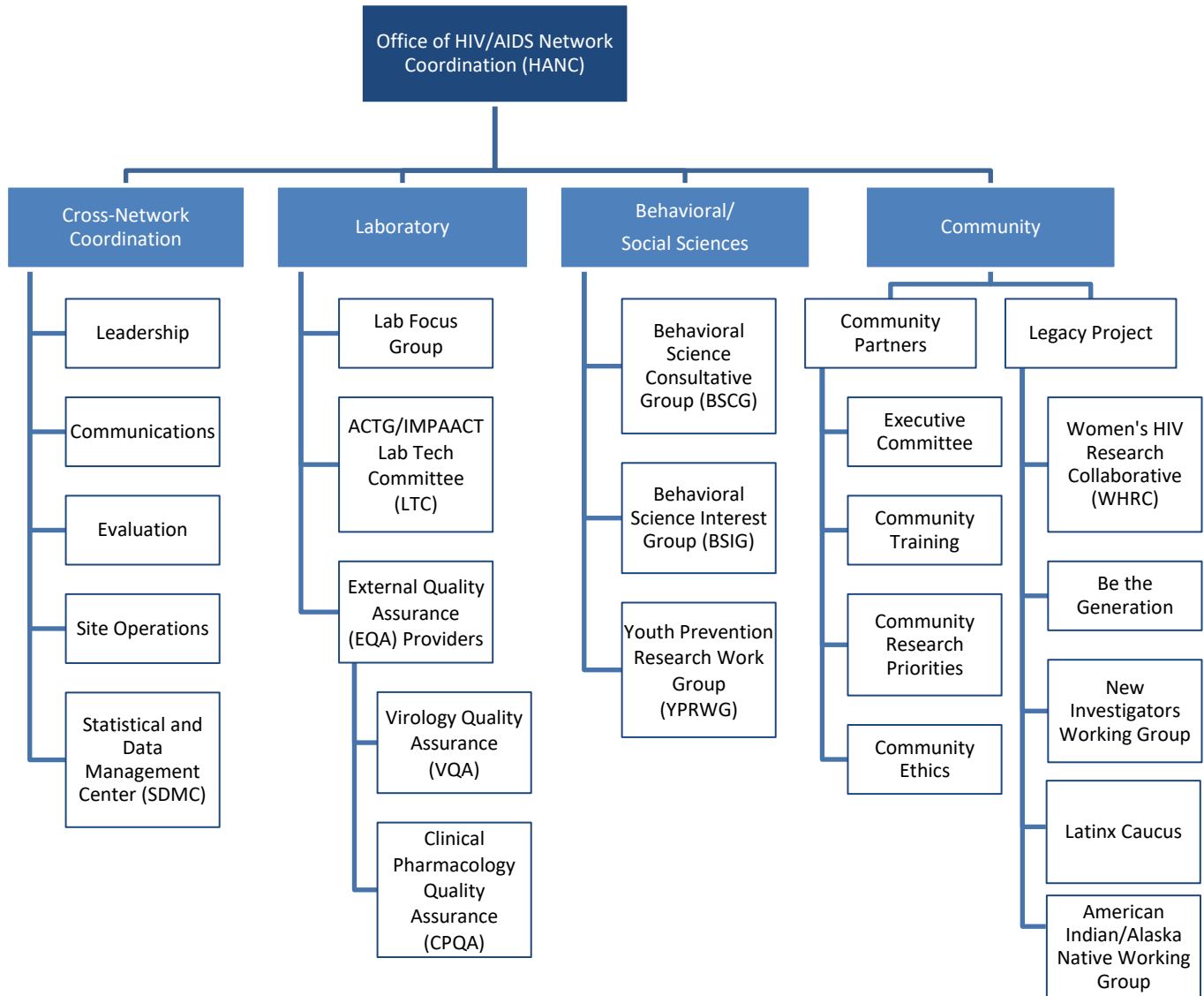
The Office of HIV/AIDS Network Coordination (HANC) works with the HIV/AIDS Clinical Trials Networks funded by the U.S. National Institutes of Health (NIH) with the intent of creating a more integrated, collaborative, and flexible research structure. The Networks are an affiliated group of national and international medical research institutions and investigators that conduct clinical HIV/AIDS research. They include the AIDS Clinical Trials Group (ACTG), the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN) and the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT). The NIH HIV/AIDS Clinical Trials Networks have been designed to address the NIH four HIV/AIDS scientific priorities:

1. Research to reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines;
2. Development of the next generation of HIV therapies with improved safety and ease of use;
3. Research towards a cure for HIV/AIDS; and
4. HIV-associated comorbidities and co-infections.

HANC is based at the Fred Hutchinson Cancer Research Center in Seattle, Washington and has provided leadership and logistical support for cross-network coordination efforts since 2004. HANC's mission is to support the science and operations of the networks by increasing efficiency and resource sharing through coordination of critical activities across networks and with other research and advocacy partners. Efforts focus on cross-network coordination, community and behavioral sciences, including: scientific leadership; site management and research logistics; laboratory operations; coordination of data management; development and application of consistent standards of performance evaluation; and facilitating effective community engagement in the research process, including the Legacy Project. HANC is accountable in its activities to Network Leadership and DAIDS.

This HANC 2022 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2021 – November 30, 2022 (GY16). The objectives, strategies and activities detailed herein have been developed in consultation with each of the relevant work groups. The document is intended to communicate and guide coordination efforts at a high level. Progress in meeting objectives will be monitored, communicated, and revised as needed on a regular basis by HANC staff.

HANC Organizational Chart (updated October 2021)



Major Cross-Network Projects

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Behavioral Science	Behavioral Science Consultative Group	Provide consultation as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral and social science components of their research agenda and studies: including but not limited to, advice on protocol design, protocol implementation and methodology for data collection, and evaluation	Increase the behavioral/social science components of network studies.	Ongoing
	HANC staff	Maintain “Behavioral Science Interest Group” alias and resource center for network-affiliated behavioral and social scientists.	Circulate notice of important tools, measures, CRFs, meeting notices, and articles. Host “topics of interest” webinar series.	Ongoing
	Youth Prevention Research Working Group	Identify, collaborate, and address matters related to international adolescent (ages 12-24) HIV prevention research; conduct training and webinars on related research topics	Increased promotion and sharing of network adolescent research agendas, strategies, and resources.	Ongoing
Communications	Communications Working Group	Convene bimonthly meetings to discuss network communications efforts, relevant topics in communications strategy and PR, and raise awareness of network engagements at scientific conferences and meetings.	Provide an open forum for network communications staff to discuss common issues and share lessons learned.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Community Coordination	Community Partners (CP)	Facilitate and enhance community representation and input at all levels in HIV/AIDS and related clinical research within the networks. Increase knowledge and awareness of CP, CP tools, and network activities. Support efficiency and effectiveness of local and network community advisory boards and engagement of stakeholders. Address challenges to community engagement in clinical research. Develop strategies and tools to address the intersecting priorities of the COVID-19 & HIV pandemics.	Provide input and recommendations to focus on meeting CP's Strategic Plan objectives to guide CP's work over the next six years.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	Community Partners Research Priorities Working Group	<p>Ongoing discussions to improve and promote transgender inclusion as outlined in the CP Memorandum, including working with DAIDS, the Networks and other groups to encourage adoption and implementation of the recommendations. Review network efforts on the CP priorities and identify priority gaps in the submitted scientific aims and focus on the following:</p> <ul style="list-style-type: none"> o Continue to support TB/HIV co-infection education efforts o Continue to support COVID-19 education efforts o Continue to support and address pediatric and adolescent research issues across networks o Support the work of the networks around the Ending the HIV Epidemic Plan o Continue to support prevention and treatment efforts with appropriate networks 	Enable involvement in the development and sharing of research priorities, and harmonization between community and investigator research priorities.	Ongoing
	Community Training Working Group	Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Assess the value of materials and determine additional priority topics. Work to make CP training modules on the DAIDS LMS available in an open access forum.	Share existing CAB training materials; identify and integrate material and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	Community Ethics Working Group	CP will identify opportunities for improvement and work in collaboration with DAIDS to provide guidance to researchers, communities and stakeholders regarding the ethical considerations and challenges in research with individuals facing stigma, discrimination, legal sanctions and/or interpersonal violence, and social harms.	Review topics across networks; identify areas where there are problems or opportunities for improvement and work in collaboration with the Network Leadership and DAIDS to address those issues.	Ongoing
	COVID-19 CAB Coalition (CCC)	The CCC will convene monthly video conferences to discuss COVID-19 community issues, maintain a COVID-19 community resource webpage, facilitate webinars as appropriate.	Disseminate information about COVID-19 trials and resources to the community	Ongoing
Data Management	Data Management Center Working Group	Convene monthly teleconferences to discuss various ongoing data quality assurance projects, identify areas for improvement, provide recommendations, and implement as appropriate.	Provide an open forum for the DMCs to discuss and identify common issues for resolution.	Ongoing
	IT Best Practices Working Group	Assess site needs in information systems and information technology. Review and update IS/IT best practices (last version published in 2018).	Assess gaps and opportunities in IS/IT management across DAIDS-sponsored sites and labs and mitigate impact on clinical trials data and ethical integrity.	June 2022

