



Office of HIV/AIDS Network Coordination

2021 Work Plan (Year 15)

December 1, 2020 – November 30, 2021

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Introduction

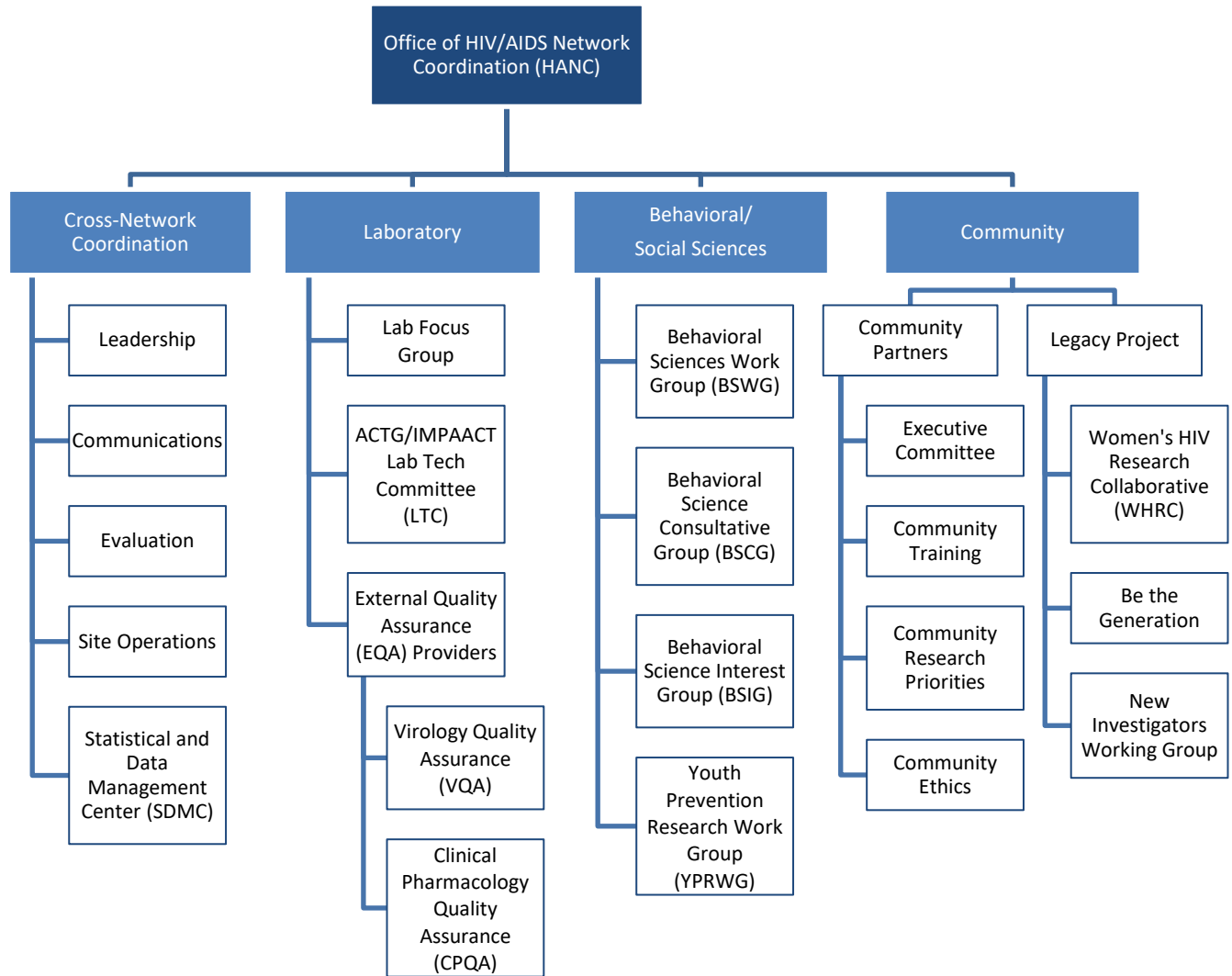
The Office of HIV/AIDS Network Coordination (HANC) works with the HIV/AIDS Clinical Trials Networks funded by the U.S. National Institutes of Health (NIH) with the intent of creating a more integrated, collaborative, and flexible research structure. The Networks are an affiliated group of national and 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), the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT), and the Microbicide Trials Network (MTN). (Note: the MTN will be phased out by December 2021.) The NIH HIV/AIDS Clinical Trials Networks have been designed to address the NIH four HIV/AIDS scientific priorities:

