



# Office of HIV/AIDS Network Coordination

## 2017 Work Plan (Year 11)

December 1, 2016 – November 30, 2017

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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). The NIH HIV/AIDS Clinical Trials Networks have been designed to address NIAID’s five HIV/AIDS scientific priorities:

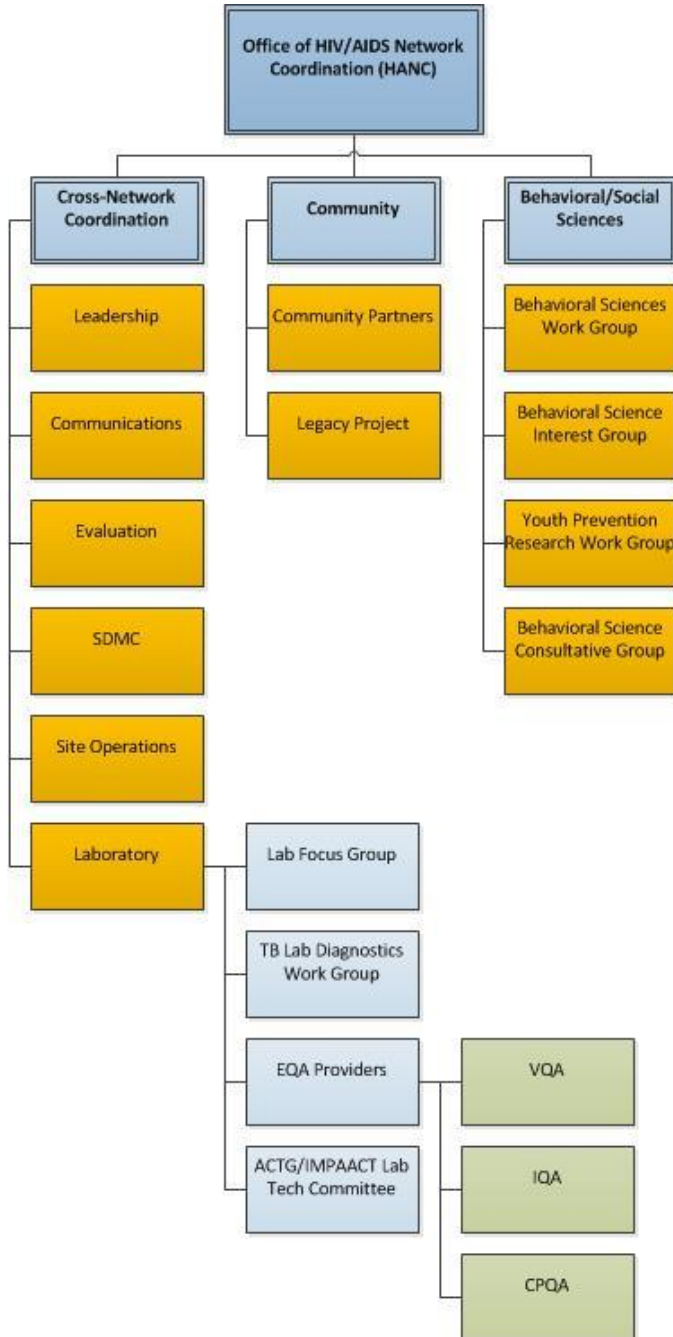


1. Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, including hepatitis and tuberculosis) (ACTG)
2. HIV/AIDS and HIV-associated infections in children and mothers (IMPAACT)
3. Integrated strategies to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

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 2017 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2016 – November 30, 2017 (Year 11). 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, as outlined on pages 29-30.

This is the organizational chart for HANC:



Updated June 2016

## Major Cross-Network Projects

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Behavioral Science	Behavioral Science Working Group and HANC staff	Maintain a repository of measures, data forms, and standardized core elements of interventions	Facilitate sharing of information and state-of-the-science practices.	Ongoing
Behavioral Science	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
Behavioral Science	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 WG	Leverage network experience and expertise; collect communications tools and measures; harmonize elements of the networks’ communications plans	Increased coordination and consistent messaging.	Ongoing
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

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Community Coordination	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
Community Coordination	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 Coordination	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
Data Management	DMC 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

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Data Management	DMC Working Group	Biannually review the Information Technology Best Practice Standards (last revised in Q4 2015).	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.	Ongoing
Data Management	ADE Clinical Working Group	The HANC-facilitated AIDS Defining Events focuses on the mapping of MedDRA codes for CDC/ WHO HIV staging classifications for protocol team use based on the semiannual up versioning of MedDRA.	Consistent MedDRA coding of adverse events across studies and a useful program (HIVSTAGE) to map events to CDC/WHO Adult and Child HIV staging classifications.	Ongoing
Evaluation	Evaluation Committee	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 and Completion Target
Laboratory Coordination	VQAAB, CPQA	Ensure standard quality assurance for all of 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
Laboratory Coordination	LFG, PBMC SOP WG	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
Laboratory Coordination	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
Laboratory Coordination	TBLD-WG	Be a resource to network protocol teams regarding TB research topics and issues. Support institution of cross-network international specialty and regional TB laboratories. Explore opportunities for the development and validation of point-of care TB Laboratory assays and EQA programs. Coordinate comparative evaluations of TB Laboratory methods.	Provide support to international HIV Labs with guidance in handling TB co-infection cases promoting safety for HCW and patients, as well as methodologies for better assay performances. Assist protocol team by providing expertise in possible issues in sites regarding co-infection studies.	Ongoing
Legacy Project	Legacy Staff	Build the capacity of domestic communities and researchers to equally partner in the research enterprise.	Increased research literacy in domestic communities most impacted by HIV and increased cultural awareness and responsiveness of research staff and sites.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
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 Management Logistics	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 identify individuals to take on each task and encourage the relevant working group to sustain the effort to complete the work, acknowledging 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 call and meeting agendas, drafting and distributing materials, coordinating logistics for and chairing teleconferences and 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 potential shared interest or overlap in activity. Additionally, HANC staff are continuously considering 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 working groups or ad hoc task forces as appropriate.