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Evaluation	Evaluation Working Group	Discuss opportunities to harmonize formats of evaluation reports across the networks and experiences using new technologies to support data tracking and visualization.	Streamline evaluation metric reporting, build collective knowledge, and encourage use of new tools to support network evaluation processes.	Ongoing
Financial Disclosure Database	Financial Disclosure Working Group	Work closely with network staff and DAIDS officers to review the harmonized financial disclosure requirements and maintain the cross-network web-based reporting interface.	Coordinated solicitation minimizes burden on sites, operation center staff, and investigators required to report. Continue to improve and adapt the SOP and secure online system for ease of use and clarity, and to ensure concordance with federal regulations	Ongoing
Infrastructure and Admin Support	HANC staff	Generate and review website and portal user statistics and member survey data to inform HANC programmatic and portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives. Increase awareness of ongoing HANC coordination activities and potential new opportunities.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Laboratory Coordination	VQAAB, CPQA	Ensure standard quality assurance for all the protocol-specified assays conducted in NIH-sponsored network clinical trials across networks and other partners through the Total Quality Management (TQM) Program.	Maintain data integrity of performed assays by testing for proficiency and tracking quality control standards. Develop proficiency testing programs for non-CLIA assays that can feasibly reflect its performance status in terms of technical skills as well as data measurement.	Ongoing
	LFG	Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories at the lab technician level.	Conserve resources for all networks by combining purchasing power, providing subject expertise, and collaborating efforts in projects that benefit the networks as a whole and individually.	Ongoing
	ACTG/IMPAACT Lab Technologist Committee	Identify and harmonize laboratory processes and procedures to reduce redundancy and increase efficiency at the lab technician level. Update SOPs in the ACTG/IMPAACT Laboratory Manual.	Conserve resources and efforts by creating standardized procedures and methodologies that can be utilized by cross-network labs.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Leadership	HANC Director and Deputy Director	Ensure that HANC is responsive to the priorities and needs of the Network Leadership Group (NLG), DAIDS Director and OCSO and OPCRO Directors.	Increase the efficiency and resource sharing through coordination of critical activities across the networks in collaboration with the NLG and DAIDS.	Ongoing
Legacy Project	Legacy Project Working Group	Build trust and collaboration between HIV research institutions and marginalized communities most impacted by the US HIV epidemic.	Build capacity among community members, researchers, and sponsors to enhance diversity, equity, and inclusion in NIH-funded HIV/AIDS and COVID-19 research conducted in the US.	Ongoing
	Women’s HIV Research Collaborative	Provides culturally appropriate guidance and leadership in development, implementation, and dissemination of information about HIV research focused on and responsive to the needs of cisgender and transgender women and girls in the United States. Raise the visibility of issues related to HIV in women in the US and promote awareness of scientific research for women in disproportionately impacted communities.	Advocating for HIV research with women living in the United States but operates with a comprehensive awareness of the potential for American women to benefit from HIV research that is being conducted internationally. To that end, WHRC’s focus is domestic, but its interests are both global and optimistic.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	New Investigators Working Group	Provides appropriate guidance and leadership in development, and dissemination of information about the various network new investigator programs and engagement of new investigators, with an emphasis on developing underrepresented minority researchers in the US.	Utilizing an equity-based approach, the NIWG focuses on supporting cross-network collaboration while strategically promoting the involvement of underrepresented researchers.	Ongoing
	American Indian/Alaska Native Working Group	Aims to increase engagement and participation of AI/AN populations in HIV, STI, and tuberculosis clinical research	The AI/AN working group supports cross-network collaboration, and provides guidance on the involvement and participation of members of the original nations of these lands in the HIV research process.	Ongoing
	Latinx Caucus	Aims to raise awareness and increase representation and participation of Latinx in social, behavioral, and clinical research in the fields of HIV, COVID-19, STI and TB.	The Latinx Caucus serves as a consultative group to provide advice and recommendations to DAIDS and the networks in the involvement of Latinx communities in research.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	Be the Generation	Finding safe and effective methods to prevent the spread of HIV is our best hope. Be the Generation stands proudly as a bridge between the researchers striving to end the HIV epidemic and the communities most affected by the disease.	Managed by the Office of HIV/AIDS Network Coordination and funded by the National Institutes of Health, our mission is to promote community awareness, understanding, and support for HIV prevention research.	Ongoing
Site Management Logistics	Network Leaders, OCSO, HANC Staff	Work closely with network staff, OCSO and other DAIDS offices to identify and address priority site management issues.	Improve communication and harmonized site operations.	Ongoing
	Site Coordinators Working Group	Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks' core operations centers.	Address issues of common concern and harmonize policies and procedures regarding site-level operations.	Ongoing
Training Resources	HANC Staff	Maintain the training resources public webpages.	Provide information on various training resources for site staff.	Ongoing

Infrastructure and Administrative Support

HANC Staff Role

HANC staff serve an administrative and project management role on each of the cross-network committees and working groups. As a working group or committee identifies areas of need or opportunity, HANC staff are responsible for developing and monitoring an action plan and documenting progress and challenges. HANC staff prioritize and delegate tasks, encourage completion of efforts, and acknowledge that members participate in working groups and take on cross-network tasks voluntarily, above and beyond their responsibilities within their primary organization.

HANC staff are responsible for setting meeting agendas, drafting and distributing materials, coordinating meeting logistics, chairing meetings, taking minutes, and ensuring that action items are communicated, tracked, and completed. HANC staff manage HANC portal team sites as a collaborative space for each working group, develop web-based tools, and train group members how to utilize them. HANC staff are an important conduit of information between different groups with shared interest or overlap in activity. Additionally, HANC staff continuously consider opportunities for cross-network coordination and collaboration. When they become aware of such opportunities, they present them to the relevant working group, or bring them to the Network Leaders and DAIDS and form new or ad-hoc working groups as appropriate.

The HANC Public Website

The HANC public website (www.hanc.info) is a repository of HANC-developed resources for HIV/AIDS Network collaborators, research sites, and the general public. Resources are categorized by topic area or audience, and include:

- An events page for upcoming scientific conferences, network meetings, and webinars.
- DAIDS memos, announcements, and supporting resources from training and event collaborations with DAIDS OCSO and OPCRO.
- HANC-developed training modules including the HIV Prevention Research (HPR) module and Basic Scientific Literacy (BSL) module.
- Archives of HANC-facilitated webinars.
- Guidance documents, educational materials, and additional resources for multiple audiences including community, laboratory staff, sites, investigators, and more.
- Extensive laboratory SOPs, including the Cross-Network Cold Chain Guidelines, Cross-Network PBMC SOP, TB Sourcebook, and ACTG/IMPAACT LTC SOP library.
- Additional directory resources for laboratory and site staff, such as the primary network laboratory (PNL) assignments and CAP/CLIA laboratory certification library.

HANC public website projects for the 2022 Work Plan include:

- Maintain content and resources on the HANC public website.
- Complete an annual review of all website content to ensure relevance and streamlined user experience.

The HANC Collaborator Portal

The [HANC portal](#) is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC portal includes document libraries; document

development and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory linked to the DAIDS-ES Master Contact system. As of October 2021, approximately 1,320 individuals have active HANC portal user accounts and 25 secure team sites are used by specific cross-network working groups for collective document development, online discussion, and sharing of materials and information. HANC maintains the following portal resources:

- DAIDS staff listing.
- DAIDS topic-specific contact list.
- Cross-network collaborator list.
- DAIDS Protocol Management feature which provides access to all approved protocols.
- DAIDS Master Contact System linkage

HANC portal projects for the 2022 Work Plan include:

The HANC Portal was upgraded to SharePoint Online in 2021. Additional work will occur in 2022 to address issues still to be resolved as a result of the Portal migration.

Communications & Information Sharing

Communications from the HANC office help to inform our partners of activities happening across the networks, latest scientific milestones, opportunities for learning or connection, and HANC's role in facilitating cross-network projects or initiatives.

HANC leverages several public-facing communication channels to share program updates with a broad audience, including social media accounts on Twitter ([@hancprograms](#)), Facebook ([Hanc Programs](#)), and LinkedIn ([Office of HANC](#)) and the monthly HANC Newsletter. For prominent scientific conferences, including the annual Conference on Retroviruses and Opportunistic Infections (CROI) and the International AIDS Conference, HANC creates webpages on the HANC public website to list upcoming network sessions and presentations.

For accountability to Network partners, HANC provides an annual research performance progress report (RPPR) to NIAID Grants Management and lists of staff who collaborate with HANC to the respective Networks and SDMCs.

HANC provides individualized trainings for networks and affiliated partners as requested. HANC uses Google Analytics to track resources and page utilization on both the HANC public and portal websites.

Clinical Research Support Contract

The HIV Clinical Research Services (CRS) support contract between DAIDS and the contract research organization can be accessed by the networks to fund a variety of clinical research support tasks, from monitoring study conduct to providing simultaneous translation services for meetings. Networks request network-specific CRS contract through their designated point of contact at DAIDS. Requests for CRS support that apply across networks are made through HANC. HANC coordinates the development of cross-network CRS requests, submits them to the CRS project officer, tracks their progress, and liaises with DAIDS. Tools on

the HANC Portal streamline CRS Request submission, tracking and status communication. Twenty-four cross-network CRS requests have been submitted since the CRS contract was initiated. Details of CRS requests can be viewed at <http://portal.hanc.info/crs>.

Objectives and Activities by Area of Coordination

Behavioral Science Coordination

HANC supports three behavioral science groups:

Behavioral Science
Consultative Group

Behavioral Science Interest
Group Digest

Youth Prevention
Research Working
Group

Behavioral Science Interest Group Digest (BSIG): The BSIG was formed as an outcome of the 2010 BSWG face-to-face meeting. The BSIG's mission is to share state-of-the-science developments and facilitate discussion amongst network investigators, independent behavioral and social science researchers, community members, statisticians, and data managers with the goal of enhancing behavioral research within DAIDS clinical trials. HANC maintains a resource center featuring relevant case report forms, articles of interest, white papers, best practices documents, funding opportunities, and meeting presentations. The over 375 members receive a weekly digest of new library additions and are encouraged to participate in the BSIG Topics of Interest webinar series. HANC also maintains a webpage describing how to propose a network behavioral studies and data analyses.