1. Reduce the incidence of HIV/AIDS, including the development of safe and effective HIV/AIDS vaccines and microbicides;
2. Develop the next generation of HIV therapies with improved safety and ease of use;
3. Discover a cure for HIV/AIDS; and
4. Reduce HIV-associated comorbidities and coinfections. Basic research, health disparities, behavioral and social sciences research, epidemiology, information dissemination, implementation sciences, and training that cut across the four priority areas are also supported.

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 the Network Leadership and DAIDS.

This HANC 2021 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2020 – November 30, 2021 (Year 1). 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 November 2020)



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	Leverage network experience and expertise; collect communications tools and measures; harmonize elements of the networks’ communications plans	Increased coordination and consistent messaging.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
Community Coordination	Community Partners	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.	Provide input and recommendations to focus on meeting CP's Strategic Plan objectives to guide CP's work over the next three years following the Network restructuring.	Ongoing
	Community Partners Research Priorities Working Group	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 and make recommendations regarding Standard of Care issues for community members. In partnership with CP Ethics WG, review and address understanding of IC among CABs. Continue to review and make recommendations on co-endorsed protocols to ensure community input.	Enable involvement in the development and sharing of research priorities, and harmonization between community and investigator research priorities.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	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
	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	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



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Area	Group Responsible	Objective	Intended Impact	Timeline / Completion Target
	IT Best Practices Working Group	Biannually review the Information Technology Best Practice Standards (last version published in 2018).	Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems used by the DMCs.	December 2021
Evaluation	Evaluation Working Group	Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks with a focus on community engagement.	Identify streamlined and harmonized reporting 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
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
	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

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) contains a collection of resources for collaborators, research sites, and the general public, including:

- A calendar of scientific conferences, network meetings, community events, and training opportunities.
- Selected DAIDS OCSO and OPCRO SOPs, memos, and announcements that are not listed on the DAIDS website, and a link to the official DAIDS Clinical Research Policies webpage on the NIAID/DAIDS website.
- A dynamic announcement section on the home page for posting notices, such as recent DAIDS policies, upcoming webinars, and upcoming training opportunities.
- Training resources including links to free Good Clinical Practice (GCP) and Human Subjects Protection and Responsible Conduct of Research Training through the Collaborative IRB Training Initiative (CITI), links to the DAIDS Learning Management System (LMS), an HIV Research Counseling and Testing (HRCT) training Curriculum, and training course library.
- Guidance documents, SOPs, and resources for multiple audiences including community (Recommendations for Community Engagement in HIV/AIDS Research, Be The Generation HIV Prevention Research Training Module, Basic Scientific Literacy Training Module, TB Resources for Communities...), laboratory (ACTG/IMPAACT Lab Manual, PBMC Processing SOP, Cold-Chain Guidelines, TB Sourcebook, shipping information...), behavioral/social scientists, sites, and data management centers.
- Webinar libraries for various working groups.



- Information for laboratories including primary network laboratory (PNL) Contact Assignment and laboratory training videos.
- A library of centralized laboratory certifications (i.e. CAP and CLIA) for site reference.
- General information about HANC's coordination activities.

HANC public website projects for the 2021 Work Plan include:

- Upgrade the HANC public website platform from SharePoint 2010 to Adobe Experience Manager. The upgrade will include updates to website navigation and user experience, design, and content.