### The HANC Public Website

The HANC public website ([www.hanc.info](http://www.hanc.info)) contains a calendar of events, network newsletters, general information about HANC’s coordination activities, training resources, laboratory resources, and other resources for collaborators, research sites, and the general public, including:



- A dynamic calendar of scientific conferences, network meetings, community events, training opportunities, and more.
- Some of the Division of AIDS’ Office of Clinical Site Oversight Clinical Research Policies and Standard Operating Procedures that are not listed on the DAIDS website and a link to the official versions of all current DAIDS Clinical Research Policies that are posted on the NIAID/DAIDS web site.
- A dynamic announcement section on the home page for posting important notices, such as recent major study results and DAIDS policies.
- An HIV News section with the most recent HIV news and research findings via RSS feeds.
- Information for community members interested in supporting HIV/AIDS research as a community advisory board member.
- Links to [clinicaltrials.gov](http://clinicaltrials.gov) for individuals interested in participating in a clinical research study.
- Free online Good Clinical Practice, Human Subjects Protection and Responsible Conduct of Research Training through the Collaborative IRB Training Initiative (CITI) and DAIDS-ES Applications Training Information.
- A dynamic, searchable map showing locations of networks and research sites around the world.
- Information for laboratories, including PNL Contact Assignments, a Laboratory Certification Library, and laboratory training videos.
- Resources and links to direct site and network staff regarding who to contact or where to find the information they are looking for, updated DAIDS organization charts, and OCSO SOPs.
- Library of all the network publications cataloged in one central location for ready access on the HANC public website, including network press releases and responses to study results such as iPrEx.
- A library of centralized laboratory certifications (i.e. CAP and CLIA) for sites.
- Links to Network websites and social media communication resources.
- Resources for communities including, but not limited to: Recommendations for Community Engagement in HIV/AIDS Research, American Indian Alaska Native Two-Spirit HIV Prevention Research Module, Be The Generation HIV Prevention Research Training Module, Basic Scientific Literacy Training Module, NAEHCR Project Guidance and Best Practices Documents, and TB Resources for Communities.

### 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. In October of 2015, 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 portal projects for the 2017 Work Plan include:

- Ongoing improvements to the HANC Portal and team site content to better support the objectives of the working groups in 2017.
- Maintaining web services that make the DAIDS-ES Master Contact system accessible to HANC portal users.
- Publicizing the linkage to the DAIDS-ES protocol report data and protocol documents allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.
- HANC program staff provides programmatic updates on the “Daily Dose” announcement box.
- HANC staff and working group members will continue to curate content for the Communications Resource Center site.
- Continued optimization of HANC “Contact Management System” which integrates the portal permissioning, email aliases, and contact lists.
- HANC plans to create a Portal Tutorial video highlighting the functions of the HANC Portal and the resources available to collaborators.

### Social Networking & Information Sharing

HANC has Twitter (search for “Hancprograms”), Facebook (search for “Hanc Programs”), and LinkedIn (search for Office of HANC) accounts to share general programmatic updates with a broader audience. Due to the interest in the resources shared in the HANC newsletter, HANC staff has increased the publication frequency from quarterly to monthly. HANC members are invited to participate in a walk-through of portal/website resources and given the opportunity to learn more about SharePoint technology through trainings that are offered periodically. HANC will provide individualized trainings for networks and affiliated partners as requested. HANC has a YouTube page ([youtube.com/officeofhanc](http://youtube.com/officeofhanc)) to broadcast and share network videos. HANC has started using Google Analytics to track the most used resources and pages on both the HANC public and portal websites.

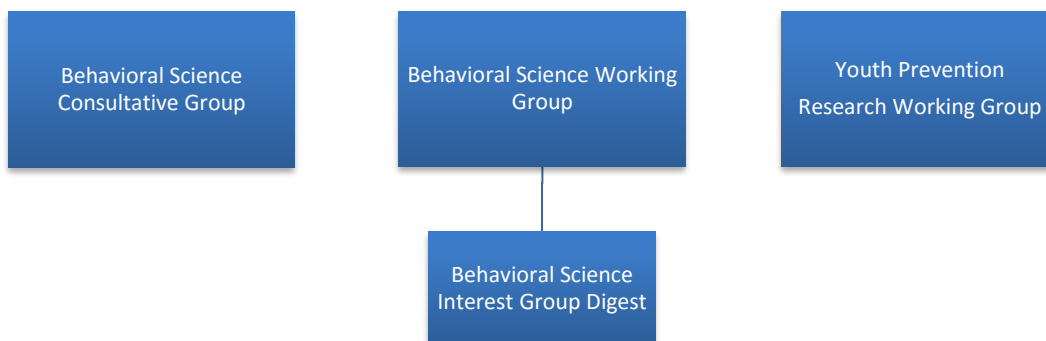
### Clinical Research Support Contract

The HIV Clinical Research Support (CRS) 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 Clinical Research Support contract through their designated point of contact at DAIDS. Requests for CRS services 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-two cross-network CRS requests have been submitted since the CRS contract was initiated. Details of CRS requests can be viewed at <https://portal.hanc.info/crs/default.aspx>.

## Objectives and Activities by Area of Coordination

### Behavioral Science Coordination

HANC supports four behavioral science groups:



**Behavioral Science Working Group (BSWG):** The Behavioral Science Working Group is a trans-NIH Institute and cross-network committee that was formed as an outcome of the July 2008 HANC and National Institute of Mental Health (NIMH) sponsored Prevention Adherence meeting. The working group is charged with ensuring that the NIH HIV/AIDS Clinical Trials Networks benefit from state-of-the-science methods and procedures that optimize adherence to product and risk reduction counseling and minimize the risk of confounding user- and product failures. Further, the Behavioral Science Working Group endeavors to maximize fiscal and scientific resources, reduce redundancies, improve cross-network communication and collaboration, and ensure that the best quality behavioral science is integrated into clinical trials. The working group, formed in Q4 of Year 3, holds monthly teleconference calls and ad hoc topic-specific calls.