Behavioral Science Consultative Group (BSCG): The Behavioral Science Consultative Group was formed after the 2013 BSWG face-to-face meeting. The NIMH provides resources through HANC to a group of within-network and external expert behavioral and social scientists to assist the networks in navigating the complex behavioral/biomedical science issues. The BSCG's overarching objectives are to provide consultation as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral components of their research agenda and studies: including but not limited to, advice on protocol design, protocol implementation and methodology for data collection, and evaluation. The BSCG has provided consultation on a variety of protocols for all the networks since the inception of the group.

Youth Prevention Research Working Group (YPRWG): The cross-network/trans-Institute Youth Prevention Working Group (YPRWG) was formed in the Q3 of Year 6. Its creation was a key recommendation emerging from the NIH "Focused initiatives for Healthier Lifestyles by the Inter Network Advisory Group on Adolescent Prevention" meeting. The group consists of representatives from the NIH HIV/AIDS Clinical Trials Networks, the Adolescent Trials Network (ATN), DAIDS, NIAID, NIMH, NIDA, NICHD, and OAR. The scope is domestic and international and focused on individuals 12-24 year of age. The members conduct bi-monthly calls and convene at network meetings as able. The group addresses the following:

- Coordinate sharing of network adolescent research agendas
- Address the challenge of conducting trials across multiple networks

- Consider tangible outcomes such as dropping the mean age of network volunteers
- Compare ongoing and upcoming studies
- Consider adolescent issues early on in design process
- Review relevant informed consent documents
- Host webinars and trainings related to adolescent prevention research

Behavioral Science Consultative Group Coordination Objective for 2022

Behavioral Science Consultative Group Objective: The Behavioral Science Consultative Group was formed after the 2013 BSWG face-to-face meeting. The NIMH provides resources through HANC to a group of within-network and external expert behavioral and social scientists to assist the networks in navigating the complex behavioral/biomedical science issues. The BSCG's overarching objectives are to provide technical expertise, consultation, and resources as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral components of their research agenda and studies: including but not limited to, advice on protocol design and implementation, methodology for data collection, and evaluation. The BSCG has provided consultation on a variety of protocols for all the networks since the inception of the group.

Ongoing activities that support the above objective:

- The BSCG will host monthly meetings.
- The BSCG will host topic-specific webinars.
- The BSCG will consider a face-to-face meeting in 2022 (either in person or virtual).
- The BSCG will continue to provide consultation on behavioral and social science aspects of Network protocols.
- Other items as Networks ask the BSCG for consultation

Youth Prevention Research Working Group Objectives for 2022:

Youth Prevention Research Working Group Objective #1: Ensure cross network/trans-institute communication around research in adolescent populations. Working group members accomplish this goal by liaising with their respective network leadership and protocol team members to share their assessment of ongoing research initiatives as well as identify potential gaps in the adolescent research agenda.

Youth Prevention Research Working Group Objective #2: Explore opportunities to provide resources (training materials, webinars, etc.) and expertise to sites conducting research with adolescents. The YPRWG will host webinars, symposiums, and trainings at network meetings and/or conferences as appropriate. Materials from YPRWG hosted webinars, symposiums, and trainings will be stored on the HANC website in the Youth Prevention Research Resource Library to increase visibility of these resources.

Youth Prevention Research Working Group Objective #3: Explore the development of co-endorsed protocols or adolescent substudies. The YPRWG will discuss protocols in development on calls. The YPRWG will advocate for the inclusion of adolescents in Network protocols.

Youth Prevention Research Working Group Objective #4: Ensure an ongoing dialogue between working group members and relevant stakeholders through regular review of working group projects, priorities, and objectives.

Ongoing strategies and activities to support the above objectives:

- Hold bimonthly videoconferences to share information, discuss trials in development, provide protocol updates
- Host two adolescent research focused webinars
- Submit symposium proposals to conferences as appropriate
- Engage with Network Leadership and NIH counterparts to discuss Network adolescent research agendas

Communications Working Group

The Cross-Network Communications Working Group was instituted in June of 2009. Since its formation, the group has considered a wide variety of issues affecting network clinical trials. The group is comprised of network communications professionals and community liaisons. Much attention has been paid to new media and social networking tools, study results messaging, and understanding the networks' respective communications strategies and policies. The Communications Working Group has bimonthly calls and topic-specific webinars are scheduled as requested.

Communications Working Group Objectives for 2022

Communications Objective #1: Discuss network communications efforts related to HIV/AIDS and COVID-19 research. Consider best practices that could be employed within the networks. Strategies and activities to support this objective:

- Share and disseminate network submissions to major conferences for HIV/AIDS research.
- Provide updates on network activities and major study milestones that may impact other studies in the field.
- Share network communications strategies, external relations policies, and strategies related to study launch, DSMB review, and results dissemination.
- Share experiences using new technologies, social media, and network sites such as Facebook, LinkedIn, and Twitter and track web traffic generated from new media sites
- Share experiences with creative design, video production, advertising, and development of materials to aid with participant recruitment for network studies.
- Share community engagement strategies.

Communications Objective #2: Invite key stakeholders, opinion-makers, and experts in the field to present on working group calls. Areas of expertise could include: journalists, advocates, bloggers, and communications professionals.

Communications Objective #3: Provide network activity updates for cross-network communications and publications. Submissions include content for the monthly HANC newsletter and accepted network submissions to major HIV/AIDS research conferences.

Community Coordination

Since the late 1990's, community representatives associated with NIH HIV/AIDS Clinical Trials Networks and studies have been working together to identify common issues and to learn new approaches and solutions

from each relating to community involvement. A Cross-CAB Working Group (CCWG) was formed in 2003, and HANC began providing facilitation for their calls shortly afterwards. In 2005, Cross-Network Best Practices for engaging community were developed by a group of community representatives and DAIDS. In June 2007 the CCWG was replaced by Community Partners (CP), an RFA-mandated body with a mission to enhance research by maximizing the effectiveness and benefits of community participation within and across the NIH HIV/AIDS Clinical Trials Networks.

Community Partners and Working Groups

HANC supports Community Partners and the topic-specific working groups that it convenes. The HANC Community Partners Project Coordinator serves as a non-voting member of CP and provides group facilitation, project coordination, fiscal oversight, and administrative support.



Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the NIH HIV/AIDS Clinical Trials Networks conduct research. CP represents cross-Network community research needs and priorities to network leadership and DAIDS and is a venue for sharing resources and experiences across the networks, avoiding duplicative efforts, identifying and addressing challenges to participation in trials. CP is tasked with ensuring effective network representation and articulation of: scientific agenda priorities; ethical conduct of clinical trials; community education; communication and information dissemination; respect for community priorities; and continued community participation. CP members are representative of the global NIH HIV/AIDS Clinical Trials Networks research sites.

The Community Partners Executive Committee is drawn from the general membership of Community Partners and is empowered to make decisions on behalf of and in the best interests of CP and its general membership in accordance with CP Organizational Guidelines.

The Community Training Working Group considers areas of community training common across networks and standardizes or develops materials that have broad application to community issues around HIV/AIDS clinical research and participation in trials.

The Community Research Priorities Working Group considers areas of community research priorities across networks and makes recommendations to DAIDS and Network Leadership.

The Community Partners Ethics Working Group solicits input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding the informed consent process, management of pregnancy and contraception in clinical trials, trial designs relative to guidelines and local standards of care, and placebo arms in prevention trials.

Community Coordination Objectives for 2022

Community Partners Objective #1: Enable involvement in the development and sharing of CP research priorities, and harmonization between community and investigator research priorities. CP Research Priorities Working Group

Strategies and activities to support this objective:

- Work directly with DAIDS Cross-Network Transgender working group to promote the Transgender Training Curriculum for HIV Research with the Networks and other groups to encourage global adoption and implementation of the recommendations
- Work with the CP Training WG on developing a training on how to review and make recommendations on COVID-19 and HIV cure/ATI protocols to ensure community input along with dissemination of materials
- Work with CP Training WG and CAB Collaborative to help increase awareness and understanding of COVID-19 research interventions.
- Work with the CP Ethics WG on addressing issues/concerns around the ethics of providing financial incentives from a global perspective.
- Work with the CP Training WG on developing resources and/or presentations to help inform communities on new treatment modalities (RNAi, MRNA and other biologics).
- Convene a working group focused on developing a comprehensive TB vaccines community engagement strategy (CP, CRAG, HVTN, TAG, AVAC, IAVI, Stop TB Partnership WG).
- Work with CP Training WG on developing FAQ sheet on Broadly neutralizing antibodies (bNAbs)
- Review network efforts on the CP priorities and identify priority gaps in the submitted scientific aims and focus on the following:
 - Continue to support TB/HIV co-infection education efforts
 - Continue to support COVID-19 education efforts
 - Continue to support and address pediatric and adolescent research issues across networks
 - Support the work of the networks around the Ending the HIV Epidemic Plan
 - Continue to support prevention and treatment efforts with appropriate networks

Community Partners Objective #2: Utilize the Community Training Working Group to identify unmet training needs that are common across the networks and determine how they can best be addressed. Strategies and activities to support this objective:

