



Office of HIV/AIDS Network Coordination

2014 Work Plan

December 1, 2013 – November 30, 2014

Introduction	1
Major Cross-Network Projects.....	2
Infrastructure and Administrative Support	6
HANC Staff Role	6
The HANC Public Website	6
The HANC Collaborator Portal	7
Social Networking & Information Sharing	7
Clinical Research Support Contract	7
Objectives and Activities by Area of Coordination	8
Behavioral Science Coordination	8
Communications Work Group	10
Community Coordination	10
Data Management Center Coordination	14
Evaluation Coordination	15
Financial Disclosure Database	15
Laboratory Coordination	16
Legacy Project.....	19
Network Leadership.....	20
Site Management Coordination	21
Training Resources.....	21
HANC Activity Updates	21

Introduction

The Office of HIV/AIDS Network Coordination (HANC) works with the NIH 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 to develop safe and effective drugs, prevention strategies and HIV vaccines. 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).

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; training development and dissemination; harmonization of data management; development and application of consistent standards of performance evaluation; and facilitating effective community engagement in the research process, including the Legacy Project. HANC is accountable in its activities to Network Leadership and DAIDS.

This HANC 2014 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2013 – November 30, 2014. 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 and communicated on a regular basis by HANC staff, as outlined on page 21-22.

Major Cross-Network Projects

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Behavioral Science	Behavioral Science Working Group	Promote sessions at network annual meetings to discuss new developments and their implications	Endeavor to maximize scientific resources, improve cross-network communication and collaboration, and ensure that the best quality behavioral science is integrated into clinical trials.	Ongoing
Behavioral Science	Behavioral Science Working Group	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
Communications	Communications WG	Leverage network experience and expertise; collect communications tools and measures; and harmonize elements of the networks communications plans.	Increased coordination and consistent messaging.	Ongoing

Area	Group Responsible	Objective	Intended Impact	Timeline and 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 Coordination	Community Partners Research Priorities Working Group	Develop and distribute a Transgender Inclusion memo to DAIDS, network leaders and community members. 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.	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.	Common community member understanding of basic concepts in HIV, TB and Hepatitis C, scientific literacy and clinical trials methodology, and CAB role. Improved training quality and consistency.	Ongoing
Community Coordination	Community Ethics Working Group	CP will provide cross-network input to DAIDS to support the development of ethical guidelines and considerations into trial design and conduct.	Solicit feedback regarding ethical considerations and provide recommendations to DAIDS	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 January 2013).	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	DMC 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 HIV staging classifications.	Ongoing
Evaluation	Evaluation Committee	Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks. Focus will be on the community engagement component.	Identify streamlined and harmonized reporting processes.	Ongoing
Financial Disclosure Database	Financial Disclose/Conflict of Interest Working Group	Work closely with network staff and DAIDS officers to review the harmonized network Conflict of Interest/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	Review website and portal user statistics and member survey data to inform HANC programmatic and portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives. Increase awareness of ongoing HANC coordination activities and potential new opportunities.	Ongoing
Laboratory Coordination	VQAAB, CPQA	Ensure standard quality assurance for all of the protocol-specified assays conducted in DAIDS-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

Area	Group Responsible	Objective	Intended Impact	Timeline and Completion Target
Laboratory Coordination	LFG, PBMC SOP WG, LFG-DCLOT	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 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 communities and researchers to equally partner in the research enterprise.	Increased research literacy in communities most impacted by HIV and increased cultural awareness and responsiveness of research staff and sites.	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 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 (e.g. ensuring that staff involved in training coordination communicate regularly with those involved in laboratory operations coordination regarding plans for Good Clinical Laboratory Practice training). 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 needed.

The HANC Public Website

The HANC public website (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 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 whom 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.

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 March of 2014, approximately 1,135 individuals have active HANC portal user accounts and 81 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 2014 Work Plan include:

- Ongoing improvements to the HANC Portal and team site content to better support the objectives of the working groups in 2014.
- 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.
- Create portal accounts for all refunded and new CTU site leaders and coordinators.
- Continued optimization of HANC “Contact Management System” which integrates the portal permissioning, email aliases, and contact lists.

