



Office of HIV/AIDS Network Coordination 2024 Work Plan (Year 18)

December 1, 2023 – November 30, 2024

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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's five HIV/AIDS scientific priorities:

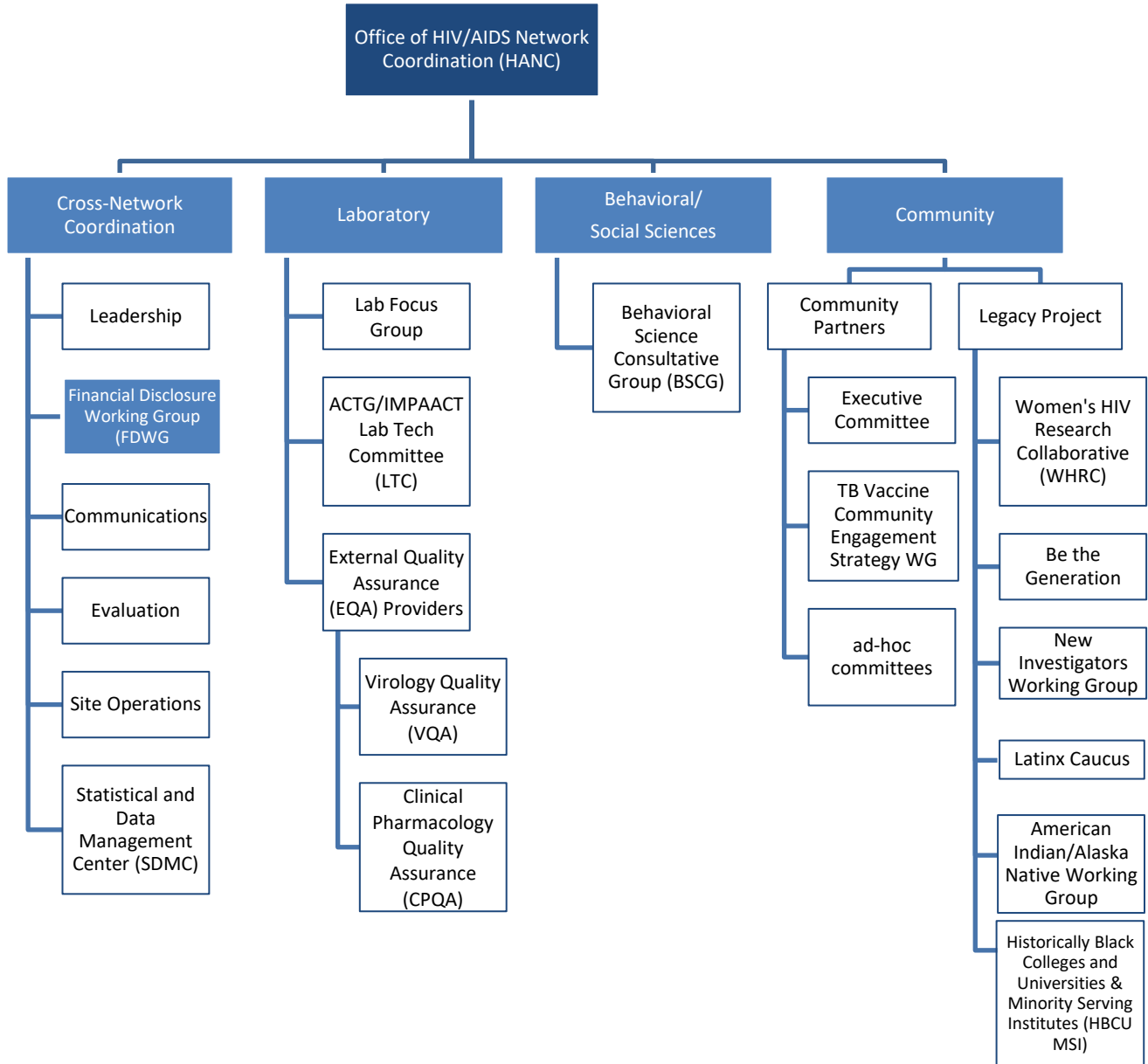
1. Reduce the incidence of HIV, including supporting the development of safe and effective HIV/AIDS vaccines, microbicides and pre-exposure prophylaxis;
2. Develop next generation HIV therapies with improved safety and ease of use;
3. Conduct research towards a cure for HIV/AIDS;
4. Address HIV-associated comorbidities, co-infections, and complications through research designed to decrease and/or manage these conditions; and
5. Advance cross-cutting areas of research in the basic sciences, behavioral and social sciences, epidemiology, implementation science, information dissemination, and research training.

HANC is based at the Fred Hutchinson Cancer 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 the Division of AIDS (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID).