- Develop and promote training materials around how to review a HIV cure/ATI protocol
- Promote training materials developed by CP and information on how to access materials during webinars and GCAB calls, Network meetings and conferences
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices and a comprehensive TB vaccines community engagement strategy
- Explore possibilities and partner with WHRC, ATN-YEAH, Soweto Youth CAB and other international groups to develop or disseminate materials addressing HIV in the context of sexual violence against girls and women
- Work with CP Research Priorities WG on developing FAQ sheet on Broadly neutralizing antibodies (bNAbs)
- Work with the HANC Cross-Network COVID-19 CAB to disseminate COVID-19 information

Community Partners Objective #3: Utilize CP to provide input and recommendations to focus on meeting the mission of Community Partners to facilitate and enhance community representation and input at all levels in HIV/AIDS and related clinical research within the networks. Community Partners Executive Committee

Strategies and activities to support this objective:

- Develop strategies and tools to address the intersecting priorities of the COVID-19 & HIV pandemics
- Develop strategies to assist diverse networks/communities on their prioritized research activities
- Develop specific strategies and tools and utilize existing tools to address stigma, including working with the TBTC CRAG community representatives
- Facilitate and enhance more effective collaboration with the Legacy Project and the WHRC with inclusion of CP membership to these groups
- Lead or collaborate on letters of support for international or domestic advocacy
- Continue to monitor and provide support to CABs and communities impacted by site closures or changes in research or protocols (e.g. Site Closure Slide Deck)
- Identify opportunities for improvement, and work in collaboration with DAIDS and Network Leadership, to ensure dissemination of research results (HANC to share NIAID press releases with CP, communities and sites)
- Host or co-host community-focused workshops/presentations/webinars on ongoing network research and community engagement activities
- Submit abstracts for workshops/presentations at HIV 2021, AIDS 2021, USCA 2020/2021 Union Conference Community Space in 2021 and other meetings/events to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG and other organizations
- Develop a White Paper to highlight the collaboration of CRAG and CP in addressing issues around TB/HIV co-infection from a community perspective

- Using information from the HANC monthly newsletter, post CP information in CAB and network newsletters and network public websites (follow-up on a quarterly basis) and organize existing network CAB newsletters to post on the HANC Website

Community Partners Objective #4: Review topics across networks; identify areas where there are problems or opportunities for improvement and work in collaboration with the Network Leadership and DAIDS to address those issues.

Community Partners & Community Ethics Working Group

Strategies and activities to support this objective:

- Identify opportunities for improvement and work in collaboration with DAIDS to provide guidance to researchers, communities and stakeholders regarding ethical considerations, human research protections (HSPs), and challenges in research with individuals facing stigma, discrimination, legal sanctions and/or interpersonal violence, and social harms
- Support CABs and community members who review protocols for stigmatizing language and make language change recommendations that improve HSPs and maintain the data integrity of the studies

Community Partners Objective #5: Utilize CP members to provide information exchange to enhance collaboration and identify further engagement topics/issues. Community Partners

Strategies and activities to support this objective:

- Engage with Martin Delaney Collaboratory, National CFAR CAB Coalition and other community groups to develop a comprehensive community engagement strategy to:
 - Convene a working group focused on providing information on how community can be involved at local, national and international levels
- Continue engagement with ATN Youth CAB
 - Facilitation of calls between the Perinatal HIV Research Unit PHRU Adolescent Soweto CAB and the ATN-YEAH as part of CP's efforts around engaging youth to better inform research
 - Communicate with ATN leadership to identify potential areas of collaboration including joint abstract submissions, webinars, and other engagement materials
 - Communicate with DAIDS and ATN leadership regarding more support for cross-network engagement with the ATN
 - Continue engagement with the AIDS Malignancy Consortium

COVID-19 CAB Coalition: In September 2020, HANC created the COVID-19 CAB Coalition to address the lack of opportunity for COVID-19 CAB members to disseminate information, facilitate resource sharing, and advocate on the behalf of overall COVID-19 research efforts in addition to specific protocols.

Objective: The group critically analyses implementation of community engagement and ethical principles. The COVID-19 CAB Coalition shares strategies, existing information and resources, educational materials, upcoming and recorded webinars across the research spectrum for prevention and therapeutics for COVID-19, and the group creates new resources as needed.

Membership: Members of the COVID-19 CAB Coalition include international and domestic representatives from ACTG's Global CAB and ACTIV-2 CAB, the CoVPN Community Engagement Working Group, AVAC's COVID Advocates Advisory Board, Stony Brook, the National CFAR CAB Coalition, Community Partners, DAIDS, and IQ Solutions.

Strategies and activities to support the group's objective:

- Convene monthly videoconferences to provide updates on ongoing trials and trials in development
- Develop/maintain a COVID-19 community resource page on the HANC website that provides information on trials, educational materials, links to webinars, etc.
- Host webinars as appropriate

Data Management Center Coordination

The network Statistical and Data Management Centers (SDMCs) have identified key areas in which the sharing of expertise, resources, and procedures will strengthen the capacity and increase the efficiency of data management operations.

The DMC Working Group includes representatives from FSTRF and SCHARP and meets on monthly teleconferences to carry out activities to address cross-network data management coordination objectives.

The IT Best Practices Working Group (ITBPWG) includes representatives from the DMCs, OCICB, and DAIDS, and meets biannually to revise the *IT Best Practices Standards at NIH HIV/AIDS Clinical Research Networks' Study Sites and Site Affiliated Laboratories* (IT Best Practices & Standards) document.

The Pregnancy Outcomes Data Working Group (PODWG) includes representatives from FSTRF and SCHARP, and initially convened in 2020 to develop the Cross-Network Pregnancy Data Standards v1.0. Thereafter, the group meets biannually to revise and update the standards document.

DMC Working Group Objectives for 2022

DMC Coordination Objective #1: Convene monthly teleconferences to discuss various ongoing data quality assurance projects, identify areas for improvement, provide recommendations, and implement new processes and procedures as appropriate.

Strategies and activities to support this objective:

- Liaise with NIAID CRMS team, as necessary, to identify areas for collaboration and enhanced data sharing across NIAID CRMS and the SDMCs.

DMC Coordination Objective #2: Work with appropriate regulatory groups to assist in the development of procedures and processes related to protocol deviation reporting, electronic data capture (EDC), etc. Share developments in these procedures and processes across networks and data management centers. Strategies and activities to support this objective:

- Liaise with OPCRO and OSCO to provide feedback on proposed policies and procedures.
- Liaise with relevant cross-network working groups to solicit site-level and other appropriate feedback on processes and policies involving the data management centers.
- Liaise with network performance/evaluation committees and OCSO to adapt new policies and procedures as appropriate for the transition to EDC as it impacts site performance evaluation metrics and site monitoring procedures.

DMC Coordination Objective #3: Collaborate to provide cross-network data management training resources for site investigators. Strategies and activities to support this objective:

- Share training development activities across DMCs and explore opportunities to generalize network-specific content to wider audiences.
- Publicize and disseminate training opportunities using HANC, DMC, and network channels.
- Respond to requests for training materials, update training topics when appropriate, and monitor resource usage via HANC staff.

IT Best Practices Working Group Objectives for 2022

ITBPWG Objective #1: Convene representatives from the SDMCs, DAIDS, and NIH OCICB to discuss salient issues and best practices in information systems (IS) and information technology (IT). Strategies and activities to support this objective:

- Convene on a monthly or as-needed basis to discuss current issues in IS/IT, changes in best practices and standards, and implications on data and ethical integrity in DAIDS-sponsored clinical trials.
- Gather and assess data on key IS/IT issues affecting DAIDS clinical research sites and laboratories, as needed.
- Develop recommendations related to IS/IT management to DAIDS sites and laboratories, as needed. Disseminate updated recommendations to DAIDS and affiliated site/laboratory stakeholders as appropriate.

Pregnancy Outcomes Data Working Group Objectives for 2022

PODWG Objective #1: Update the Cross-Network Pregnancy Data Standards to align with current standards for capturing pregnancy outcome data variables. Strategies and activities to support this objective:

- Convene on a monthly or as-needed basis to review current standards and recommend revisions.
- Post the updated Cross-Network Pregnancy Data Standards to the HANC website. Disseminate the updated document to the HIV/AIDS network statistical and data management centers (SDMCs).

Evaluation Coordination

The Evaluation Working Group provides a forum to share network approaches to evaluation, including the site evaluation processes. The Working Group consists of representatives from each Network Evaluation Committee, Frontier Science, SCHARP, and OCSO.

Evaluation Working Group Objectives for 2022

Evaluation Objective #1: Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks. Strategies and activities to support this objective:

- Quarterly cross-network evaluation teleconferences will provide a forum to discuss and address opportunities.
- Ongoing discussions regarding revisions to the network evaluations processes and setting site performance criteria and expectations.
- Share experiences around software programs for real-time reporting of evaluation metrics.

Evaluation Objective #2: Share any modifications to definitions, calculations, or standards for data management evaluation metrics. Strategies and activities to support this objective:

- Periodic discussions with evaluation and data management center staff regarding the ongoing use of data management metrics as part of the site evaluation process.
- Updates to the Evaluation Working Group regarding changes to network standards for data management metrics.

Evaluation Objective #3: Share approaches to reporting protocol deviations as part of site evaluation reports. Strategies and activities to support this objective:

- Track developments in DAIDS policies and network activities related to protocol deviation reporting.
- Ongoing discussion of network approaches to and utility of reporting protocol deviations as part of the site evaluation process.

Financial Disclosure Database

Financial Disclosure Database Objective: Work closely with network staff and DAIDS to periodically review the harmonized network financial disclosure requirements and maintain the cross-network web-based reporting interface developed in 2011.