**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, OAR, and UNICEF. The scope is international and focused on 12-24 year olds. 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 Working Group Coordination Objectives for 2017***

Behavioral Science Working Group Objective 1: Maintain a repository of behavioral and adherence measures, data forms (CFRs), and standardized core elements of interventions accessible to partnering networks. The documents and links are housed on the HANC public website under “Behavioral Science Publications” and/or the HANC portal’s “Behavioral Science Interest Group Resource Center”.

Behavioral Science Working Group Objective 2: Improve information exchange among network-affiliated behavioral and social scientists. Identify and address opportunities to harmonize behavioral science research and tools across network studies.

Behavioral Science Working Group Objective 3: Members of the BSWG will report back from plenary sessions at network annual meetings to discuss new developments and their implications for network science, take stock of lessons from related domains, provide new and ongoing adherence counseling training, elicit community working group input on adherence measures and counseling, etc.

Behavioral Science Working Group Objective 4: Collaborate on shared products such as white papers or manuscripts, conference proceedings, and workshops. The Working Group will explore hosting a topic-specific focus group in 2017 if funding is available.

Behavioral Science Working Group Objective 5: HANC will continue to manage a “Behavioral Science Interest Group” list serve and resource center whereby researchers can receive updates from the field, links to influential articles, network study updates, meeting information, etc. HANC will continue to host a “BSIG Topics of Interest” webinar series. Webinar recordings will be archived on the BSIG Resource Center. Expand the “BSIG Rx Connect” listserv, allowing members to pose research questions and receive comments and recommendations from the BSIG research community.

Behavioral Science Working Group Objective 6: Collate and identify behavioral data elements across network studies for analysis by scholars/fellows in network mentor programs and other junior investigators.

***Behavioral Science Consultative Group Coordination Objective for 2017:***

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 continue to provide consultation on behavioral and social science aspects of the following protocols

- An MTN qualitative sub-study of VOICE evaluating rapid feedback from focus groups and structured interviews
- Adherence counseling and assessments for the PHOENix study
- A cross-network mucosal sampling acceptability survey
- Adherence counseling and risk assessments for HPTN 083
- ACTG A5359- a study of injectable ARVs in people not virally suppressed
- Risk assessment measures for multiple protocols
- Adherence assessment measures and counseling in numerous protocols

### ***Youth Prevention Research Working Group Coordination Objectives for 2017***

Youth Prevention Research Working Group Objective #1: Assess results of the site survey conducted in Year 8 to assess site-level access and experience in conducting research with adolescents within the NIH-sponsored networks for future trials.

Youth Prevention Research Working Group Objective #2: Maintain a resource library on the HANC website dedicated to youth prevention research. Resources will include protocols, best practices, case report forms, webinars, trainings articles, etc. from both within and outside of HIV/AIDS research relevant to the conduct of clinical research in the adolescent/young adult population (12-24). Publicize materials and topics to engage the research community, increasing visibility of these resources when possible.

Youth Prevention Research Working Group Objective #3: Analyze the existing research imperatives, trial results, and protocols in development to identify gaps in the scientific enterprise, especially in the area of adolescent consent and autonomy, parental knowledge of their child's sexual behavior, and the potential resulting skew arising from these issues in adolescent HIV research. Consider creating a white paper on these topics and best practices for adolescent HIV researchers.

Youth Prevention Research Working Group Objective #4: Working Group members will liaise with their respective Network Leadership and protocol team members to share the assessment of the ongoing research and consider ways to address the gaps. Ensure cross-network/trans-Institute communication around research in the youth population.

Youth Prevention Research Working Group Objective #5: Explore and promote the development of co-endorsed protocols or adolescent sub-studies.

Youth Prevention Research Working Group Objective #6: Monitor the success of the working group efforts over the course of its existence.

Youth Prevention Research Working Group Objective #7: Host informative webinars and trainings related to adolescent prevention research at the site and network levels. Disseminate these resources via webinars, the HANC website, and at HPTN and IMPAACT network meetings as appropriate.

### **Communications Working Group**

The 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, community liaisons, and web masters. 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 WG has bimonthly calls and topic-specific webinars are scheduled as requested.

### ***Communications Working Group Objectives for 2017***

Communications Objective #1: Review communications efforts and consider which practices could be employed within the networks. Activities to support this objective include:

- Share video production tools and experiences.

- Share experiences using social media and network sites such as Facebook, LinkedIn, and Twitter and track web traffic generated from new media sites.
- Share network communications strategies and external relations policies
- 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: Share messaging strategies around and leading up to major studies, particularly for high profile studies and multi-network studies

### 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.

Map of Community Partner members’ locations:



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 2017***

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

Strategies and activities to support this objective:

- Continue to promote the Transgender Inclusion Initiative, as outlined in the CP Memorandum, including working with DAIDS, the Networks and other groups to encourage adoption and implementation of the recommendations
- Select a chair or co-chairs for the working group
- In partnership with DAIDS, develop and distribute Standard of Care memo for community members

- In partnership with CP Ethics WG, review and address understanding of Informed Consent among CABs
- Continue to review and make recommendations on co-endorsed protocols to ensure community input
- Review network efforts on the research priorities and identify priority gaps in research

Community Partners Objective #2: Utilize the Community Training Working Group to 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.

Strategies and activities to support this objective:

- Query CABs/community members to determine the usefulness of developing storyboards based on current format focused on:
  - Standard of care
  - Stored specimens
  - Placebo, blinding and randomization
  - Genetics Training
- Query site CABs to determine how translation of CP training materials are handled and by whom
- Develop a multi-level strategy to distribute and promote cross-network Community Partners and DAIDS resources and training materials to networks, sites and other community groups
- Develop a multi-network CAB lessons learned/best practices document (protocol review, CAB meetings, etc.)
- Query networks on whether and/or how CAB members are mentored to assume leadership roles and review protocols, and develop a guidance document on how to mentor CAB members
- Continue partnership with TB CABs in developing TB/HIV presentations, materials, best practices
- Gather and catalogue available training resources on the HANC website and DAIDS Learning Portal

Community Partners Objective #3: CP will collaborate on the analysis and manuscript of the network-level community input survey conducted in 2013.