This HANC 2024 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2023 – November 30, 2024 (FY18). 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 2023)



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
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 emerging infectious diseases & HIV pandemics.	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
	Community Partners Executive Committee	Provide leadership on behalf of CP, including identifying priorities. 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)	Utilize Community Partners (CP) to provide input and recommendations to facilitate and enhance community representation and input at all levels in HIV and related clinical research including TB within the networks	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	TB Vaccine Community Engagement Strategy WG	The TB Vaccine Community Engagement Strategy WG will develop a comprehensive TB vaccine community engagement strategy on behalf of three of the four Networks (ACTG, HVTN, & IMPAACT) involved in upcoming TB vaccine protocols.	Provide a recommended community engagement strategy for TB vaccine studies.	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
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.	Coordinated solicitation minimizes burden on sites, operation center staff, and investigators required to report. Continue to improve and adapt the SOP to ensure concordance with federal regulations.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Infrastructure and Admin Support	HANC Behavioral Science PM	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
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



HIV/AIDS Network Coordination 2024 Work Plan (YR18)

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Leadership	HANC 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	Builds 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 other infectious diseases 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



HIV/AIDS Network Coordination 2024 Work Plan (YR18)

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 early career and 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/AIDS and other infectious diseases 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 HIV/AIDS clinical trials networks in the involvement of Latinx communities in research.	Ongoing
	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



HIV/AIDS Network Coordination 2024 Work Plan (YR18)

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	Historically Black Colleges and Universities & Minority Serving Institutes (HBCU MSI)	Promote HIV workforce related professions and address barriers HBCU/MSI students have accessing HIV prevention strategies to address longer term strategies to end the HIV epidemic	Increase HBCU/MSI campus and student engagement in HIV workforce related professions, health science literacy, research, and HIV prevention strategies in a culturally sensitive manner that addresses stigma and equity.	Ongoing
Site Management Logistics	Network Leaders, OCSO, HANC Director, HANC Cross-Network PM	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 Cross-Network PM	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.
- 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.
- The Red Ribbon Registry resource page.
- Understanding Science educational video series in English, Spanish and Portuguese.
- A repository of H=H, the H is for Human podcast episodes, produced by the Legacy Project.

HANC public website projects for the 2024 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 2023, approximately 1,560 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

Red Ribbon Registry

HANC will provide support to DAIDS-funded clinical research sites that use the Red Ribbon Registry. The Red Ribbon Registry is a database that connects volunteers with local clinical studies to strengthen the connection between the community and the doctors and scientists working on clinical research studies. The Red Ribbon Registry Resource Page includes the following:

- Links to trainings conducted by HANC staff (Site Admin training and Site User training)
- Shared documents including protocol documents, regulatory documents, documents for site admin and site users
- Volunteer experience overview
- Contact information for general registry support and technical support
- Registry request forms
- Data use agreement

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 X (former 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 the Statistical and Data Management Centers (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.

Objectives and Activities by Area of Coordination

Behavioral Science Consultative Group

HANC supports one behavioral science group.



Behavioral Science Consultative Group

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.

Behavioral Science Consultative Group Coordination Objective for 2024

Behavioral Science Consultative Group Objective: The Behavioral Science Consultative Group was formed after the 2013 BSWG face-to-face meeting. 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 regular meetings.
- The BSCG will consider a face-to-face meeting in 2024
- The BSCG will continue to provide consultation on behavioral and social science aspects of Network protocols.
- The BSCG will discuss potential collaboration projects w/ NIAID's BSSPT; invite a BSSPT representative to join BSCG calls.
- The BSCG will identify experts to assist in creating a common set of assessment measures to be used across the Networks

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. 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 2024

Communications Objective #1: Discuss network communications efforts related to HIV/AIDS, COVID-19, and other infectious disease research that may impact the conduct of research studies in the networks. Consider best practices that could be employed within the networks. Strategies and activities to support this objective:

- Share experiences related to social media strategy development and execution. Identify opportunities for the networks to support each other around projects related to social media.
- Share experiences with website design, creative design, advertising, and development of materials to support network branding efforts. Share network communications strategies, crisis communications strategies, external relations policies, and strategies related to study launch, DSMB review, and results dissemination.
- Engage with the National Institutes of Health (NIH) / National Institute of Allergy and Infectious Diseases (NIAID) Media Team and Division of AIDS (DAIDS) to establish clear processes for network-to-sponsor engagement around press releases.
- Provide updates on network activities and major study milestones that may impact other studies in the field.

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. Strategies and activities to support this objective:

- Identify existing and potential connections to experts specializing in media training, media relations, key message development, and/or social media. Plan one engagement (e.g. presentation, webinar, or training) focused on the professional development of CWG members and other network communications staff in the selected topic area.
- Identify existing resources and opportunities to build capacity among non-communications staff for media engagements and other communications-related activities.