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 regularly solicits suggestions for the portal and updates the site accordingly. HANC maintains the following portal resources:

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

HANC portal projects for the 2021 Work Plan include:

Upgrade the HANC portal from SharePoint 2010 to a SharePoint 2013/SharePoint Online hybrid.

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. # were submitted during this reporting period. 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 2021

Behavioral Science Consultative Group Objective: The BSCG’s overarching objectives are to 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.

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 2021 if allowed.
- The BSCG will continue to provide consultation on behavioral and social science aspects of the following protocols
 - HVTN 706
 - PHOENix Study
 - ACTG 5359
 - HPTN 083-01/HPTN 084-01
- Other items as Networks ask the BSCG for consultation

Youth Prevention Research Working Group Objectives for 2021:

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.

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.

Youth Prevention Research Working Group Objective #5: • The Youth Prevention Research Working Group will develop and send a survey to engage with the new CTUs/CRS configurations to access the sites' experience with adolescent research and necessary training needed.

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
- Develop and distribute a survey for the new CTUs/CRS'.
- Submit symposium proposals to conferences as appropriate

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 2021

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.

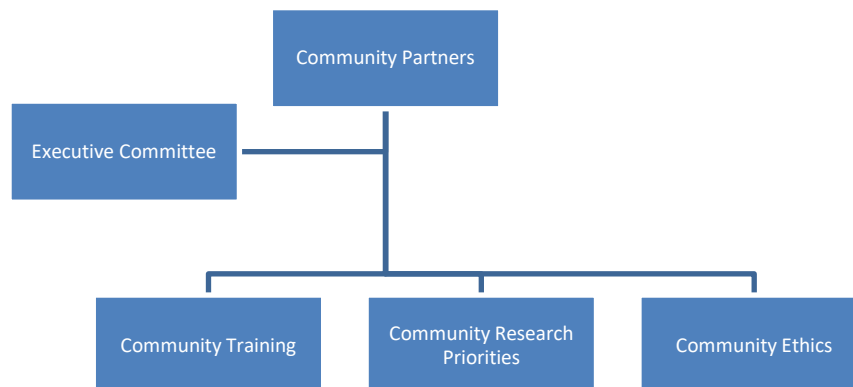
Communications Objective #3: Provide network activity updates for cross-network communications and publications. Submissions include content for the monthly HANC newsletter and accepted network submissions to major HIV/AIDS research conferences.

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 2021

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 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 at Network meetings and conferences
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices
- Explore possibilities and partner with WHRC 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)

Community Partners Objective #3: CP will collaborate on the analysis and manuscript development of the network-level community input survey.

Strategies and activities to support this objective:

- Analyze survey data evaluating the impact of network-level community input
- Collaborate with colleagues from Concept Systems Inc. in this effort
- Submit a manuscript for publication with the network-level community impact survey data

Community Partners Objective #4: 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 #5: 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 #6: 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:

- Continue engagement with ATN Youth CAB
 - 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 AIDS Malignancy Consortium

COVID-19 CAB Coalition: In September 2020, HANC created a working group 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. Members of the group represent the ACTG's ACTIV-2 CAB, CoVPN's Community Engagement Group, AVAC's CAAB, Stony Brook's COVID-19 CAB, The National CFAR CAB, Community Partners, and DAIDS.

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.

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. Hereafter, the group will meet biannually to revise and update the standards document.

DMC Working Group Objectives for 2021

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:

- Monitor cross-DMC standardization support needs for AE/EAE reconciliation. Work with DAIDS to identify data elements that are required to be reconciled and maintain ongoing dialogue with DAIDS staff regarding challenges encountered with reconciliation.
- 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 MedDRA coding, 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:

- Advocate for revised guidelines regarding MedDRA coding policies and implementation.
- 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 2021

ITBPWG Objective #1: Update the IT Best Practices & Standards in accordance with current information technology and cybersecurity best practices, and regulatory authority, NIH, and DAIDS policies.