Strategies and activities to support this objective:

- Continue to review U.S. Health and Human Services financial disclosure regulations and audit requirements.
- Continue to clarify with DAIDS, sites, and product sponsors' FDA-specific financial disclosure requirements and SOPs.
- Consult network grantee institutions on matters of financial disclosure requirements, processes, and reporting.
- Coordinate investigator lists across the NIH HIV/AIDS Clinical Trial Networks and PHACS.

Laboratory Coordination

Laboratory Committees and Working Groups

HANC coordinates the Lab Focus Group and provides support to the ACTG/IMPAACT Lab Technologist Committee and the DAIDS EQA Provider Working Groups.

The Lab Focus Group (LFG) is comprised of Network Laboratory Leadership and management staff. It holds teleconferences monthly to oversee all cross-network laboratory activities, including policy and process

development and follow-up work to complete cross-network projects and tasks that address laboratory training, operations, and support issues. Representatives from the LFG will contribute to policies and guidelines drafted and disseminated by DAIDS. The LFG teleconferences provide a forum for identifying, discussing and resolving issues, sharing information, and identifying new projects and tasks to be included in cross-network laboratory coordination efforts.

LFG Objectives for 2022:

1. Continue to identify laboratory issues that require input from all the networks, in collaboration with DAIDS Clinical Laboratory Oversight Team (DCLOT) and the applicable regulatory representatives (e.g., DAIDS Regulatory Affairs Branch; Quality Group), to assure that network labs are implementing appropriate lab processes to meet study and network-specific needs.
2. Continue to identify where economies of scale can be achieved by sharing resources, shared pricing agreements, technician training opportunities, laboratories, etc. and address these opportunities in existing or new working groups as necessary.
 - a. Continue to monitor reagents or materials for possible issues that may affect multiple networks.
3. Continue to identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.
 - a. Review and revise the Cross-Network Guidelines for Diagnosis of HIV Infection on a biennial basis.
4. Continue to identify areas in lab operations and processes to incorporate principles of GCLP and ensure that data generated are of the highest quality, including but not limited to timeliness, accuracy, and clinical appropriateness. GCLP guidelines will be reviewed on a biennial basis.
5. Review and provide laboratory context for DAIDS policies and how they may be interpreted or adopted by laboratories supporting network activities.

The PBMC SOP Working Group is charged with developing, publishing and reviewing the Cross-Network PBMC Processing SOP for all network-affiliated labs that process PBMC. The SOP is reviewed and updated by the PBMC Working Group on a bi-annual basis.

The Cross Network Cold Chain Guidelines Working Group (CCGWG) is charged with maintaining guidelines for utilizing and maintaining optimal cold chain temperature of specimens during the retrieval process within the laboratory or upon shipment to an external laboratory/repository. The SOP is reviewed and updated by the CCGWG at the direction of the LFG.

The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is a joint ACTG/IMPAACT committee. Voting and nonvoting protocol support members serve on protocol teams and provide technical expertise in the development of the laboratory components of protocols, and standards for handling, processing, labeling, storage and shipping of clinical specimens across all ACTG/IMPAACT clinical sites and laboratories.

LTC Objectives for 2022:

1. Promoting uniform handling, processing, labeling, storage, and tracking of specimens (according to consensus procedures) across all clinical sites and laboratories; maintaining a regularly updated

laboratory manual of consensus procedures readily available for access by all ACTG/IMPAACT laboratories.

- a. HANC staff facilitates regular teleconference and email communications to review and update consensus procedures and manages the document control processes. Examples include guidelines and templates to guide developing protocol lab processing charts and budget cost lists used to create clinical trial processing budgets.
 - b. HANC provides a forum to share technical expertise and resolve laboratory issues including, but not limited to, assay/processing procedures, LDMS use, and laboratory operations. Topics may also include discussions on protocol complexity as well as upcoming novel/esoteric assays.
 - c. HANC staff develops and maintains resources on the LTC Protocol Support Member Website, including the Protocol Lab Technologist Workload Tracker.
2. Serving as a resource to the NIAID/Division of AIDS, Statistical and Data Analysis Center, Data Management Center, Operations Center, and Clinical Site Monitoring Group; acting as a liaison between site personnel, laboratories, clinics and the leadership of the ACTG/IMPAACT and its contractors as well as facilitating communication and networking among the laboratories, clinics and Data Management Center
- a. HANC serves as a resource for facilitating communication between the LTC and other the NIAID/ Division of AIDS, Statistical and Data Analysis Center, Data Management Center, Operations Center, and clinical site members.
3. Providing information and education for laboratory personnel in the areas of protocol implementation, collection and regular export of quality data, regulatory requirements, new procedures and policies.
- a. HANC staff supports new LTC member training by facilitating the creation of training materials and training webinars and maintaining training documents on the HANC website.

EQA Provider Working Groups ensure standard quality assurance for all the protocol-specified assays conducted in DAIDS-sponsored network clinical trials across networks and other partners through the Total Quality Management (TQM) Program. The TQM Program improves the transparency and responsiveness of decision-making regarding results of proficiency testing at DAIDS- funded site laboratories by improving communication and timely access to relevant information.

- The cross-network QA working groups including the CPQA groups and VQAAB will continue to provide a forum for the review and discussion of program-specific proficiency testing results and other questions that affect external quality assurance on regular teleconference calls.
- Cross-network QA working groups and the LFG (for patient safety QA) will develop, review, and/or modify as needed standard operating procedures for the monitoring of external quality assurance and investigation and reporting of root cause and corrective action.

The Clinical Pharmacology Quality Assurance Program provides a comprehensive quality assurance program for clinical pharmacology laboratories (CPL) testing samples from participants enrolled in clinical trials supported by the National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS). The CPQA programs include clinical pharmacology study conduct tutorial certification for research professionals at clinical sites, peer review of CPL developed tests to assure international compliance with bioanalytical method validation standards, proficiency testing [twice annually] for CPLs to assure analyte-specific results

are acceptably equivalent, laboratory assessments for CPLs and technical guidance for the networks, sites and CPLs. To assure that CPQA resources meet the current needs of the networks, external communications with the following are facilitated by HANC:

The Clinical Pharmacology Quality Assurance (CPQA) External Advisory Board. The Leadership of the CPQA External Advisory Board (AB) is composed of a balance of leadership members from DAIDS funded research and laboratory networks, the community of established HIV investigators, the contract sponsor, and CPQA. To implement the functions of the CPQA, the AB may form such committees, subcommittees, and working groups as are necessary to carry out the mission of the CPQA. The Advisory Board provides the following:

- Communication regarding scientific and regulatory changes and developments that are likely to influence the operation of the CPQA.
- Feedback from NIAID/DAIDS and the HIV Research Networks that includes items discussed at NIAID/DAIDS leadership meetings, HIV Network leadership meetings and Laboratory Center Network meetings.
- Expertise and guidance in areas that are on the horizon for network research priorities such as new biomatrices, point of care diagnostics and strategies for therapeutic approaches.
- Review of controversial areas that arise within the ongoing CPQA activities with regard to proficiency testing, CPL site performance, guidance for current and future CPLs, and longitudinal analysis of the CPQA program and its performance.
- Recommendations for program additions, revisions and quality improvements.

The CPQA Cross-Network Clinical Pharmacology Laboratory Forum (CNCPL Forum) is an open forum comprised of technical and scientific representatives from DAIDS-designated pharmacology programs, including Network Clinical Pharmacology Laboratory (as well as other clinical pharmacology laboratories such as the International Laboratory Branch at the Centers for Disease Control). PIs, as well as leadership and members of the DAIDS-supported Laboratory Center Networks, are also welcomed to join the calls. During the forum, members discuss new and current research strategies, policies, laboratory technologies and methods, as well as updates on CPQA programmatic activities. The CPL members are invited to voluntarily provide feedback and dialogue regarding pharmacology quality assurance activities and needs.

Bioanalytical Method Validation Group (BRAG) is tasked with revising the CPQA AVR Assay Method Guidelines to incorporate the changes made by the FDA, EMA, ISO and other regulatory agencies. The last revised CPQA guidance was implemented in October 2019. However, an internationally harmonized standard, ICH M-10 is expected to be finalized and, at that time, BRAG will re-convene to assure the guidance reflects appropriate changes to this standard.

HANC support staff provides the following in support of the CPQA Program:

- Participate in the CPQA Steering Committee to assure synchronous activities among external stakeholders.
- Provides a virtual communication platform for CPQA groups, including ad hoc calls for committees, working groups, leadership and/or collaborators:
 - Polls for calls as needed

- Sends out call announcements with agenda and materials
- Sends call reminders and reports back to CPQA on “regrets” responses
- Provides draft minutes to CPQA groups for edits and approval
- Sends out final call minutes to respective CPQA groups
- Provides document development support; provides and maintains webpages for maintaining CPQA group documents, agendas and minutes.
- Provides web-based access to webinar presentations with permission from speaker(s).

The Virology Quality Assurance Advisory Board (VQAAB) serves as an external group that reviews data generated for the Virology Quality Assurance (VQA) proficiency testing programs, provides input and guidance on new issues/ideas/programs, and provides an open forum for discussing new topics raised by other VQAAB members during bi-monthly teleconferences. The VQAAB is comprised of non-voting representatives from the VQA Laboratory, DAIDS, and a voting representative from each of the respective NIH-funded HIV Research networks.