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.

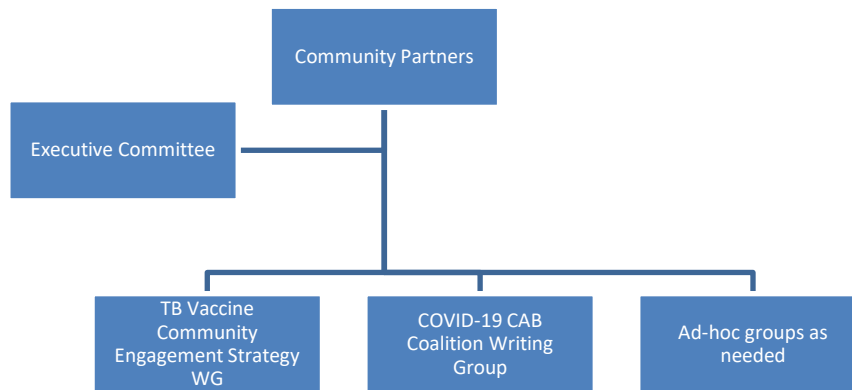
Community Coordination

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 ad-hoc topic-specific working groups that it convenes. The HANC Community Partners Project Manager 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 TB Vaccine Community Engagement Strategy WG is a cross-network body charged with developing a comprehensive TB vaccine community engagement strategy on behalf of three of the four Networks (ACTG, HVTN, & IMPAACT) involved in upcoming TB vaccine protocols.

The Ad-hoc Working Groups will form as needed. Each member of CP is expected to participate in at least one ad-hoc working group.

Community Coordination Objectives for 2024

Community Coordination Objective #1: Utilize Community Partners (CP) to provide input and recommendations to facilitate and enhance community representation and input at all levels in HIV and

related clinical research including TB within the networks. This is a key mission of CP. CP Executive Committee strategies and activities to support this objective:

- Provide leadership on behalf of CP, including identifying priorities and setting agendas for calls with full CP membership.
- Report regularly to CP general membership on Executive Committee activities.
- Select two CP Executive Committee members to serve as members of the HIV/AIDS Clinical Trials Networks Strategic Work Group (SWG).
- Develop strategies to assist the four diverse networks/communities on their prioritized research activities.
- Lead or collaborate on letters of support for international or domestic advocacy.
- 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)

Community Partners Objective #2: Review topics across networks; identify areas where there are challenges for research participation or community representation and involvement; identify opportunities for improvement and work in collaboration with the Network Leadership and DAIDS to address those issues.

Community Partners activities include:

- Address issues as raised by Network and/or DAIDS leadership and the global CABs.
- Using information from the HANC monthly newsletter, post CP information in CAB and network newsletters and network public websites and organize existing network CAB newsletters to post on the HANC Website.
- 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.
- Members of CP to participate in TB Vaccine Community Engagement Strategy Work Group.
- Continue engagement and collaboration with Martin Delany Collaboratories.
- Address issues/concerns around the ethics of providing financial incentives/compensation from a global perspective.
- Submit abstracts for workshops/presentations to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG and other organizations.
- 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.
- Host or co-host community-focused workshops/presentations/webinars on ongoing network research and community engagement activities
- Develop strategies and tools to address the intersecting priorities of emerging infectious diseases & HIV pandemics.

Community Partners Objective #3: Form ad-hoc groups to complete the list of projects below. It is expected that each CP member will participate in at least 1 project from the list below.

- Establish the Community Volunteers Mentorship Programme (CVMP) to develop skills among the community volunteers (CWGs/CABs) in partnership with the research staff and stakeholders.
- Review and modify existing Participant Bill of Rights and Responsibilities to address TB in partnership with CRAG and TB Vaccine Community Engagement Strategy Work Group.
- Work with TBTC CRAG community representatives to develop new strategies and tools and utilize existing tools to address HIV and TB stigma.
- Develop a White Paper to highlight the collaboration of CRAG and CP in addressing issues around TB/HIV co-infection from a community perspective.
- Identify panelists and host webinars on a variety of topics including:
 - Informed consent process according to DAIDS policy
 - Research ethics and ethical considerations in the informed consent process.
 - Procedures for obtaining and documenting the IC process.
 - “How to” series (how to write abstracts, how to submit study proposals, etc.)
 - Safety and follow up post-trial – post trial access to participants.