Strategies and activities to support this objective:

- Convene on a monthly or as-needed basis to review current standards and recommend revisions.
- Disseminate updated IT Best Practices & Standards document to DAIDS OCSO and NIH HIV/AIDS Clinical Trials Network sites and laboratories.

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 2021

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.
- Update and improve online reporting system functionality.
- 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. The 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 2021:

1. Continue to identify laboratory issues that require input from all the networks, in collaboration with DAIDS Clinical Laboratory Oversight Team (DCLOT), to assure that network labs are implementing quality and efficient lab processes.
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.

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 (CCGWG) group 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 2021:

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 NIAID’s five HIV/AIDS scientific priorities, including:

1. Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, including hepatitis and tuberculosis) (ACTG)
2. HIV/AIDS and HIV-associated infections in children and mothers (IMPAACT)
3. Integrated strategies to prevent HIV infection (HPTN)
4. Vaccines to prevent HIV infection (HVTN)
5. Microbicides to prevent HIV infection (MTN)

The Legacy Project 2021 Work Plan is in line with the [National HIV/AIDS Strategy](#), 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, transgender antagonism, homonegativity, misogyny, poverty, stigma, and discrimination.

Legacy Project 2021 Goals and Objectives:

Goal: 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.

Objectives and activities to support this goal:

1.0	Monitor and promote improved representation of underrepresented populations’ participation in clinical trials through collaboration with partners (such as network communications and community engagement staff, Community Partners, the WHRC, 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, and race as well as the intersections of these categories.
1.2	Consult/collaborate with populations especially vulnerable to HIV, 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.

1.3	Engage with networks/protocol teams to recommend/facilitate a percentage of enrollment of women and other underrepresented populations as part of protocol development in select trials.
1.4	Hold monthly teleconferences with the Legacy Project Working Group to continuously engage stakeholders in the mission of the Legacy Project.
1.5	Participate in Network meetings and other local and national conferences to monitor and promote underrepresented populations’ participation in HIV research.
1.6	Provide technical assistance to researchers and research staff on projects that promote trust and collaboration between underrepresented populations and the HIV research establishment.
2.0	Collaborate with underrepresented populations to increase awareness and knowledge of HIV clinical research and community readiness to engage in trial participation activities through presentations, abstracts, meetings, conferences, podcasts, and webinars.
2.1	Engage the Conference Engagement Working Group to discuss and plan for network meetings and to promote cross-network abstracts and activities at national conferences and events.
2.2	Host or co-host community-focused workshops/presentations on ongoing network research at meetings/events focused on key populations impacted by the domestic HIV epidemic.
2.3	Host community-focused webinars on HIV research conducted by the NIH-funded HIV/AIDS clinical trials networks and related community-engagement issues.
2.4	Implement the HPR module in collaboration with HBCUs to increase knowledge of HIV prevention research.
2.5	Develop and broadcast a podcast on HIV 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 research and community engagement.
2.7	Review, update, and disseminate the guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project.
2.8	Develop partnerships with individuals as well as local and national organizations representing underrepresented populations in HIV research to collaborate on capacity-building projects.
2.9	Engage and collaborate with the National CFAR CAB Coalition to exchange information and resources to support the NIH’s efforts to implement the “ Ending the HIV Epidemic: A Plan for America. ”
3.0	Disseminate training materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic.
3.1	Oversee publication of the quarterly Be The Generation e-newsletter, <i>BTG News</i> , in collaboration with the HPTN, HVTN, and MTN.
3.2	Promote the BTG HIV Prevention Research and Basic Scientific Literacy Modules.

3.3	Regularly maintain and promote the BTG website.
3.4	Collaborate with stakeholders to promote and disseminate the cross-network <i>Transgender Training Curriculum for HIV Research</i> and <i>Guidance for Gender-Inclusive Research</i> document.
3.5	Develop and disseminate an information sheet on bnAbs.
4.0	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 Clare Collins, MA, MEd (MTN staff) and Morénike Giwa Onaiwu, MA (community). Clare’s tenure as co-chair will expire on February 1, 2021, and Morénike will be up for re-election, should she choose to run, on February 1, 2021. The HANC facilitator assigned to the WHRC is Brian Minalga.