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) 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

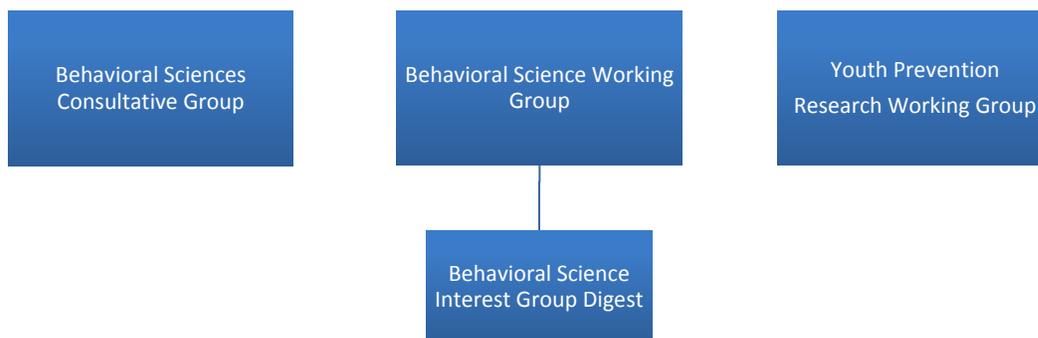
The HIV Clinical Research Support (CRS) contract between DAIDS and the contract research organization can be accessed by the networks to fund a variety of clinical research support tasks, from monitoring study conduct to providing simultaneous translation services for meetings. Networks request network-specific 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 <http://portal.hanc.info/crs>.

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 DAIDS 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. The BSWG also hosted a “Technologies and Measures Task Force” pursuant to a recommendation emerging from the Year 7Q2 “Electronic Behavioral Data Capture Focus 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.

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 DAIDS 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 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
- Validate existing tools
- Compare ongoing and upcoming studies
- Consider adolescent issues early on in design process
- Review relevant informed consent documents
- Collate a set of core competencies

Behavioral Science Working Group Coordination Objectives for **2014**

Behavioral Science Objective #1: Promote 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 counselor training, elicit community working group input on adherence measurement and counseling, etc.

Behavioral Science Objective #2: Maintain a repository of measures, data forms, 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 Objective #3: 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 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 2014.

Behavioral Science Objective #5: Facilitate discussions to identify places where the current scientific agendas intersect and identify additional ways to coordinate the data analyses. Build on the discussions and recommendations considered at the 2012 and 2013 BSWG meetings.

Behavioral Science Objective #6: 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. Presentations have addressed issues such as community viral load, validation of qualitative measures, risk perceptions, novel technologies, etc. Webinar recordings will be archived on the BSIG Resource Center. Expand the “BSIG Rx Connect” listserv, allowing members to pose research questions and receive answers and recommendations from the BSIG research community.

Youth Prevention Research Working Group Coordination Objectives for 2014

Youth Prevention Research Working Group Objective #1: Develop, administer and evaluate survey 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: Collect and collate articles relevant to the conduct of clinical research in the adolescent/young adult population (12-24). Resources will include protocols, best practices, case report forms, articles, etc. from both within and outside of HIV/AIDS research.

Youth Prevention Research Working Group Objective #3: Identify key metadata terms; expand a custom robust and searchable database of relevant materials; and identify search parameters to identify research gaps. The database lives on the HANC portal and be available to the research community.

Youth Prevention Research Working Group Objective #4: Analyze the existing research imperatives, trial results, and protocols in development to identify gaps in the scientific enterprise.

Youth Prevention Research Working Group Objective #5: 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 #6: Explore the development of co-endorsed protocols or adolescent sub-studies.

Youth Prevention Research Working Group Objective #7: Monitor the success of the working group efforts over the course of its existence.

Communications Work 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 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.