TB Vaccine Community Engagement Strategy WG:

The Office of HIV/AIDS Network Coordination (HANC) has been tasked by the NIH HIV/AIDS Clinical Trials Networks Leadership to convene a work group to help develop a comprehensive TB vaccine community engagement strategy on behalf of three of the four Networks (ACTG, HVTN, & IMPAACT) involved in upcoming TB vaccine protocols. The TB Vaccine Community Engagement Strategy work group was formed in August 2023 and started meeting in September 2023. Ongoing activities that support developing a comprehensive TB vaccine community engagement strategy:

- Review documents and provide input into developing a plan to engage communities with limited knowledge around TB and/or vaccines.
- Discuss and develop materials, resources and trainings for site staff and communities for upcoming and future TB vaccine trials including:
 - The use of ART & other TB comorbidities treatments
 - The role of TB preventive treatment in TB vaccine studies
 - Concerns about particular vaccine types (e.g., live vaccines based on MTB)
 - Misinformation/rumors around TB vaccines
 - TB care services
- Convene calls with the TBTC CRAG to develop a TB Participant Bill of Rights and Responsibilities document based on the HIV Participant Bill of Rights and Responsibilities document
- Post-trial access strategies to ensure equity

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 Frontier Science and Technology Research Foundation (FSTRF) and Statistical Center for HIV/AIDS Research and Prevention (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 Data Management Centers (DMCs), Office of Cyber Infrastructure and Computational Biology (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 ITBPWG will reconvene in 2024.

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. Hereafter, the group will meet biannually to revise and update the standards document. The PODWG will reconvene in 2024.

DMC Working Group Objectives for 2024

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 implementation 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 network and sponsor stakeholders. Strategies and activities to support this objective:

- Update the data management training curriculum for DAIDS staff.
- 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.

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 2024

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.
- Ad-hoc meetings through June 2024 to harmonize site performance evaluation reports submitted to DAIDS annually.
- 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.

Financial Disclosure Work Group

Financial Disclosure Work Group Objective: Work closely with network staff and DAIDS to periodically review the harmonized network financial disclosure requirements.

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, ATN, and PHACS.

Laboratory Coordination

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 2024:

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 laboratories are implementing appropriate laboratory 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 laboratory 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 biennially.
5. Review and provide laboratory context for DAIDS policies and how they may be interpreted or adopted by laboratories supporting network activities.

The Cross Network PBMC SOP Working Group is charged with developing, publishing and reviewing the “Cross-Network PBMC Processing SOP” for all network-affiliated laboratories that process PBMC. The SOP is reviewed and updated by the Cross-Network PBMC Working Group on biennially.

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, processing laboratories, repositories, and testing laboratories.

LTC Objectives for 2024:

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 (e.g., guidelines and templates to guide developing protocol Laboratory Processing Charts).
 - 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 Laboratory 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.

The ACTG/IMPAACT Laboratory Technologist SOP Working Group (SOPWG): The SOPWG operates as a specialized subgroup under the lab technologists committee. Its primary responsibility is to regularly update the standard operating procedures and associated guidance materials located on the ACTG/IMPAACT Laboratory Manual section of the HANC Public website. HANC staff organizes bi-monthly meetings and maintains frequent email communication to collaboratively review and refine consensus procedures. HANC staff oversees all processes related to document control and management.

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:

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

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 infection
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 2024 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 2024 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 research staff, HANC working groups, external stakeholders, and others).
1.1	Monitor and promote the collection and reporting of participants’ gender identity, sex assigned at birth, race, and ethnicity as well as the intersections of these categories.
1.2	Promote and apply the Representative Studies Rubric (RSR) to address systemic barriers to representative study populations in clinical trials.
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 individuals and 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	Engage in collaborative efforts to develop trainings and resources to promote the inclusion of people who use drugs in clinical research.
1.5	Hold meetings/teleconferences with the Legacy Project Working Groups and external stakeholders to continuously facilitate engagement in the mission of the Legacy Project.
1.6	Participate in Network and non-Network meetings and conferences to monitor and promote underrepresented populations’ participation in HIV and other infectious diseases research.
1.7	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.

2.1	Host or co-host community-focused workshops/presentations/webinars on research conducted by the HIV/AIDS research 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	Produce H=H podcast episodes on topics related to health, wellbeing and community including, HIV/infectious diseases research and community engagement in collaboration with research and community stakeholders.
2.5	Maintain the Legacy Project’s presence on social media to disseminate information related to HIV/infectious diseases research and community engagement.
2.6	Develop and maintain partnerships with individuals, institutions, and organizations representing populations that are underrepresented in HIV/infectious diseases research to collaborate on capacity-building projects to increase interest/engagement in trial participation as well as HIV workforce development/research careers.
2.7	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 research networks and stakeholders in addressing the intersecting priorities of emerging infectious diseases with the HIV pandemic.
4.0	Execute the work plan of the American Indian/Alaska Native Working Group
5.0	Provide leadership and support to the DAIDS Cross-Network Transgender and Gender Diverse Working Group, including creation, promotion, and implementation of resources to promote transgender inclusion in clinical research.
6.0	Develop a work plan for the MSI Working Group and engaging HBCU students as part of Evidence 2 Practice program
7.0	Execute the work plan of the Latinx Caucus
8.0	Execute the work plan of the New Investigators Working Group
9.0	Execute the work plan of the Women’s HIV Research Collaborative