WHRC Work Plan 2021

Goal: Promote the engagement of women¹ in HIV prevention, treatment, and cure-related research, as well as COVID-19 research, across the NIH-funded HIV/AIDS clinical trials networks.

Objective 1: Monitor the inclusion and exclusion 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 the inclusion and exclusion of women (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.

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

- 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: Interrogate systems, processes, and practices in Network clinical research that may help or hinder women’s involvement.

- Help study teams and Network leadership apply the [Guidance on the Use of Gender-Inclusive HIV Research Practices](#).
- 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, and menopause.
- 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.
 - Develop abstracts and proposals for workshops and sessions on non-stigmatizing language at HIV and other public health-focused meetings.
- 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.
- Build out a WHRC section on the HANC website to better showcase the 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.

- Join the Legacy project's efforts to harmonize activities across the minority investigator programs of the ACTG, HPTN, HVTN, and IMPAACT.

Objective 5: Recruit new WHRC members with a focus on racial, ethnic, and gender diversity.

- 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.

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

Strategies and activities to support this objective:

- Development of a slide deck focused on promoting the various new investigator programs across networks.
- Creation of a print friendly version of the New Investigator Programs Chart as a promotional tool.
- 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.

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

Strategies and activities to support this objective:

- Establishment of NIWG chair or co-chairs to assist with working group activities and objectives, while providing leadership to determine how the NIWG can better serve the needs of new investigators and new investigator programs.
- 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.

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

Strategies and activities to support this objective:

- Engaging Historically Black Colleges and Universities, Tribal Colleges, and Hispanic Colleges and Universities through the attendance of conferences, meetings, and networking.
- Development of a document and presentation in collaboration with the website BlackPast.org highlighting the scientific contributions of early HIV researchers of color.
- Development of a webinar focused on women researchers.

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 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. The next SWG meeting is tentatively scheduled for June 2021.

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.

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 2021

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. This list may include: SDMC issues, reducing confusion around site monitoring by clarifying site new performance monitoring policies, clarifying DAIDS and networks respective responsibilities, harmonizing site establishment and protocol activation processes, identifying fiscal management best practices, and ensuring site preparedness for regulatory audits.
- HANC will disseminate OPCRO and OCSO policies, memos, SOPs for comment and/or general distribution to network operation centers as requested.
- 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.
- 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.
- Identify opportunities to harmonize the protocol site activation process and procedures across the core/op centers and SDMCs.

Site Coordinators Working Group Objective #3: Communicate to newly funded and re-funded clinical research sites (CRSs) and clinical trials units regarding the cross-network Site Coordinators Working Group purpose, goals, and membership.

Strategies and activities to support this objective:

- Issue open solicitation for cross-network SCWG members, with emphasis on pluripotent CRSs and geographic representation.
- Conduct HANC and cross-network SCWG introduction and orientation to new members.
- 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 2021

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 2021.
- The BSCG will consider holding a face to face meeting in 2021 if allowed/safe.
- BSCG members Dr. Rivet Amico and 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 2021.
- The YPRWG will develop and distribute a site survey asking the new CTUs about their knowledge and preparedness for conducting adolescent research.
- The YPRWG will likely submit an abstract for a satellite symposium to AIDS 2021. The symposium will highlight NIH-sponsored multi-center international adolescent prevention research. The symposium will likely include participants from network studies.
- Greg Davis, Project Manager of the BSCG, YPRWG, and BSIG, will likely attend the following conferences in 2021: Adherence 2021, IAS 2021 (if the YPRWG's satellite symposium abstract is accepted), network meetings (depending on agendas) and the CFAR SBSRN Meeting (if scheduled to occur).