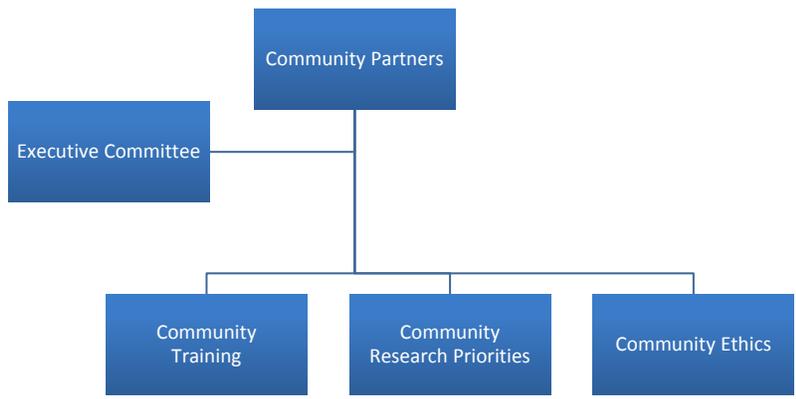
Communications Objective #2: Invite key stakeholders, opinion-makers, and experts in the field to present on working group calls. Areas of expertise could include: journalists, advocates, bloggers, and communications professionals.

Community Coordination

Since the late 1990's, community representatives associated with DAIDS-funded research 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 **2014**

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:

- Develop and distribute a Transgender Inclusion memo to DAIDS and community members
- Review and make recommendations regarding Standard of Care issues for community members
- Review and make recommendations based on adherence overtime
- In partnership with CP Ethics WG, review and address understanding of Informed Consent among CABs
- Review and make recommendations on co-endorsed protocols and community representation
- Review network efforts on the research priorities and identify priority gaps in research.
- Develop questions to make the current priorities more detailed and specific.

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:

- Develop a strategy and/or strategies to promote cross-network Community Partners training materials to networks, sites and other community groups during conferences, meetings and conference calls.
- Revise and update the CP Recommendations document to promote understanding among networks for the value added of community engagement for the entire research process, and facilitate network efforts to engage communities.
- Assist CP members and CABs to share information with and solicit feedback from specific communities to improve understanding of and contribution to HIV/AIDS clinical research.
- Develop a staff guidance document for site staff working directly with CABs.

- In partnership with DAIDS and the CP Ethics WG, revise and develop genetics training materials for community groups and site staff.
- Partner with TB CABs to develop TB/HIV presentations
- Gather and catalogue available training resources on the HANC website.

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:

- Created a 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. 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.
- 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.
- Continue to monitor and provide support to CABs and communities impacted by site closures.

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.

Strategies and activities to support this objective:

- Identify opportunities for improvement and work in collaboration with DAIDS to provide guidance in developing and updating DAIDS informed consent assessment documents and processes for supported and/or sponsored protocols.
- 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.
- Provide guidance around Standards of Care for trial participants
- Provide cross-network input to DAIDS to support the development of ethical guidelines and considerations into trial designs.
- Identify opportunities for improvement and generate recommendations regarding placebo arms in prevention trials.
- In partnership with DAIDS and the CP Training WG, develop documents and materials regarding genetics for community and site staff.
- Collaborate with DAIDS and the CP Training WG on developing a presentation regarding Incidental Findings and Stored Specimens samples for community and site staff.

Community Partners Objective #6: Utilize CP members to provide information exchange to enhance collaboration and identify further engagement topics/issues.

Strategies and activities to support this objective:

- Identify potential contacts for information exchange
- Provide guidance regarding Standards of Care for trial participants focusing on access to medical care, social and psychological support and care, compensation, role of IRBs, etc.
- Increase awareness of CP training materials
- Promote capacity building
- Promote CP training materials at full network group meetings
- 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 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 on monthly teleconference calls, to review and recommend possible applications of IT best practices at DAIDS-funded sites.

DMC Coordination Objectives for 2014

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:

- Monitor Laboratory Data Management Systems / Multi-LIMS Manifest harmonization. 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.
 - Harmonize CDISC implementation activities across DMCs; e.g., develop a mechanism to share SDTM mapping decisions to ensure compatibility across networks and share knowledge learned from participation on various CDISC working groups and CDISC conferences across the DMCs

DMC Coordination Objective #2: Annually review the Information Technology Best Practice Standards (last revised in January 2013) and monitor infrastructure changes.