The VQAAB holds a scheduled conference call every two months and ad hoc calls to:

- Review and approve proposed scoring from VQA proficiency testing (PT) analyses which include programs for Quantitative HIV-1 RNA testing, Qualitative HIV-1 total nucleic acid (whole blood and DBS), and genotypic HIV-1 drug resistance testing for reverse transcriptase (RT), protease (PR) and integrase (INT) gene regions.
- Establish monitoring standards that differentiate between technical problems and non-technical problems (e.g. late data, query unresponsiveness, or data containing patient identifiable information [PII] or protected health information [PHI]).
- Request, review and approve proposed method evaluation/validation studies.
- Review and approve proposed changes in policies or procedures to promote quality assurance in virology assay testing.
- Review and approve proposed implementation of external quality control standards for use in virology assay testing.
- Review and approve changes in VQAAB approval status for protocol testing laboratories.
- Review proposals for new proficiency testing programs for other virology assays such as: Quantitative HCV RNA, Quantitative HBV DNA, Qualitative HPV DNA, and SARS-CoV-2 testing.

HANC support staff provides the following in support of the VQA and VQAAB:

- Maintain the VQA web page for posting of VQA documentation on the public domain and maintain the VQA reagent order form on the HANC password-protected portal site.

Legacy Project

The Legacy Project builds trust and collaboration between HIV research institutions and marginalized communities most impacted by the US HIV epidemic. The Legacy Project works to support DAIDS efforts to develop and support the infrastructure and biomedical research needed to end the HIV epidemic by:

1. Reducing HIV incidence through the development of an effective vaccine and biomedical prevention strategies that are safe and desirable
2. Developing novel approaches for the treatment and cure of HIV
3. Developing interventions to treat and/or prevent co-infections and co-morbidities of greatest significance
4. Fostering partnerships with scientific and community stakeholders to develop and implement effective interventions

The Legacy Project 2022 Work Plan is in line with the [Ending the HIV Epidemic: A Plan for America](#) plan cutting across areas of basic research, health disparities, and training, including research to reduce health disparities in HIV incidence, research in treatment outcomes for those living with HIV/AIDS, research training of the workforce required to conduct high priority HIV/AIDS-related research, and addressing health and social issues that are linked with HIV such as racism, LGBTQ+ antagonism, misogyny, poverty, stigma, and discrimination.

Legacy Project 2022 Goal and Objectives:

Goal: Build capacity among community members, researchers, and sponsors to enhance diversity, equity, and inclusion in NIH-funded HIV/AIDS, COVID-19 and other infectious diseases research conducted in the US.

Objectives and activities to support this goal:

1.0	Monitor and promote improved representation of underrepresented populations in clinical trials through collaboration with partners (such as network communications and community engagement staff, Community Partners, the Women’s HIV Research Collaborative, the DAIDS Cross-Network Transgender Working Group, the HPTN Black Caucus, the HANC-facilitated Communications Working Group, the New Investigators Working Group, and others).
1.1	Monitor and promote the collection and reporting of participant gender identity, sex assigned at birth, race, and ethnicity as well as the intersections of these categories.
1.2	Promote and apply the RSR to validate inclusion/exclusion criteria, appropriately define study populations, set specific and measurable goals/plans for the enrollment of underrepresented populations, prioritize underrepresented populations in community engagement strategies, and eliminate stigmatizing language from studies.
1.3	Consult with populations disproportionately impacted by HIV and other infectious diseases, as well as those underrepresented in HIV clinical research (Black and Latinx MSM, women, transgender persons, house/ballroom communities, indigenous and two-spirit peoples, etc.) to identify community-level priorities and raise awareness of these priorities among the NIH-funded HIV/AIDS clinical trials networks and sites.
1.4	Hold regularly scheduled teleconferences with the Legacy Project working groups to continuously engage stakeholders in the mission of the Legacy Project: American

	Indian/Alaska Native Working Group, Legacy Project Working Group, Latinx Caucus, New Investigators Working Group, and Women’s HIV Research Collaborative.
1.5	Provide leadership and support to the DAIDS Cross-Network Transgender Working Group, including creation, promotion, and implementation of resources to promote transgender inclusion.
1.6	Engage in collaborative efforts to develop trainings and resources to promote the inclusion of people who use substances and people who inject drugs (PWID).
1.7	Participate in Network meetings, local and national conferences to monitor and promote underrepresented populations’ participation in HIV and other infectious diseases research.
1.8	Provide technical assistance to researchers and research staff on projects that promote trust and collaboration between underrepresented populations and the HIV/infectious diseases research establishment, including assisting in increasing Phase I and IIA enrollment in vaccine trials in the US.
2.0	Collaborate with underrepresented populations to increase awareness and knowledge of clinical research and community readiness to engage in trial participation activities through presentations, abstracts, meetings, conferences, podcasts, and webinars.
2.1	Host or co-host community-focused workshops/presentations/webinars on research conducted by the Networks and related community engagement issues.
2.2	Maintain and promote the Be the Generation (BTG) website on a regular basis.
2.3	Oversee publication of the quarterly Be the Generation e-newsletter in collaboration with the HPTN and HVTN.
2.4	Review, update and promote the BTG HIV Prevention Research (HPR) and Basic Science Literacy (BSL) modules, including implementation of the HPR module in collaboration with HBCUs to increase knowledge of HIV prevention research.
2.5	Produce a podcast and periodically broadcast content on HIV/infectious diseases research and community engagement in collaboration with research and community stakeholders.
2.6	Maintain the Legacy Project’s presence on social media to disseminate information related to HIV/infectious diseases research and community engagement.
2.7	Develop partnerships with individuals, local and national organizations representing underrepresented populations in HIV/infectious diseases research to collaborate on capacity-building projects.

2.8	Produce, publish, and disseminate position papers/opinion pieces and other resources that contribute to address the challenges of health disparities and underrepresentation of communities heavily impacted by the HIV epidemic and other infectious diseases.
3.0	Engage and collaborate with COVID-19 research networks and stakeholders in addressing the intersecting priorities of COVID-19 & HIV pandemics.

The Women’s HIV Research Collaborative (WHRC)

The WHRC is a cross-network working group of the Legacy Project comprised of women who are leaders in women’s health and HIV from around the United States. With community and staff representatives from all five NIH-funded HIV/AIDS clinical trials networks, this group provides culturally appropriate guidance and leadership in development, implementation, and dissemination of information about HIV research focused on and responsive to the needs of cisgender and transgender women and girls in the United States. The WHRC works to raise the visibility of issues related to HIV in women in the US and promote awareness of scientific research for women in disproportionately impacted communities. The WHRC focuses on advocating for HIV research with women living in the United States but operates with a comprehensive awareness of the potential for American women to benefit from HIV research that is being conducted internationally. To that end, WHRC’s focus is domestic, but its interests are both global and optimistic.

The current WHRC co-chairs are Morénike Giwa Onaiwu, MA and Dazon Dixon Diallo, MPH. Morénike’s tenure as co-chair will expire on February 1, 2023, and Dazon will be up for re-election, should she choose to run, on February 1, 2023. The HANC facilitator assigned to the WHRC is Brian Minalga.

WHCR Goal: Promote the engagement of women¹ in HIV prevention, treatment, and cure-related research, as well as other relevant research, across the NIH-funded HIV/AIDS clinical trials networks.

Objective 1: Monitor the inclusion, exclusion, screening, and enrollment of women in studies across the NIH-funded HIV/AIDS clinical trials networks.

- Leverage WHRC membership to monitor studies and report back to the group on women’s participation (in inclusion/exclusion criteria, recruitment plans, screening, and enrollment data, etc).
- Create a spreadsheet of specific studies to monitor progress in women’s enrollment and areas for potential advocacy.
- Survey protocols underway or in development across research networks that include or are specific to pregnant and breastfeeding individuals to assess progress being made in this area of research, and to identify gaps and needs.

Objective 2: Question and monitor systems, processes, and practices in Network research that may help or hinder women’s involvement.

- Support implementation and dissemination of the [Representative Studies Rubric](#) as a tool to facilitate women’s inclusion in research.

¹ Cisgender, transgender, and all persons who identify as women

- Solicit measurable goals and plans for the enrollment of women from study teams.
 - Advocate for epidemiologically representative enrollment goals as well as support for meeting those goals.
 - Solicit scientific rationale in cases of women's exclusion (as required by NIH).
- Advocate for analyses and reporting of study product interactions with hormone use, menstruation, menopause, pregnancy, and breastfeeding.
- Advocate for the use of non-stigmatizing and inclusive language.
 - Help Network and study staff apply the [WHRC's guidance on accurate and affirming language](#)
 - Work with partner organizations to develop trainings for journalists that address the need for non-stigmatizing language in clinical research.
- Encourage social-behavioral research questions and/or frameworks in HIV clinical research.
 - Intimate partner violence as a variable in safety, efficacy, feasibility, and acceptability of study products
 - Sexual and reproductive justice and bodily autonomy as variables in safety, efficacy, feasibility, and acceptability of study products

Objective 3: Promote women's awareness of and engagement in Network clinical research taking place within and outside the US.

- Support US trial sites with efforts to engage women.
- Synthesize and contextualize Network clinical research as it pertains to the lives of women in the US.
 - New studies and study concepts, ongoing studies, and study findings
 - Webinars, local events, conferences, infographics, social media
 - Partner with local and national organizations to promote scientific developments in HIV clinical research.
- Add to the WHRC section on the HANC public website to better showcase WHRC resources, guidelines, work plan, accomplishments, and membership.
- Continue to update, promote, and disseminate the WHRC's training, "Women & Biomedical HIV Prevention" and the Be the Generation website.
- Continue to update, promote, and disseminate the WHRC's training, "Women in HIV Cure-Related Research."

Objective 4: Promote increased representation of women of color in the field of research.

- Continue to support the Legacy project's efforts to harmonize activities across the minority investigator programs of the ACTG, HPTN, HVTN, and IMPAACT.
- Identify potential new members in and outside the NIH-funded HIV/AIDS clinical trials networks.
- Invite new members to participate in regular calls and WHRC events/activities.
- Cultivate leadership within the WHRC membership with a focus on historically underrepresented voices.