Strategies and activities to support this objective:

- Reconstitute writing team
- 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 CP's Strategic Plan objectives. Community Partners Executive Committee

Strategies and activities to support this objective:

- Facilitate and enhance community representation and input at all levels in HIV/AIDS and related clinical research within the networks
- Support efficiency and effectiveness of local and network community advisory boards, and engagement of stakeholders
- Develop specific strategies to address stigma, including working with the TBTC CRAG community representatives



- Develop strategies to assist communities to prioritize research activities globally and locally
- 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
- Address challenges to community engagement in clinical research
- Continue to monitor and provide support to CABs and communities impacted by site closures or changes in research or protocols
- 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)
- Host or co-host community-focused workshops/presentations on ongoing network research and community engagement activities
- Host workshops/presentations at USCA 2017, 22nd International AIDS Conference 2018 Global Village and other meetings/events to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG
- Develop strategies to measure community engagement globally and locally from a community perspective
- Post CP information in CAB and network newsletters and network public websites (follow-up on a quarterly basis)

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 the ethical considerations and challenges in research with individuals facing stigma, discrimination, legal sanctions and/or interpersonal violence, and social harms
- Provide cross-network input to DAIDS and Network Leadership to support the development of ethical guidelines and considerations into trial designs
- Collaborate with DAIDS and the CP Training WG on communicating and providing input regarding Incidental Findings and Stored Specimens samples for community and site staff
- Collaborate with CP Training WG on developing new strategies to discuss randomized trials in light of PrEP Identify opportunities for improvement and generate recommendations regarding standard of care

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:

- Identify contact for engagement with ATN
- Provide guidance regarding compensation for injuries during research and role of IRBs
- Promote CP training materials at full network group meetings and other trainings as requested
- Gather and organize existing network CAB newsletters to post on the HANC Website

## 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, SDAC and SCHARP, and meets on monthly teleconferences to carry out activities to address cross-network data management coordination objectives.

AIDS Defining Events Working Group includes representatives from SCHARP, SDAC, FSTRF, DAIDS and clinicians and meets semi-annually. The group is charged with mapping Adult and Child CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use when MedDRA is updated. The IT Best Practices Task Force includes representatives from the DMCs, OCICB, and DAIDS, and meets ad hoc to review and revise the HANC-facilitated IT Best Practices Guidance Document biannually.

### **DMC Coordination Objectives for 2017**

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

Strategies and activities to support this objective:

- Solicit agenda items from the DMC WG for the monthly DAIDS-ES All Collaborators call.
- Monitor cross DMC standardization support needs for AE/EAE reconciliation. Strategies to support this include: working with DAIDS to identify data elements that are required to be reconciled, maintain ongoing dialogue with DAIDS staff regarding challenges encountered with reconciliation
- Liaise with DAIDS Enterprise System (DAIDS ES) team to identify areas for collaboration and enhanced data sharing across DAIDS ES and the SDMCs.
- Share CDISC implementation activities across DMCs; e.g., regularly check in with CDISC consultant, assist in coordination, and discuss developments across the networks

DMC Coordination Objective #2: Harmonization of MedDRA coding and revisions of the HIVSTAGE coding program.

Strategies and activities to support this objective:

- The HANC-facilitated AIDS Defining Events Working Group (ADEWG) mapped MedDRA codes for CDC and WHO HIV stages for protocol team utilization. The ADEWG consults with the MedDRA Implementation Work Group, facilitated by DAIDS, on MedDRA up-versioning and related MedDRA issues. The HIVSTAGE program is revised based on the recommendations of the ADEWG and maintained by SDAC.

DMC Coordination Objective #3: Work with appropriate regulatory groups to assist in the development of procedures and processes related to electronic data capture (EDC), electronic signatures, protocol deviation reporting, etc. share developments in these procedures and processes across networks and data management centers

Strategies and activities to support this objective:

- Consider revising and combining Essential Documents and Source Documents guidance into one document for ease of use by sites.
- Disperse information on EDC to networks and sites for new and transitioning studies.
- 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.
- Liaise with OPCRO and OSCO to provide feedback on proposed policies and procedures related to electronic signing of CRFs and protocol deviation reporting

DMC Coordination Objective #4: Work with HANC to provide broad access to DMC-related online training resources on topics such as DAIDS toxicity table and MedDRA codes, and Electronic Data Capture (EDC).

Strategies and activities to support this objective:

- Select appropriate training resources for consolidation in the HANC training library, working with other groups to ensure relevant and broad selection of appropriate training materials.
- Publicize training opportunities by reaching out to network DMCs and other network members through HANC and other means as appropriate.
- Respond to requests for training materials, update training topics when appropriate, and monitor resource usage via HANC staff.

## Evaluation Coordination

### **Evaluation Committee**

The Evaluation Committee discusses and provides a forum to share network approaches to evaluation, including the site evaluation processes. The Committee consists of representatives from each Network Evaluation Committee and additional network evaluation committee members as determined by the network.

### **Primary evaluation coordination objectives for 2017 include:**

Evaluation Objective #1: Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks.

Strategies and activities to support this objective:

- Monthly-bimonthly cross-network evaluation teleconferences will provide a forum to discuss and address opportunities.
- Ongoing discussions on the revisions to the network evaluations processes and setting site performance criteria and expectations.

Evaluation Objective #2: Continued evaluation of the process and assessment of impact and quality of community participation at the CAB and site level, in collaboration with representatives for Community Partners.

Strategies and activities to support this objective:

- Assess the revisions to the community indicator surveys across networks and identify potential opportunities to qualitatively evaluate the impact of community participation on the research enterprise. Determine the relationship between community involvement in protocol development/implementation and protocol enrollment and the perceived relevance of network research to the community.

## Financial Disclosure Database

Financial Disclosure Database Objective #1: 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, a TB focused group, provides support to the ACTG/IMPAACT Lab Technologist Committee and co-facilitates the DAIDS EQA provider calls.

The Lab Focus Group (LFG) 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.