Strategies and activities to support this objective:

- Ongoing monitoring to ensure that infrastructure changes made by one group would not negatively impact the systems used by another IT and will be done with DMC Harmonization calls as a forum for discussing any proposed changes.

DMC Coordination Objective #3: 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.

Evaluation Coordination

Evaluation Committee

The Evaluation Committee has recently re-convened to discuss and provide input to ongoing cross-network evaluation projects. The Committee consists of Chairs from each Network Evaluation Committee and additional network evaluation committee members as determined by the network.

Evaluation Coordination Objectives for 2014

Primary evaluation coordination objectives for 2014-2015 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 cross-network evaluation teleconferences will provide a forum to discuss and address opportunities.
- Determine how to reconfigure new reporting processes for new networks.

Evaluation Objective #2: Understand the nature of involvement and the impact of community members' participation in network protocol development and implementation, and the relationship to the perceived community relevance of network research.

Strategies and activities to support this objective:

- Conduct an analysis on the community liaison structured interviews and both the community and investigator surveys to identify and profile best practices in community involvement across networks.
- Determine the relationship, if any, between community involvement in protocol development/implementation and perceived relevance of network research.

Financial Disclosure Database

Financial Disclosure Database Objective #1: Work closely with network staff and DAIDS officers to periodically review the harmonized network Conflict of Interest/Financial Disclosure requirements, and maintain the cross-network web-based reporting interface developed in 2014.

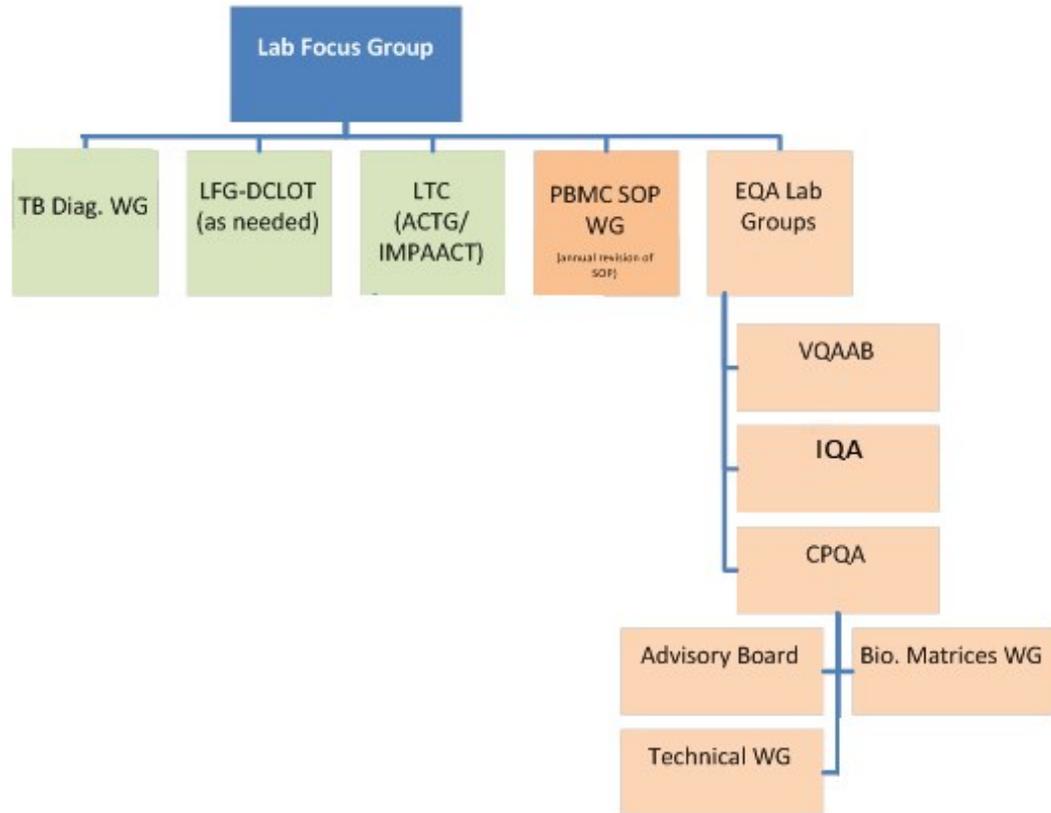
Strategies and activities to support this objective:

- Continue to review U.S. Health and Human Services financial disclosure regulations and audit requirements.
- Provide feedback to DAIDS 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 DAIDS 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. 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.
 - Develop a plan for increased costs of training requirements in South Africa
 - Collaborate on strategies in lowering costs of World Courier shipping
2. 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. 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.