Communications Coordination

- Provide content for the “Network Announcements” section detailing network activities and major studies as part of the monthly HANC newsletter.
- Provide lists of network submissions to major HIV/AIDS and COVID-19 research conferences. Develop page(s) on the HANC website to host collated lists of network conference sessions.

Community Coordination

- Develop FAQ sheets to promote Community Partners resources and training materials
- Promote and disseminate slide deck focused on Site Closures and the importance of community engagement following the announcement of the results of the site recompetition.
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices
- Continue working with PHOENix Study Protocol Team on developing community messaging materials and resources
- Submit a manuscript for publication with the network-level community impact survey data
- 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 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
- Develop and maintain a COVID-19 CAB Coalition and Community Resource webpage.
- Host webinars aimed at the community on COVID-19 trials/related topics of interest.
- Host monthly calls with the COVID-19 CAB Coalition.
- Develop COVID-19 materials as necessary for information dissemination to the community

DAIDS

- Continue to disseminate DAIDS memos and MOB newsletters for distribution to network operation center and/or clinical research sites.
- Assist DAIDS in implementation of ad-hoc projects, surveys, consultations, or webinars as requested.

Data Management Center Coordination

- Follow up on the revised scope proposal submitted for the MedDRA Implementation Working Group and identify opportunities to improve MIWG collaboration with DAIDS.
- Provide comments on draft DAIDS policies relevant to data collection and management.
- Refine the Safety Data Reconciliation policy and automation processes for reconciliation of adverse events in the DAERS and safety database.
- Convene the IT Best Practices Working Group to review and revise the IT Best Practices Standards document for 2020/2021.
- Pursue development of a cross-network Protocol Deviation Standardization Working Group.

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

- Update the Virology External Quality Assurance Monitoring Standard Operating Procedure v1.0 in coordination with the Duke VQA Program, VQAAB and LFG.
- Facilitate cross-network coordination and implementation of new lab site requirements described in DAIDS' Guidelines for Good Clinical Laboratory Practice Standards (v4.1, expected 03/01/2021).

- Organize and facilitate a series of LFG sub-working group calls to update the Cross-Network Peripheral Blood Mononuclear Cell (PBMC) Processing Standard Operating Procedure.
- Facilitate with the LFG a review of the Cross-Network Guidelines for Diagnosis of HIV Infection in NIH HIV/AIDS Network Clinical Trials.
- 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.
- Facilitate weekly conference calls with the LTC SOP Sub-Working Group to review and revise ACTG/IMPAACT Laboratory Manual guidance documents and SOPs.
- 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.
- Attend and support face to face laboratory sessions at the 2021 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 a virtual pilot 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 a Legacy Project/WHRC virtual meeting in December 2020 to discuss and develop engagement strategies for the upcoming HIV research networks 2020-2027 funding cycle.

- Convene a face-face work group meeting of Legacy Project/WHRC in Q4 2021 pending funding and travel restrictions.

Site Management Coordination

- Issue a solicitation for new SCWG members. Conduct at least one webinar for new SCWG members to orient them to the working group goals and HANC.
- Summarize and report back SCWG yearly activities to working group members.
- Disseminate DAIDS policies, memos, SOPs for comment and/or general distribution to network operation center and/or clinical research sites as requested.
- 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 Age and Identity Verification policy, Co-Enrollment Prevention policy, Protocol Funding Distribution mechanism, Electronic Information Systems policy, Essential and Source do and cross-network protocol deviation form.
- Coordinate with DAIDS to host webinars focused on DAIDS policies, process changes, or other developments affecting site activity.

Training Resources

- Maintain archives of previous HANC-hosted webinar recordings.
- Maintain bi-annual updates of resources on the HANC website.

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.
- Publish bi-monthly updates to the CTU/CRS listing on HANC website.
- Maintain all the NIH/Network contact lists on the HANC portal.
- Pursue development of the HANC public website on the AEM platform.
- Complete migration of the HANC portal to Sharepoint Online/Sharepoint 2013.