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 members representing the 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 Dázon Dixon Diallo, MPH and Typhanye Dyer, PhD. Dázon will complete 4 years as co-chair (the maximum term) on February 1, 2025. Typhanye will complete 2 years as co-chair and be up for re-election, should she choose to run, on March 1, 2024. The HANC facilitator assigned to the WHRC is Gabriella Olague.

WHRC 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).
- Support implementation and dissemination of the [Representative Studies Rubric](#) (RSR) as a tool to facilitate women's inclusion in research across NIH-funded HIV/AIDS clinical trials networks by providing it to colleagues and promoting its use to trial sites.
- Solicit measurable goals and plans for the enrollment of women from study teams by forging relationships with the teams of ongoing studies.
- Solicit scientific rationale in cases of women's exclusion (as required by NIH).
- Advocate for the use of non-stigmatizing and inclusive language and help Network and study staff apply the [NIAID Language Guide](#) and the [WHRC's guidance on accurate and affirming language](#).
- Conceive of a new research paradigm that is women-centered, trauma-informed, and that addresses the realities women face when participating in HIV prevention, treatment, and cure-related clinical trials.
 - Create Still We Rise: Forging a Women Centered Research Paradigm website timeline and manuscript publication.
 - Advocate for addressing intimate partner violence (IPV), sexual and reproductive justice and bodily autonomy as variables in safety, efficacy, feasibility, and acceptability of study products by conducting webinars, submitting abstracts to conferences, and developing additional training opportunities on these variables.

Objective 2: 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 meaningfully engage women in HIV prevention, treatment, and cure-related clinical trials by creating material to provide to these sites advising how best to do this.
- Synthesize and contextualize Network research as it pertains to the lives of women in the US.
 - Report on new studies and study concepts, ongoing studies, and study findings through webinars, local events, conferences, infographics, social media, and other means.
 - Partner with local and national organizations to promote scientific developments in HIV clinical research.

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

Objective 3: 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 *by* connecting with and/or participating on other Legacy Project working groups on mutual goals.
- Identify and invite potential new WHRC members from within and outside the NIH-funded HIV/AIDS clinical trials networks, including potential collaborations with organizations such as:
 - The Centers for AIDS Research (CFARs)
 - NIH Office of Research on Women’s Health (ORWH)
 - Positive Women’s Network (PWN)
 - Virology Education
 - Well Project
 - WomenNow!
- Cultivate leadership and training opportunities within the WHRC membership with a focus on historically underrepresented voices by inviting guest speakers to join our calls and giving WHRC members the opportunity to take more leadership roles in the group for non-co-chair members.

The New Investigators Working Group

The New Investigators Working Group (NIWG) is a cross-network working group of the Legacy Project, comprised of the project managers that coordinate the early career investigators, young investigators, and minority scholars’ programs of the HIV/AIDS clinical trials networks (ACTG, HVTN, HPTN, IMPAACT, and ATN).

The NIWG provides appropriate guidance and leadership in the development, and dissemination of information about the various network’s scholars programs and contributes to promote the engagement of potential candidates in these programs, with an emphasis on underrepresented minority researchers in the US and internationally.

The NIWG objectives are:

- Increase awareness of training opportunities for new investigators
- Facilitate and promote the exchange of experiences and ideas among program scholars/fellows.
- Promote equity and representation in HIV research across the HIV/AIDS clinical research networks, with an emphasis on engaging underrepresented minority researchers in the US and internationally.

Workplan 2024

Legacy Project New Investigators Working Group Work Plan 2024				
#	Activity	Delegation	Means of verification	Timeline
OBJECTIVE 1: Increase awareness of training opportunities for new investigators				
1.1	Promote early career/ young investigators and minority scholars’ programs on the HANC monthly newsletter and the HANC portal.	Project Manager (PM) & working group members	Published notes on HANC Newsletter Publication of fellowship announcements	On-going

1.2	Feature investigators on the HANC newsletter	PM & scholars programs project managers	Published notes on HANC newsletter	Monthly
OBJECTIVE 2: Facilitate and promote the exchange of experiences and ideas among fellows/investigators				
2.1	Development of an ongoing webinar series highlighting the work, background, and career stories of new HIV researchers across networks	All	Webinar invitation Webinar recording	Three times a year
2.2	Plan and organize activities to help support young investigators work	All	Webinar invitation Webinar recording	Biannual
OBJECTIVE 3: Promote equity and representation in HIV research across the networks, with an emphasis on engaging underrepresented minority researchers in the US.				
3.1	Engaging Historically Black Colleges and Universities, Tribal Colleges, and Hispanic Colleges and Universities	All	Attendance of conferences, meetings, and networking	On-going

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.
- To design, produce and conduct training activities and promote educational opportunities for new Latinx leaders and advocates in research.
- To convene and educate a critical mass of Latinx leaders and advocates that promote Latinx representation and participation in research.