The LFG-DAIDS Clinical Laboratory Oversight Team (DCLOT) Collaborative Working Group includes members of the LFG and DCLOT and serves as a forum for discussion of various laboratory matters that require input from all the networks and DAIDS. This group schedules ad hoc calls as necessary.

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 is currently developing version 5 of the SOP. Revisions are considered bi-annually, thus the group only meets every two years.

The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is a joint ACTG/IMPAACT committee. Voting members serve on protocol teams and provide those teams with technical expertise in the development of the laboratory components of protocols as well as standardizing the handling, processing, labeling, and storage of clinical specimens across all ACTG/IMPAACT clinical sites and laboratories. HANC support staff coordinates specific projects and give technical support to the committee's team site and workload tracking site on the HANC portal, which contains a variety of development and resource document libraries and a discussion board to facilitate distance communication. The LTC also posts a number of resources, including the ACTG/IMPAACT Laboratory Manual, on the HANC public website. The LTC holds teleconferences twice per month.

Objectives:

1. Standardize ACTG/IMPAACT procedures, processes, as well as development of LPCs
 - Provide a forum to share technical expertise discussing and resolving lab issues including but not limited to assay procedures, LDMS, and lab operations.
2. Track LTC workload in protocol and working group teams

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.

Objectives:

1. Be a resource to network protocol teams
 - Maintain 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
 - 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
 - ii. Continue development of Microbank Tube assay
 - iii. Assist with development of EQA assays
 - Draft/compile and implement standard guidelines for sample collection, transport and diagnostics
2. Coordinate comparative evaluations of TB Laboratory methods.

3. Support institution of cross-network international specialty and regional TB laboratories
 - Continue implementation of Infection Control Checklist Program in all TB sites
4. Explore opportunities for the development and validation of point-of care TB Laboratory assays.
 - 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 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, IQA CD4 WG, ICAG, 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 serves as a forum for the networks to communicate their pharmacology quality assurance needs to the CPQA program, and provides oversight for the activities of the CPQA. The CPQA Advisory Board includes the directors of the Network Pharmacology Specialty Laboratories, DAIDS, statisticians, the CPQA and other experts who meet during monthly teleconferences.

- The CPQA Cross-Network Lab Group (CNLG)– Technical serves as a forum for communications between the CPQA program and Pharmacology Laboratories regarding the status of testing in the proficiency testing program, provides feedback on the upgrades made to the online AVR/SOP submission utility, and gives input regarding CPQA proficiency testing policy changes during bimonthly teleconferences.
 - Provide guidance with FDA's new requirements in Bioanalytical assays
- The Biological Matrices Working Group develops data-driven analytical protocols necessary to develop various approaches to collect, handle (stabilize, transport for processing, process, store, ship and store long term) human biological samples for pharmacological testing.
 - Provide presentations of novel biomatrices from experts, discussing current studies, challenges and benefits and its possible future trend in HIV studies.
 - Face-to-face meeting planned for network Pharmacology labs as well as PK field experts in various biomatrices.

The Virology Quality Assurance Advisory Board (VQAAB) addresses virology external quality assurance issues identified by Virology Quality Assurance (VQA) and other VQAAB members during monthly teleconferences. The VQAAB includes representatives of the NIH HIV/AIDS networks, DAIDS, the VQA, and sub-contractors.