The New Investigators Working Group

The New Investigators Working Group (NIWG) is a cross-network working group of the Legacy Project comprised of network and non-network representatives from across the United States. This group provides

appropriate guidance and leadership in development, and dissemination of information about the various network new investigator programs and engagement of new investigators, with an emphasis on developing underrepresented minority researchers in the US. Utilizing an equity-based approach, the NIWG focuses on supporting cross-network collaboration while strategically promoting the involvement of underrepresented researchers.

The NIWG objectives are:

- Increase awareness of training opportunities for new investigators
- Provide support to the NIH-funded HIV research networks in the development and engagement of new investigators
- Engaging Historically Black Colleges and Universities, Tribal Colleges, and Hispanic Colleges and Universities through the attendance of conferences, meetings, and networking

Workplan 2022

Objective 1: *Increase awareness of training opportunities for new investigators*

- Promotion of specimen and data repositories to increase awareness and interest in these resources for minority investigators.
- Development of an ongoing webinar series highlighting the work, background, and career stories of new HIV researchers across networks.
- Collaboration with the CFAR's to engage non-network affiliated new investigators.
- Promotion of the new investigator programs through the HANC monthly newsletter; incorporating brief descriptions of each of program and (possibly) feature scholars from each program.

Objective 2: *Provide support to the NIH-funded HIV research networks in the development and engagement of new investigators*

- Development of a cross-network database of mentors for new investigators (incorporating mentors of mentors), with a listing of their specialties.
- Invitation of two (2) investigators from each network to join the NIWG.

Objective 3: *Promote equity and representation in HIV research across the networks, with an emphasis on engaging underrepresented minority researchers in the US.*

- Engaging Historically Black Colleges and Universities, Tribal Colleges, and Hispanic Colleges and Universities through the attendance of conferences, meetings, and networking.

The Latinx Caucus

The Latinx Caucus is a working group that aims to raise awareness and increase representation and participation of Latinx communities in social, behavioral, and clinical research in the fields of HIV, COVID-19, STI and TB. We intentionally use the term Latinx as an act of inclusion and solidarity with people of all genders in the Latin American diaspora. The Latinx Caucus serves three purposes:

- ***To increase Latinx participation and representation in research conducted by the HIV/AIDS research networks:*** The Latinx Caucus serves as a consultative group to provide advice and recommendations to DAIDS, the HIV/AIDS Network Leadership, researchers, IRB/Ethics Committees and Community Advisory Boards (CABs) in the involvement of Latinx communities in research (clinical, behavioral, sociological/anthropological) with a culturally appropriate perspective and to promote the work

conducted by Latinx researchers.

- ***To design, produce and conduct training activities and promote educational opportunities for new Latinx leaders and advocates in research:*** The Latinx Caucus identifies gaps in research knowledge and organizes activities to narrow such gaps. Additionally, identifies educational opportunities to promote the interest in clinical, behavioral, sociological/anthropological research in HIV, STIs, tuberculosis and COVID-19 among Latinx communities, in coordination with other Legacy Project working groups, the HIV/AIDS Research Networks, CoVPN and the Division of AIDS.
- ***To convene and educate a critical mass of Latinx leaders and advocates that promote Latinx representation and participation in research:*** The Latinx Caucus identifies other Latinx/Hispanic organizations to promote the work of the Legacy Project around HIV, STI, tuberculosis, COVID-19 and other infectious diseases with the aim of working collaboratively promoting the interest of their constituents in the field.

Work plan 2022

Objective 1: *To increase Latinx participation and representation in research conducted by the HIV/AIDS research networks*

- Promote the Latinx Caucus activities in the HANC Newsletter
- Conduct a systematic review of the peer reviewed literature on the participation of Latinx in clinical research

Objective 2: *To design, produce and conduct training activities and promote educational opportunities for new Latinx leaders and advocates in research*

- Customize, update, and translate the HIV Prevention Research (HPR) module produced by HANC
- Organize and participate in training activities, webinars, and conferences on behalf of the Latinx Caucus
- Identify and promote a directory of colleges and universities that traditionally enroll Latinx individuals

Objective 3: *To convene and educate a critical mass of Latinx leaders and advocates that promote Latinx representation and participation in research*

- Organize webinars highlighting issues related to Latinx health and behavioral research
- Participation in meetings representing the Latinx Caucus

The American Indian/Alaska Native Working Group

The American Indian/Alaska Native Working Group aims to increase engagement and participation of AI/AN populations in HIV, STI, and tuberculosis clinical research.

Work plan 2022

Objective 1: *To increase the participation of American Indian/Alaska Native populations in HIV, STIs, and tuberculosis clinical research sponsored by the HIV/AIDS Research Networks.*

- Produce recommendations on the identification, recruitment, and referral of American Indian/Alaska Native potential participants in HIV, STIs, and tuberculosis research.
- Organize a webinar on the ethical considerations of the inclusion of American Indian/Alaska Native in clinical research.

Objective 2: *To collaborate and coordinate the organization of training opportunities for leaders and advocates of American Indian/Alaska Native communities on HIV/AIDS, STIs, and tuberculosis research.*

- Review and update the “Native American-2-Spirit HIV Prevention Research” training module.
- Review and update the “Native American Engagement in HIV Clinical Research. Project Guidance & Best Practices”.
- Organize and/or participate in conferences and webinars on topics pertaining to the conduct of research with American Indian/Alaska Native populations.

Objective 3: *To establish collaboration agreements with other organization to contribute with the efforts to end the HIV epidemic (EHE) in the American Indian/Alaska Native communities.*

- Coordinate with the Indian Health Service on mechanisms to support their efforts to EHE in the Indian Country.
- Establish collaboration agreements with other organizations working with American Indian/Alaska Native populations to strategize on mechanisms to promote the representation and participation of these populations in clinical research.

Network Leadership

Strategic Working Group (SWG)

The Strategic Working Group is an advisory group convened by NIAID that is intended to provide strategic review and planning for the coordinated research efforts of the NIH HIV/AIDS Clinical Trials Networks. The SWG provides input on strategic issues that cut across the HIV/AIDS clinical trials networks, including overall priority setting for research plans, assessment of research opportunities and coordinated strategic planning across the networks. The working group is convened as needed up to 1-2 times a year by NIAID to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC director participates in the SWG, but the group is organized and facilitated by NIAID.

Network Leaders and DAIDS

HANC organizes focused monthly and ad hoc conference calls with the network Principal and Co-Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also hold bimonthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a monthly call with OPCRO leadership and a bimonthly call with OCSO leadership.

DAIDS Collaboration Objective #1: Support DAIDS OCSO and OPCRO communications to HIV/AIDS Clinical Trials Network stakeholders as requested. Strategies and activities to support this objective:

- Disseminate OPCRO and OCSO policy announcements, memos, newsletters, documents for comment and/or general distributions to network operations centers, sites, and/or labs as requested.
- Maintain the DAIDS Resources page on the HANC website for posting DAIDS announcements, memos, presentations, and other resources not found on the NIAID website.
- Support efforts related to roll-out of DAIDS initiatives, policies, or requirements as requested. Provide planning and logistical support for webinars, broadcast distributions, and ad-hoc working groups.

Site Management Coordination

Clinical trial logistics and operations, site management, and site oversight have been identified as areas of high priority for coordination and harmonization across the networks.

Site Management Working Groups

Site management and clinical trials logistics issues are diverse, and addressing these issues is likely to require different individuals with specific expertise. Network Leadership, DAIDS Leadership, and HANC work closely with the Office of Clinical Site Oversight (OCSO) and Office of Policy in Clinical Research Operations (OPCRO) at DAIDS to identify site concerns and identify appropriate individuals to engage in order to address issues raised.

HANC facilitates a cross-network Site Coordinators Working Group (SCWG) to address topics of common concern as well as to harmonize policies and procedures related to site-level operations.

Site Coordinators Working Group Objectives for 2022

Site Coordinators Working Group Objective #1: Work closely with network staff, OCSO, OPCRO, and other DAIDS offices to identify and address priority site management issues. Strategies and activities to support this objective:

- Network Leaders, OCSO, OPCRO, and other stakeholders will identify an evolving list of site management issues and opportunities to better coordinate their respective efforts.
- HANC will hold regular calls with OCSO and OPCRO leadership to facilitate communication and coordination of site-level activities.
- HANC will convene topic-specific working groups on an ad-hoc basis to address site-level issues.

Site Coordinators Working Group Objective #2: Discuss and address issues relevant to harmonization of policies, procedures, and training at the site level across the networks core operations centers. Strategies and activities to support this objective:

- Hold monthly site coordinator teleconferences dedicated to addressing significant site issues common across the networks. Potential topics of discussion may include: implementation of in-person, remote, and hybrid site monitoring, site establishment and protocol activation processes, tracking systems for site staff training, fiscal management best practices, increased utilization of electronic and remotely operated technologies, integration of local and central IRB documentation, and site preparedness for regulatory audits.
- Discuss issues that emerge with network leadership, core/operations centers, OCSO, OPCRO, and/or the Office of the DAIDS Director as appropriate.
- Provide site-level perspective to DAIDS, SDMCs, and or core/operations centers on new or revised policies and procedures.

Site Coordinators Working Group Objective #3: Communicate updates regarding the activities of the Cross-Network Site Coordinators Working Group. Strategies and activities to support this objective:

- HANC staff will provide to SCWG members a summary of SCWG activities for the past year for reporting, tracking, and documentation purposes.