Objectives:

1. 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.
  - Explore more inexpensive methods of obtaining IQA-approved quality fetal bovine serum (FBS) for distribution in African labs, especially South Africa.
2. 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.
  - Develop a cross network method for acute HIV diagnosis
3. Continue to assist EQA groups to 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. LFG will be tracking the IQA PBMC Cryopreservation program and addressing any minor issues.
4. Continue to identify areas in lab operations and processes to incorporate principles of GCLP and ensure that data generated of highest quality, including but not limited to timelines, accuracy, and clinical appropriateness
5. 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.

The PBMC SOP Working Group 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 group recently reviewed the document and agreed that it does not need any to be updated. The SOP will be re-visited in 2018.

The group, however, decided to create a Cross Network Cold Chain Guidelines document providing best practices instructions for handling of sensitive temperature specimens during storage and shipping transfers.

The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is a joint ACTG/IMPAACT committee. Voting members serve on protocol teams and provide technical expertise in the development of the laboratory components of protocols as well as standardizing the handling, processing, labeling, storage and shipping of clinical specimens across all ACTG/IMPAACT clinical sites and laboratories. HANC support staff coordinates specific projects and gives technical support to the committee and maintains the committee's site on the HANC portal. HANC support staff also helps to track LTC member workloads, helps to maintain existing documents and develop new documents stored in the resource document libraries, and maintains a discussion board to facilitate communication across the members of the committee. A number of other resources, including the ACTG/IMPAACT Laboratory Manual, are posted on the HANC public website, and HANC support staff helps to facilitate the review of new and updated SOPs and provide standardization of templates and formatting. The LTC holds teleconferences twice per month, and HANC support staff attends the calls, records them, and drafts minutes which are reviewed by the committee members and posted on the HANC website.

***The main objectives of the LTC, for which HANC staff provides support include:***

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.
  - 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.
  - HANC support staff helps to facilitate the regular review and update of laboratory standard operating procedures (SOP) and maintains the document control processes.
  - HANC support staff helps to facilitate the regular update and maintenance of Standardized Wording documents for use in developing LPCs, and maintains other documents, such as the LPC templates and the budget cost list used by the LTC for creating processing budgets for ACTG clinical trials.
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
  - 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;
  - HANC support staff helps the LTC members train new members by facilitating the creation of training packets, offering training webinars, and maintaining support documents on the HANC website.

HANC support staff helps The LTC leadership to track committee member participation through workload tracking, conference call participation and provides summary updates on the status of document development.

The TB Laboratory Diagnostics Working Group (TBLDWG) includes SMILE, DAIDS, NICHD, CDC, IMPAACT and ACTG members who convene on monthly teleconferences. It identifies and evaluates international TB diagnostic laboratories for participation in clinical trials with TB diagnostic endpoints, and works with SMILE to conduct evaluation site visits to these laboratories and monitor ongoing external quality assurance. In addition, the TBLDWG pursues a coordinated international approach to TB diagnostics and quality assessment. It explores opportunities for collaboration with other organizations that are developing new TB diagnostics techniques, and the use of network laboratories for the validation of new point-of-care diagnostic technologies in pediatric and adult, HIV-positive and HIV-negative populations.

The Working Group will collaborate to improve TB Laboratories, TB proficiency testing and participation of labs with TB diagnostic capacity in network protocols where TB is a component.

***The TB Laboratory Diagnostics Working Group Objectives:***

1. Be a resource to network protocol teams
  - Continue maintaining a list of US and non-US labs with reliable TB diagnostic capacity as a resource for networks and their partners when conducting studies when TB is a component
  - Continue to recommend laboratories for participation in studies

- Propose and implement relevant EQA and QC approaches to ensure the quality of study data:
    - i. Implement EQA program for GeneXpert and GenoType MTBDR*plus*V2 assay (LPA)
    - ii. Continue development of Microbank Tube assay
    - iii. Assist with development of EQA assays
  - Continue support of the TB lab EQA programs
  - Continue drafting/compiling and implement standard guidelines for sample collection, transport and diagnostics
2. Continue to Coordinate comparative evaluations of TB Laboratory methods.
    - Explore TB Biomarkers procedures regarding specimen collection, processing, and transport.
  3. Continue to support institution of cross-network international specialty and regional TB laboratories
    - Continue implementation of Infection Control Checklist Program in all TB sites
  4. Continue to explore opportunities for the development and validation of point-of care TB Laboratory assays.
    - Explore use of the Xpert Omni
    - Develop rapid drug susceptibility
    - Typing TB Strain

The Cross-Network Lab Interest Group (XNLIG) serves as a central communication center for the other HANC laboratory groups. It includes Network Laboratory Leadership and management staff, DAIDS Clinical Laboratory Oversight Team (DCLOT) members, and representatives of NICHD, the statistical data management centers, and quality assurance contractors. Group members receive bi-monthly updates from the other HANC lab groups and schedule ad hoc calls as necessary.

**EQA Provider Working Groups:** Ensure standard quality assurance for all of 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 (CPQA) Advisory Board The Leadership of the CPQA Advisory Board (AB) is composed of a balance of leadership members from DAIDS funded laboratories, NIAID and DAIDS related leadership, and CPQA. The Advisory Board provides the following for the CPQA Executive Committee: Communication regarding scientific and regulatory changes and developments that are likely to influence the operation of the CPQA, feedback from DAIDS and the HIV Research Networks that includes items discussed at 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 biomarkers, 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 and recommendations for program additions, revisions and quality improvements.

The CPQA Cross-Network Clinical Pharmacology Laboratory Forum (CNCPLForum) The Cross-Network Clinical Pharmacology Laboratory Forum is an open forum comprised of technical and scientific representatives from each Network Clinical Pharmacology Laboratory (as well as other DAIDS funded clinical pharmacology laboratories), DAIDS, and CPQA. The

CNPLForum provides a forum to present new pharmacology research areas and the associated technical laboratory technologies and details. The CNPLForum facilitates communications between the CPQA program and DAIDS Clinical Pharmacology Laboratories. Members of administrative laboratory support systems for the Networks are also welcome to join the calls.