Work plan 2024

Legacy Project Latinx Caucus Work Plan 2023 – 2024				
#	Activity	Delegation	Means of verification	Timeline
OBJECTIVE 1: To increase Latinx participation and representation in research conducted by the HIV/AIDS research networks				
1.1	Promote the Latinx Caucus activities in the HANC Newsletter	Pedro	Published bimonthly notes on HANC Newsletter	Bimonthly
1.2	Assess the representation of Latinx individuals in community advisory boards (CABs) of clinical research sites in the US.	Pedro & TBD	<ul style="list-style-type: none"> - Research protocol - Data collection instruments - Implementation - Analysis - Report - Paper 	6 – 12 months
OBJECTIVE 2: To design, produce and conduct training activities and promote educational opportunities for new Latinx leaders and advocates in research				
2.1	Present the Módulo de Entrenamiento en Investigación en Prevención del VIH (MIPreVIH) at different organizations and events.	All	<ul style="list-style-type: none"> - Request from sites or community organizations - Planning presentations in person/remotely - Evaluation 	12 months
2.2	Support the production of HIV/AIDS research educational and training materials in Spanish for Hispanics and Latinx audiences of limited English proficiency	All	<ul style="list-style-type: none"> - Prioritization of HIV research topics (prevention -HIV vaccines-, therapeutics, and cure) - Drafting, field testing, production, and publication 	12 months
2.3	Promote and enforce the provision of language access services under the language justice framework at HIV/AIDS research networks and their clinical research sites	Pedro Rafael Gonzalez Patricia Segura Alison Cardinal Other Caucus members	<ul style="list-style-type: none"> - Rapid assessment - Report - Recommendations - Publication: position paper or article 	12-24 months
2.4	Organize and participate in training activities, webinars, and conferences on behalf of the Latinx Caucus	All	<ul style="list-style-type: none"> - Abstract submissions - Training plans - Meeting agendas - “Thank you” letters 	On-going
OBJECTIVE 3: To convene and educate a critical mass of Latinx leaders and advocates that promote Latinx representation and participation in research				

3.1	Organize of webinars highlighting issues related to Latinx health and behavioral research	All	- Webinar Announcement - National Latinx AIDS Awareness Day, 10/15	On-going
3.2	Advocate for language access in AIDS related activities enabling the participation of Spanish speakers of limited English proficiency	All	- Position statements - Letters	On-going
3.3	Participation in meetings representing the Latinx Caucus	All	- Invitation letter - Meeting agenda - "Thank you" letters	On-going
3.4	Produce a position paper on the relevance of participation of Latinx in HIV clinical research	All	- Organization of a writing team - Literature review - Manuscript	3 – 6 months

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 2024

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.*

- 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.

Historically Black Colleges and Universities & Minority Servings Institutes

To increase HBCU/MSI campus and student engagement in HIV workforce related professions, health science literacy, research, and HIV prevention strategies in a culturally sensitive manner that addresses stigma and equity.

Work plan 2024

Objective 1: *Promote HIV workforce related professions to address longer term strategies to end the HIV epidemic.*

- Increase WG representation of HBCU/MSI students and other relevant representatives.

Objective 2: *Develop informative training materials for presentations and workshops to increase the health sciences literacy of HBCU/MSI students.*

- Finalize adaption of HIV Prevention Research (HPR) module produced by HANC for HBCU/MSI Students.
- Develop adaption of HIV Prevention Research (HPR) module produced by HANC for HBCU/MSI Pharmacy Students.
- Submit publications on behalf of the HBCU MSI WG.

Objective 3: *Increase awareness of HIV research and biomedical interventions (e.g., PrEP, PEP, and other antiretrovirals) & incorporate non-biomedical intervention strategies that support ending the HIV epidemic.*

- Present webinars and submit abstract to conferences

Objective 4: *Address barriers HBCU/MSI students have accessing HIV prevention strategies.*

- Create guidelines for campus policy around HIV prevention, access, support, & safety.

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.