Training Resources

Training Resources Objective for 2022

Training Objective #1: Maintain the training resources public webpages. The HANC public website provides CTU/CRS staff with information on upcoming training events and training resources available in various formats.

Appendix I: Tangible Deliverables by Area of Coordination

Behavioral Science Coordination

- The Behavioral Science Interest Group (BSIG) continues to produce a bi-weekly newsletter informing recipients of recently published articles, upcoming meetings related to behavioral and social sciences, funding opportunities, and available new resources that may be useful to the BSIG members work.
- The Behavioral Science Consultative Group (BSCG) will continue to host webinars in 2022.
- The BSCG will consider holding a face to face (or virtual) meeting in 2022.
- BSCG member Dr. Jessica Haberer will continue providing effort for the PHOENix Study on the adherence counseling and evaluations.
- The Youth Prevention Research Working Group (YPRWG) is planning to host two webinars in 2022.
- The YPRWG will consider meeting with Network Leadership and NIH counterparts to review Network adolescent research agendas.

Communications Coordination

- Provide content submissions for monthly Network Announcements in the HANC newsletter.
- Provide lists of network submissions to major HIV/AIDS and COVID-19 research conferences. Developed webpages to collage network conference presentations for IAS 2021, CROI 2021, and HIVR4P.

Community Coordination

- Develop FAQ sheets to promote Community Partners resources and training materials
- Develop and promote training materials around how to review a HIV cure/ATI protocol
- Promote training materials developed by CP and information on how to access materials during webinars and GCAB calls, Network meetings and conferences
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices and a comprehensive TB vaccines community engagement strategy
- Host or co-host community-focused workshops/presentations on ongoing network research and community engagement activities
- Draft a White Paper to highlight the collaboration of CRAG and CP in addressing issues around TB/HIV co-infection from a community perspective
- Continue engagement with ATN & other global youth CAB
- Continue engagement with the Martin Delaney Collaboratory
- Continue engagement with the AIDS Malignancy Consortium
- Identify opportunities for improvement and work in collaboration with DAIDS and Network Leadership to ensure dissemination of research results (NIAID to share press releases with HANC to share with CP, communities and sites)
- Work directly with DAIDS Cross-Network Transgender working group to promote the Transgender Training Curriculum for HIV Research with the Networks and other groups to encourage global adoption and implementation of the recommendations
- Submit abstracts to host workshops/presentations at national and international meetings/events to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG

DAIDS

- Disseminated DAIDS memos and MOB newsletters for distribution to network operation center and clinical research sites.
- Supported implementation of DAIDS projects including the DAIDS SCORE Manual rollout, DAIDS Critical Events Policy obsolescence, DAIDS Electronic Information Systems (EIS) Policy trainings, DAIDS Co-enrollment Prevention Requirement webinar, and ongoing Cross-Network Protocol Deviation Working Group. Provided project management, communications, and logistical support.

Data Management Center Coordination

- Developed a draft proposal for harmonized protocol deviation categorization and reporting. Engaged in the Cross-Network Protocol Deviation Working Group led by DAIDS.
- Provide comments on draft EMA guidance on computerized systems and electronic data in clinical trials.
- Published the cross-center Safety Data Reconciliation Manual for reconciliation of adverse events in the DAERS and safety database.
- Convened the IT Best Practices Working Group to review and revise the IT Best Practices Standards.
- Conducted a survey to assess current site IT practices, receiving 93 responses. Developed and delivered training content for the DAIDS EIS Policy trainings. Conducted three, 2-hour training sessions in total.

Financial Disclosure Database

- Provide coordination with Network Regulatory Affairs Coordinators to update investigator, company, and site coordinator lists to use for the HANC-facilitated annual solicitation.
- Review and update the Financial Disclosure and Conflict of Interest Guidelines SOP to ensure compliance with Federal policies.
- Work closely with Freelock to maintain the database/ensure stability of database.

Laboratory Coordination

- Work with the LFG to facilitate cross-network coordination and implementation of new training and other lab site requirements described in DAIDS' Guidelines for Good Clinical Laboratory Practice Standards v4.1).
- Facilitate with the LFG a review of the Cross-Network Guidelines for Diagnosis of HIV Infection in NIH HIV/AIDS Network Clinical Trials.
- Facilitate conference calls with the LTC SOP Sub-Working Group to develop and update ACTG/IMPAACT Laboratory Manual guidance documents and SOPs, including drafting and disseminating the new ACTG/IMPAACT Standard Wording Guidance Chart.
- Coordinate with the ACTG/IMPAACT Network Laboratory Center to maintain current vendor pricing, ordering details, and product information for Fetal Bovine Serum on the HANC webpage.
- Continue to provide avenues of virtual communication and participate in laboratory working group teleconferences and webinars to assure synchronous activities among stakeholders, including ad hoc calls for leadership and/or collaborators.
- Continue to provide software and document development support to laboratory working groups and provide a website for maintaining group documents, agendas and minutes.

- Coordinate with CPQA leadership to organize and host webinars focused on areas of pharmacology laboratory quality assurance.
- Conduct a webinar training session with the LTC focused on LTC-related tools and resources available on the HANC Public and Portal websites.
- Organize a training webinar with LTC members focused on Lab Processing Chart development; post a webinar recording on the HANC Portal.
- Actively maintain and solicit input from LTC members on shared resources and documents on the LTC online portal, including the Laboratory Technologists Workload Tracking Sheet, Lab Processing Chart (LPC) Template, Protocol Support Training Resources, LPC Standardized Wording documents, and LTC Attendance Tracker.
- Provide user support and web-maintenance for the new HANC laboratory reagent ordering system in coordination with the Virology Quality Assurance (VQA) Program.
- Attend and support face to face and/or virtual laboratory sessions at the 2022 ACTG and IMPAACT Annual Meetings.

Legacy Project

- Host community-focused webinars on HIV prevention, treatment, and cure clinical research advances in collaboration with the NIH HIV/AIDS clinical trials networks.
- Host or co-host community-focused workshops/presentations on ongoing network research including cure, PrEP, TasP, microbicides, and vaccines at meetings/events focused on key populations impacted by the domestic HIV epidemic.
- Submit at least one abstract to the United States Conference on AIDS.
- Oversee publication of the quarterly Be The Generation e-newsletter, *BTG News*, in collaboration with the HPTN, HVTN, and MTN.
- Update and promote the BTG HIV Prevention Research (HPR) and Basic Scientific Literacy Modules.
- Conduct trainings of the HPR Module as part of engaging HBCUs.
- Collaborate with DAIDS, WHRC, Community Partners and the NIH HIV/AIDS Clinical Trials Networks and other stakeholders with the development and implementation of the *Transgender Training Curriculum for HIV Research* and related guidance documents.
- Review and update the guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project.
- Convene annual Legacy Project/WHRC virtual meetings/presentations during the remainder of the 2020-2027 funding cycle to discuss and develop engagement strategies.

American Indian/Alaska Native Working Group

- Review and update the “*Native American-2-Spirit HIV Prevention Research*” training module.
- Review and update the “*Native American Engagement in HIV Clinical Research. Project Guidance & Best Practices*”.
- Produce recommendations on the identification, recruitment, and referral of American Indian/Alaska Native potential participants in HIV, STIs, and tuberculosis research.
- Organize a webinar on the ethical considerations of the inclusion of American Indian/Alaska Native in clinical research.

- Submit at least one abstract to the US Conference on AIDS 2022 and the Biomedical HIV Prevention Conference 2022

New Investigators Working Group

- Feature the work of HIV/AIDS research networks minority scholars and fellows through the organization of webinars
- Recruit additional investigators/new investigators from each network to join the NIWG
- Submit at least one abstract to the US Conference on AIDS 2022 and to the Biomedical HIV Prevention Conference 2022

Latinx Caucus

- Conduct a narrative systematic review of the literature on “Participation of Hispanics and Latinos in HIV/AIDS Clinical Research funded by the NIAID/DAIDS in the past 20 years”.
- Review, update and translate to Spanish the HIV Prevention Research module
- Submit at least one abstract to the US Conference on AIDS 2022 and to the Biomedical HIV Prevention Conference 2022

Site Management Coordination

- Issued a solicitation for new SCWG members and disseminated orientation materials to 12 new members.
- Develop an annual summary to report back SCWG yearly activities to working group members.
- Facilitate site presentations of approaches for co-enrollment prevention.
- Collate site management resources to support implementation of the new DAIDS co-enrollment prevention requirement, including a listing of example co-enrollment prevention SOPs.
- Solicit site-level feedback and perspective on site management issues, processes, and monitoring. Relay concerns and emerging problems to relevant DAIDS offices, including OCSO and OPCRO. Track development and evolution of policies and projects impacting site operations, including the Co-Enrollment Prevention policy, Electronic Information Systems policy, and cross-network protocol deviation pilot.

Training Resources

- Maintain archives of HANC-hosted webinar recordings.
- Participate in efforts to revise the HIV Research Counseling and Testing (HRCT) training module.

Women’s HIV Research Collaborative (WHRC)

- Develop trainings/presentations for webinars, local events, and/or regional/national conferences to help contextualize HIV clinical research within the lives of women in the US
- Submit at least one abstract to the United States Conference on AIDS.
- Create and disseminate a fact sheet on NIH-funded HIV/AIDS research relevant to transgender and cisgender women for National Women and Girls HIV/AIDS Awareness Day.
- Recruit new WHRC members from historically underrepresented backgrounds.



General Activities

- Publish monthly issues of the HANC Newsletter covering updates from HANC programs, networks, and other partners.
- Maintain all the NIH/Network contact lists on the HANC portal.