- Bioanalytical Method Validation Group (BRAG) is tasked with revising the CPQA AVR Assay Method Guidelines to incorporate the changes made by the FDA, published in the draft version of the 2013 Revised Bioanalytical Method Validation (and Application) Guidance and consensus paper from the corresponding Crystal City V meeting (ref). Once the revised CPQA guidance are approved, the BRAG will be taking a break and will start up once again shortly after the FDA publishes its final Revised Bioanalytical Method Validation Method (and Application) Guidelines. Nonconsensus issues discussed in Crystal City V paper will be added at that time.
- The Regulatory Requirements Working Group (RRWG) began meeting in September 2016. Its goal is to formulate recommendations to DAIDS regarding the regulatory requirements as they would apply to Pharmacology Specialty Laboratory Operations that analyze specimens from DAIDS funded clinical studies and network protocols. This group will also review the final revisions made to the CPQA Bioanalytical Guidance documents by BRAG.

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

1. Participate in Steering Committee to assure synchronous activities among stakeholders
2. Provides virtual communication platform for CPQA groups, including ad hoc calls for leadership and/or collaborators
3. Provides software and document development support.

The Virology Quality Assurance Advisory Board (VQAAB) serves as an external group that reviews data from external quality assurance (EQA) programs and provides input and guidance on new issues/ideas/programs identified by Virology Quality Assurance (VQA) program and provides an open forum for discussing new topics raised by other VQAAB members during monthly teleconferences.

The VQAAB is comprised of non-voting representatives from the VQA laboratory, the VQA Data Management Group (DMG) at Frontier Science and Technology Research Foundation (FSTRF), the VQA Statistical Analysis Group (SAG) at the Research Triangle Institute (RTI) International, DAIDS, the Statistical & Data Analysis Center (SDAC), and a voting representatives from each of the respective NIH-funded HIV Research networks.

The VQAAB holds monthly and ad hoc calls to:

1. Review and approve proposed scoring from VQA proficiency testing (PT) analyses which include programs for Quantitative HIV- RNA testing, Qualitative HIV-1 RNA TMA assay, Qualitative HIV-Total NA testing (whole blood), Qualitative HIV Total NA on Dried Blood Spots (DBS)), Genotypic HIV Drug Resistance testing for reverse transcriptase (RT), protease (PR) and integrase (INT) gene regions.
2. Establish monitoring standards that differentiate between missing data, transcriptional or computational errors, and technical problems.
3. Request, review and approve proposed method evaluation/validation studies.
4. Review and approve proposed changes in policies or procedures to promote quality assurance in virology assay testing.
5. Review and approve proposed implementation of external quality control standards for use in virology assay testing.
6. Review and approve changes in VQAAB approval status for protocol testing for Testing Labs
7. Review proposals for new EQA Proficiency Testing programs for other virology assays such as:
  - a. Quantitative HCV RNA
  - b. Quantitative HBV DNA
  - c. Qualitative HPV DNA

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

1. Provide a forum and communication channels for discussion of PT results via teleconferences or e-mails.
2. Help organize conference calls and distribute documents prior to the call.
3. Facilitate the sending and tallying of VQA report reviews which occur outside the regularly scheduled conference calls, and report those results to the VQA SAG.
4. Maintain the VQA web page for posting of VQA documentation on the public domain and they maintain the VQA reagent order form on the HANC password protected portal site.
5. Post updates from the VQA that document laboratory status for virology testing based on proficiency testing scores, and
6. Post and maintain minutes generated by the VQA for each conference call.

## Legacy Project

### *Legacy Project Working Groups and Committees*

The Legacy Project Work Group (LPWG) is comprised of members from HANC, Community Partners, network operations centers, clinical research site representatives, DAIDS, Office of AIDS Research, and other NIH Institutes and Centers. The LPWG ensures that the Legacy Project assists the NIH-funded HIV clinical trials networks to achieve increased inclusion of those populations most underrepresented in HIV prevention and therapeutic research. Setting program objectives and monitoring progress toward those objectives are the fundamental tasks of this group. The LPWG works with the HANC and Legacy Project staff to establish annual programmatic objectives that are specific, measurable, achievable, relevant, and time-phased.

The Women's HIV Research Collaborative (WHRC), a subcommittee of the Legacy Project Working 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 women and girls—transgender and cisgender—in the United States. The WHRC works to raise the visibility of issues related to HIV in women in the U.S. and promote awareness of scientific research to 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 women in America 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 Legacy Project seeks to increase knowledge about HIV clinical prevention and therapeutic research, cure research, scientific literacy, and participation in HIV/AIDS Clinical Research among the most disparately impacted communities in the United States.

The Legacy Project 2017 Work Plan is in line with the **2016 NIH HIV/AIDS Research Priorities and Guidelines for Determining AIDS** cross cutting areas of basic research, health disparities and training including: Research to reduce health disparities in the incidence of new HIV infections or in treatment outcomes of those living with HIV/AIDS; Research training of the workforce required to conduct high priority HIV/AIDS or HIV/AIDS related research; and addressing health and social issues that are clearly linked with HIV (transmission/acquisition, pathogenesis, morbidity and mortality, stigma) in the context of HIV (i.e., in populations or settings with high HIV prevalence or incidence).

The Legacy Project will work to pursue funding opportunities to continue its valuable work. Legacy's continued success depends on the support and cooperation of DAIDS and the networks. Legacy will continue to work to coordinate activities and meet the following objectives outlined in the following Legacy 2017 Work Plan.

Legacy Project Objective #1: Facilitate collaborative (community, site and network) involvement throughout the research process among the NIH HIV/AIDS clinical trials networks.

Strategies and activities to support this objective:

- Consult/collaborate with all of the NIH HIV/AIDS clinical trials networks, the Women's HIV Research Collaborative (WHRC), and Community Partners to identify research priorities.



- Consult/collaborate with populations at high risk for HIV acquisition and burden, as well as those underrepresented in HIV clinical research (Black and Latino MSM, women, transgender persons, house/ball communities, Black gay pride attendees, other events focused on Black MSM, HBCUs, TCUs, and Historically Serving Institutions, etc.), to identify community-level priorities and raise awareness of these priorities among all of the NIH HIV/AIDS clinical trials networks and sites.
- Promote and support the work of the DAIDS Cross-Network Transgender Working Group to identify and address challenges and issues that impact transgender inclusion in the NIH-funded HIV/AIDS network trials.
- Maintain relationships with network communications and community engagement staff in collaboration with Community Partners and the HANC-facilitated Communications Working Group.