Cross-Network Collaboration Objective #1: Increase collaboration/harmonization across networks to reach consensus whenever possible. Strategies and activities to support this objective:

- Focus on system-wide issues and avoid duplication efforts as requested.
- Enhanced cross-network conversations with DAIDS through scheduled calls with DAIDS leadership.
- Enhance feedback loop from community to let community know Network leadership is responsive.
- Support efforts related to network efforts to elevate/recruit/engage individuals who are most impacted by HIV and other health disparities, including more engagement of youth, to be represented at all areas of research throughout the networks.

- Focus on cross-network value added for groups/priorities that overlap through scheduled presentations to the the leadership group during calls.

DAIDS Collaboration Objective #2: 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 2024

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: development of a business continuity plan template for public health emergencies, development and maintenance of site CABs, training and mentorship needs for new study coordinators, and opportunities for cross-network networking between clinical research sites.
- 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.
- Conduct a solicitation for new members to the SCWG.

Training Resources

Training Resources Objective for 2024

Training Objective #1: Maintain and update HANC-developed training modules for network staff, partners, and community.

Training Objective #2: Support the publication and dissemination of training resources, opportunities, and events.

- Maintain webpages on the HANC public website for internal and external training resources.
- Disseminate opportunities for upcoming training events, webinars, and training resources via HANC communication channels.

Appendix I: Tangible Deliverables by Area of Coordination

American Indian/Alaska Native Working Group

- Organize a webinar on the ethical considerations of the inclusion of American Indian/Alaska Native in clinical research.
- Produce educational material to raise awareness on the state of the HIV/AIDS epidemic in AI/AN populations.
- Submit abstracts to national and international conferences.

Behavioral Science Coordination

- The BSCG will host a face to face meeting in 2024.
- The BSCG will help identify experts to assist in developing a common set of assessment measures.

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. Develop webpages to collate network conference presentations for CROI 2024, IAS 2024, and HIVR4P.
- Host one webinar, training, or event focused on professional development of network communications staff.
- Add to the internal CWG repository for network-developed toolkits, resources, and templates for communications planning, messaging development, website design, social media management, and media relations.

Community Coordination

- Develop TB Participant Bill of Rights and Responsibilities in partnership with CRAG
- Establish and pilot the Community Volunteers Mentorship Programme (CVMP) to develop skills among the community volunteers (CWGs/CABs) in partnership with the research staff and stakeholders.
- 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
- 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)
- Develop strategies and tools to address the intersecting priorities of emerging infectious diseases & HIV pandemics

- 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
- Submit manuscript on lessons learned from the COVID-19 pandemic

Data Management Center Coordination

- Update Data Management Training curriculum and conduct training sessions with DAIDS staff.
- Identify opportunities to support jointly-developed Clinical Data Management (CDM) trainings.

Evaluation

- Deliver proposal to DAIDS for common site performance metrics to be reported annually by all networks to DAIDS.

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.

Historically Black Colleges and Universities & Minority Servings Institutes

- Conduct trainings of the HPR Module adapted to HBCU campus students, faculty and staff as part of engaging HBCUs.
- Finalize the adaption of HIV Prevention Research (HPR) module produced by HANC for HBCU/MSI campus and submit a manuscript detailing the iterative process to support other organizations interested in creating similar culturally aligned materials.
- Submit at least two abstracts to one of the following: [USHCA](#), [Biomedical Summit](#), [NAESM](#), [Historically Black Colleges and Universities Conference 2024](#), [16th health disparities](#), [NBNA - national black nurses association](#)
- Create guidelines for campus policy around HIV prevention, access, support, & safety. Guidelines will be promoted via webinars, conferences and the HANC website.

Laboratory Coordination

- Continue to manage and provide specialized support for laboratory webpages on the HANC Portal and Public websites, including user account setup, addressing technical issues, and maintaining key resources like SOPs, webinar archives, and supplier details to ensure uninterrupted access for lab personnel and working group members.
- 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.
- Collaborate with CPQA leadership to design and conduct webinars that specifically address key aspects of pharmacology laboratory quality assurance to deepen the understanding and expertise of pharmacology laboratory staff.

- Facilitate with the LFG a review of the Cross-Network Guidelines for Diagnosis of HIV Infection in NIH HIV/AIDS Network Clinical Trials.
- Facilitate bi-monthly conference calls with the Laboratory Technologists SOPWG to develop and update ACTG/IMPAACT Laboratory Manual guidance documents and SOPs, including the "ACTG/IMPAACT Guidelines for Shipping & Receiving Biological Substance, Category B Specimens", "ACTG/IMPAACT Specimen Shipment Notice", and "ACTG/IMPAACT Specimen Shipment Checklist."
- Conduct a webinar training session with the LTC focused on LTC-related tools and resources available on the HANC Public and Portal websites.
- In partnership with Network Laboratory Centers and DCLOT, oversee and regularly update the laboratory supply shortage tracking system, ensuring efficient reporting, monitoring, and handling of shortages across network sites.
- Review, update and publish the cross-network Primary Network Laboratory Listing (PNL List), working closely with the Network Laboratory Centers, DCLOT, and regulatory contractors to ensure its accuracy and currency.
- Attend and support face to face and/or virtual laboratory sessions at the 2024 ACTG and IMPAACT Annual Meetings.