Legacy Project Objective #2: Provide information exchange to enhance collaboration and identify additional engagement topics/issues in the field.

Strategies and activities to support this objective:

- Maintain collaborations/partnerships with former Be the Generation (BTG) partners and select CBOs and ASOs across the U.S.
- Conduct capacity building and HIV scientific literacy training with Legacy Project collaborators and populations underrepresented in HIV clinical research to increase awareness and knowledge of HIV clinical research and community readiness to engage in trial participation activities.
- Conduct capacity building and HIV scientific literacy training with faith initiatives to increase culturally appropriate messengers who value research environments and support clinical trial participation. Activities will be evaluated on their ability to provide opportunities to remove obstacles to spiritually-informed HIV education.
- Utilize the Framework for Dialogue tool to engage faith leaders and people living with HIV to address stigma and discrimination.
- Submit abstracts to NAESM and other conferences that have a specific focus on key populations impacted by the Domestic HIV epidemic to identify HIV decriminalization as a priority
- Host community-focused presentations on women and PrEP, basic prevention and scientific literacy, and decriminalizing HIV.
- Establish and/or enhance site-level linkages/partnerships with specialized institutions/networks by continuing engagement with the Center for Black Equity Black gay prides (Atlanta, Dallas, and LA) and house/ball communities.
- Establish and/or enhance site-level linkages/partnerships with Latino/a communities focused on addressing disparities, health and social issues in the context of HIV among Latinos and Latinas, including Hispanic Serving Institutions.
- Establish collaborations with the medical schools at historically black colleges and universities (HBCUs) Meharry, Charles Drew, Howard and Morehouse, to help address/eliminate HIV-related disparities and stigma.
- Develop strategies to establish linkages/partnerships with Tribal Colleges and Universities (TCUs) focused on addressing disparities, health and social issues in the context of HIV among Native Americans.
- Establish formal collaboration with AVAC by inviting AVAC staff member to join Legacy Project Working Group.
- Invite Martin Delaney Collaboratory to Legacy call or webinar to present on HIV cure research.
- Develop strategies to establish and/or enhance linkages/partnerships with other Legacy stakeholders.
- Develop strategies to provide information/messaging focused on HIV treatment.

- Provide support to HPTN and HVTN in educating communities about the Antibody Mediated Prevention (AMP) Study.
- Provide support to HPTN and HVTN in educating communities through increasing awareness and understanding of monoclonal antibodies.
- Provide support to MTN in educating communities about microbicide research.
- Provide suggestions to PACHA regarding how to address HIV-related disparities for young BMSM in the southern U.S. where there are few or no NIH HIV/AIDS clinical research sites.

Legacy Project Objective #3: Share and disseminate information, training materials and resources.

Strategies and activities to support this objective:

- Coordinate dissemination and promotion of the BTG HIV Prevention Research and Basic Scientific Literacy Modules.
- Disseminate training materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic.
- Host community-focused webinars on HIV prevention, treatment and cure clinical research advances in collaboration with the NIH HIV/AIDS clinical trials networks.
- Provide input/technical assistance in the work of the Faith Initiative for Black HIV/AIDS Awareness Day 2017, The Week of Prayer 2017 and USCA 2017.
- Disseminate the guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project.
- Host community-focused webinar on Native American engagement in HIV/AIDS clinical trials.
- Host workshops/presentations at the National Pow Wows, NASEM, APHA, USCA 2017 and other meetings/events aimed at improving community research literacy and support for 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 among high risk populations at meetings/events.
- Host community-focused webinar on stigma and discrimination related to religion, faith and spirituality.
- Submit abstracts to present findings from HBCU and House Ball Projects to APHA, NAESM and USCA.
- Host events through CATA to raise scientific literacy about HIV and scientific research in underrepresented and disproportionately affected communities.
- Publish and disseminate results of the HBCU Lincoln Project and the House Ball Project.
- Oversee publication of quarterly BTG e-newsletter in collaboration with the HPTN, HVTN and MTN.
- Utilize Community Partners to help promote the Legacy Project practices to address disparities, health and social issues in the context of HIV which can be applied in various populations and settings globally with high HIV prevalence or incidence.

Legacy Project Objective #4: Review topics across networks; identify areas where there are gaps and/or opportunities for improvement and work in collaboration with network leadership and DAIDS to address those issues.

Strategies and activities to support this objective:

- Collaborate with DAIDS, WHRC, Community Partners and the NIH HIV/AIDS clinical trials networks to address transgender cultural competency and inclusion in network protocols.

- Collaborate with HBCUs, to build on the findings and recommendations of the HBCU Project to increase awareness and support for HIV/AIDS clinical research among HBCU faculty and students.
- Collaborate with House Ball Project community partners to build on the findings and recommendations of the National House Ball Community Change Project to increase awareness and support for HIV/AIDS clinical research among house/ball communities nationally.

Legacy Project Objective #5: Provide culturally appropriate guidance and leadership in development, implementation and dissemination of information about HIV research focused on and responsive to the needs of women and girls.