Latinx Caucus

- Assess the representation of Latinx individuals in community advisory boards (CABs) of clinical research sites in the US.
- Present the Módulo de Entrenamiento en Investigación en Prevención del VIH (MIPreVIH) at different organizations and events.
- Support the production of HIV/AIDS research educational and training materials in Spanish for Hispanics and Latinx audiences of limited English proficiency.
- Promote and enforce the provision of language access services under the language justice framework at HIV/AIDS research networks and their clinical research sites.
- Organize of webinars highlighting issues related to Latinx health and behavioral research.
- Produce a position paper on the relevance of participation of Latinx in HIV clinical research
- Submit at least one abstract to the US Conference on AIDS 2024 and to the Biomedical HIV Prevention Conference 2024.
- Submit at least one abstract to the National Latinx Conference on HIV/HCV/SUD 2024

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 abstracts to conferences.
- Oversee publication of the quarterly Be The Generation e-newsletter, *BTG News*, in collaboration with the HPTN, HVTN, and IMPAACT.
- Support ongoing implementation of the Representative Studies Rubric.
- Convene annual Legacy Project/WHRC virtual meetings/presentations during the remainder of the 2020-2027 funding cycle to discuss and develop engagement strategies.

Network/DAIDS Leadership

- Continue to focus on system-wide issues and avoid duplication efforts as requested.
- Work to enhance cross-network conversations with DAIDS through scheduled calls with DAIDS leadership.
- Work to enhance feedback loop from community to let community know Network leadership is responsive.
- Support efforts related to network efforts to elevate/recruit/engage individuals who are most impacted by HIV and other health disparities, including more engagement of youth, to be represented at all areas of research throughout the networks.
- Focus on cross-network value added for groups/priorities that overlap through scheduled presentations to the the leadership group during calls.
- Continue to disseminate DAIDS memos and MOB newsletters for distribution to network operation center and clinical research sites.
- Develop webpage(s) on the HANC website to host and share the DAIDS Applied Research Training (DART) 2.0 curriculum.
- Conduct 6-month and 12-month review of the Cross-Network Protocol Deviation eCRF and reference guide. Facilitate ongoing evolutions to the reference guide and other supporting documentation for collecting and reporting protocol deviations.

New Investigators Working Group

- Contribute to promote the Networks scholars programs through the HANC Newsletter and other means available at HANC.
- Promote early career/ young investigators and minority scholars' programs on the HANC monthly newsletter and the HANC portal.
- Feature the work of HIV/AIDS research networks minority scholars and fellows through the organization of webinars.
- Development of an ongoing webinar series highlighting the work, background, and career stories of new HIV researchers across network.
- Engage Historically Black Colleges and Universities, Tribal Colleges, and Hispanic Colleges and Universities.

Site Management Coordination

- Conduct a solicitation for new Cross-Network Site Coordinators Working Group (SCWG) members.
- Write an annual summary to reporting back SCWG yearly activities to working group members.
- Finalize the *Site Start-up Checklist* and *CRS Coordinator Onboarding/Training Checklist* template to assist onboarding new study coordinators to DAIDS-funded research. Identify additional resources or tools to support onboarding of new site staff.
- Explore creation of a cross-network directory to facilitate networking and community between site coordinators.
- Continue to add content on the "DAIDS Deadlines" page on the HANC website to summarize upcoming deadlines for DAIDS requirements that apply to DAIDS-funded clinical research sites.

Training Resources

- Facilitate expansion of the Red Ribbon Registry (R3) to additional network studies.
 - Maintain the *R3 Resources* page on the HANC website to support ACTG, HPTN, and IMPAACT sites.
 - Develop processes and workflows to facilitate various communications between external stakeholders and R3 internal team, including processes for regulatory approval of site-developed advertising materials and requests for communications to volunteers.
 - Conduct training sessions for site administrators and users;

Women's HIV Research Collaborative (WHRC)

- Complete and publish a manuscript for Still We Rise: Forging a Women Centered Research Paradigm.
- Publishing a virtual timeline of historic events which have shaped the way women are involved in research.
- Host multiple webinars as well as invite guest speakers to present to the WHRC and provide continued education on up-and-coming, women-related HIV/AIDS research, such as MPT's.
- Submit abstracts to multiple conferences including the Biomedical HIV Summit and USCHA.

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.