Strategies and activities to support this objective:

- Increase awareness of HIV prevention modalities for transgender and cisgender women.
  - Establish relationships with women-focused prevention initiatives, programs, and studies such as Philadelphia and New York Women & PrEP study.
  - Highlight the dapivirine ring and other PrEP modalities for women through webinars or local events
  - Invest in a presentation or paper on hormone use, pregnancy, contraception and guidelines and HIV prevention products for women
  - Gather and present data on the vaginal microbiome and HIV susceptibility
- Increase awareness of the intersection of disability and HIV with a focus on mental health in women and girls.
  - Host a webinar exploring the links between mental health, trauma, gender, and HIV acquisition
  - Highlight HIV stigma as a mental health hazard for women and girls with HIV
  - Present data from the AMP study and other studies that have measured mental health and its impact on HIV prevention and treatment for women and girls
- Advocate for the meaningful involvement of women in HIV cure research
  - Craft a policy or activist recommendations document based on conclusions from the 2016 WHRC Women & HIV Cure webinar series
  - Share a recommendations document with the Division of AIDS Clinical Trials Networks and the general public
- Engage in efforts to curb the effects of gendered violence on HIV acquisition with a focus on transgender and cisgender women
  - Develop a policy recommendations document on assessing for violence in clinical/behavioral research settings
  - Present a recommendations document to the Division of AIDS Clinical Trials Networks
- Increase the social media presence of the WHRC to reach a broader and younger audience
  - Develop a WHRC twitter account to promote the WHRC's activities
  - Develop a WHRC blog site to feature the work of the WHRC, stories from WHRC members, and guest bloggers whose visions align with that of the WHRC
- Promote increased representation of women scientists in the field of research
  - Partner with Centers for AIDS Research that are engaged in promoting the work of women in research
  - Host discussions with other women-focused health and STEM organizations
- Recruit new WHRC members with a focus on transgender inclusion
  - Identify potential new members in and outside the DAIDS clinical trials networks
  - Invite new members to participate in regular calls and WHRC events/activities
- Establish collaboration with the Black Women's Health Imperative
- Utilize Community Partners to help promote the Legacy Project practices to address disparities, health and social issues in the context of women and HIV which can be applied in various populations and settings globally with high HIV prevalence or incidence.

Legacy Project Objective #6: Build out BTG website content and updates in collaboration with the HPTN, HVTN and MTN.



- Restructure BTG website content and update content in collaboration with the HPTN, HVTN and MTN.
- Maintain and promote the BTG Google Group to facilitate communication among the former BTG B partners.

## Network Leadership

### **SWG**

The Strategic Working Group (SWG) 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 January 31- February 1, 2017.

### **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 bimonthly call with the leadership of OCSO.

## Site Management Coordination

Site management and oversight, harmonization of clinical trial logistics and operations at the site level across the networks has been identified as an area of high priority for coordination.

### **Site Management Working Groups**

Site management and clinical trials logistics issues are diverse and addressing each issue is likely to require involving a different group of individuals with specific expertise. Network and DAIDS Leadership and HANC work closely with the Office of Clinical Site Oversight (OCSO) at DAIDS to identify issues and identify appropriate individuals to involve in ad-hoc working groups that are likely to be convened on a short-term basis to address specific issues. HANC also facilitates a cross-network Site Coordinators working group to address issues of common concern and harmonize policies and procedures of site-level operations.

### **Site Management Coordination Objectives for 2017**

Site Management Coordination Objective #1: Work closely with network staff, OCSO and other DAIDS offices to identify and address priority site management issues.

Strategies and activities to support this objective:

- Network Leaders, OCSO, 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 and harmonizing site establishment and protocol activation processes.
- HANC will disseminate OPCRO and OCSO policies, memos, SOPs for comment and/or general distribution to network operation centers as requested.
- HANC will hold monthly calls with HANC and OCSO 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 Management Coordination 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:

- The Site Management Coordination Working Group will hold monthly site coordinator teleconferences dedicated to address significant site issues common across the networks.
- The Site Management Coordination Working Group will identify opportunities to harmonize the protocol site activation process and procedures across the core/op centers and SDMCs.
- The Site Management Coordination Working Group will collaborate with representatives from the Cross-Network Evaluation Committee and Community Partners on the process and assessment of impact and quality of community participation at the CAB level.
- The Site Management Coordination Working Group will discuss issues that emerge from the Site Coordinator WG with the network leaders, core/operations centers, OCSO and/or the Office of the DAIDS Director as appropriate.
- The Site Management Coordination Working Group will provide site-level perspective to DAIDS, SDMCs and or core/operations centers on new or revised policies and procedures.

Site Management Coordination Objective #3: Analyze and address security issues associated with physical mailing of Investigator Brochures to institutions and sites.

Strategies and activities to support this objective:

- Advocate for a secure online electronic database where investigator brochures can be made accessible to sites, institutions, and other stakeholders. This system would eliminate the risks associated with sending physical media in the mail, eliminate the cost of postage, and provide a unified and secure means of accessing sensitive material.
- Publicize tool if implemented, working with HANC and regulatory groups to ensure broad dissemination.

## Training Resources

### ***Training Resources Objective for 2017***

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.

## HANC Activity Updates

Clear progress updates from the HANC office inform our partners of cross-network activities undertaken, progress made and challenges encountered. HANC progress reports are shared with stakeholders via:

- An annual HANC research performance progress report provided to NIAID Grants Management.
- Lists of HANC collaborators are provided to the Networks and SDMCs annually for inclusion in their research performance progress reports.
- HANC produces monthly newsletters distributed to all portal users and posted on the home page of the HANC portal.
- HANC distributes a biannual survey to all of HANC's collaborators, which evaluates HANC efforts and inform HANC of any changes needed. The most recent survey was sent in October 2015.
- Maintain and add functionality to a dynamic web-based map of all NIH HIV/AIDS Clinical Trials Network Sites.
- Maintain the "Network Study Results & Publications" page and library on the HANC public website.
- Maintain and expand the Communications Resource Center (CRC) on the HANC portal. The CRC is available to all Communications Working Group members and invited guests. The CRC houses a library of communications resources

including: articles, guides, presentations, contact information, best practices, and white papers, and a media list featuring over 500 international contacts.

- Topic-specific webpages (e.g., network presentations at prominent scientific conferences: “Network Conference Presentations” (including CROI and IAS) on the HANC public website.
- HANC plans to create two different website tour/tutorial videos. One video will highlight the resources on the public website and the second video will highlight the resources on the HANC portal.
- HANC maintains the following portal resources:
  - DAIDS staff listing.
  - DAIDS topic-specific contact list.
  - Cross-network collaborator list.
  - Network newsletter library.
  - Network press releases and study results.
  - DAIDS Protocol Management feature which provides access to all approved protocols.
  - DAIDS Master Contact System linkage.