Objectives:

- Review of PT programs: HIV- RNA, HIV-DNA, HIV-DNA-DBS (Dried Blood Spot), Genotyping, and Integrase
- Explore methods of increasing efficiency with PT programs
- Develop PT programs for other assays

General Lab Coordination Objectives:

1. Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.
 - The HANC public website “Laboratory Resources” section will be increasingly utilized to share cross-network information with the sites and labs.
 - The laboratory database on the HANC portal will be used to maintain updated lists of PNL assignments, network-laboratory affiliations, and participation in proficiency testing programs. It will be further developed to contain additional parameters useful to the Network Laboratories, as necessary.
 - Various laboratory working groups will coordinate the development of questionnaires for collecting laboratory information for cross-network use, as necessary.
 - HANC support staff will maintain a team site on the HANC portal for each working group for information sharing and collaborative document development.
 - Coordinate scheduled and ad hoc teleconference, providing continuity of information by providing minutes, tracking email discussions, and editing team sites for usability.
 - Provide user support for HANC Public and Portal Sites.
2. Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories
 - a. HANC staff will continue to expand listings of laboratory training resources on the HANC public website.
 - b. HANC staff and ACTG/IMPAACT network staff will continue to populate the Laboratory Certificate Library on the HANC public website.
 - c. HANC staff will work with network staff to coordinate the negotiation of memoranda of understanding and/or purchasing/service agreements with suppliers as necessary.
 - d. Provide user software support for group members

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 assist 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 researched focused on and responsive to the needs of women and girls 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.

Legacy Project partners and collaborators include representatives from trans-institutes under the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Office of Minority Health (OMH), and serve on various working groups steering committees to foster coordination and knowledge transfer between NIH-funded clinical trial networks and external agencies that focus on HIV/AIDS policy, education, advocacy, and care. All institutes funded by the

United States Department of Health and Human Services with a vested interest in HIV/AIDS have an organizational seat on the LPWG; which can be determined by designation or through appointment.

The Legacy Project Working Group and Legacy staff completed a three year strategic plan in Year 5 Q4. The Year 7 Extension objectives are based on the Legacy Project goals outlined in that plan.

Legacy Project Objectives and Activities

Legacy Project Objective # 1: Establish and or enhance partnerships and collaborations with government agencies, scientist, CBOs and ASOs, medical/academic institutions, specialized institutions/networks, experts /advisors.

Strategies and activities to support this objective:

- The Legacy Project will maintain collaborations/partnerships with CBOs and ASOs across the US.
- The Legacy Project will enhance formal partnerships with all the NIH funded HIV clinical research networks and sites.
- The Legacy Project will increase the number of formal partnerships with Historically Black Colleges and Universities (HBCUs).
- The Legacy Project will establish and/or enhance partnerships with specialized institutions/networks by continuing engagement with the house/ball community, Black and Gay Prides.
- The Legacy Project will work collaboratively with Network partners, the Women's HIV Research Collaborative and Community Partners to identify community research priorities.

Legacy Project Objective #2: Build the capacity of communities and researchers to equally partner in the research enterprise.

Strategies and activities to support this objective:

- The Legacy Project will develop training modules and other educational and promotional materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic.
- The Legacy Project will host webinars on HIV prevention and treatment clinical research advances among its stakeholders.
- The Legacy Project will disseminate a Guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Pilot Project.
- The Legacy Project will host workshops/presentations at conferences and other meetings that are aimed at improving community research literacy and the capacity of HIV prevention and treatment clinical research sites, community advisory boards (CABs), and/or researchers.

Network Leadership

SWG

The Strategic Working Group (SWG) is a working group of ARAC 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 DAIDS 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 DAIDS. The next SWG meeting is scheduled for September 2014.

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 monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a monthly call with the leadership of OCSO and a bimonthly call with OPCRO leadership.

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 will work closely with 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 facilitates a cross-network Site Coordinators working group to address issues of common concern and harmonize policies and procedures regarding site-level operations.

Site Management Coordination Objectives for 2014

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. Topics may include such issues as: SDMC issues; reducing confusion around site monitoring by clarifying site new performance monitoring policies; clarifying DAIDS and networks respective responsibilities and harmonizing site establishment processes.
- HANC to disseminate OPCRO and OCSO policies, memos, SOPs for comment and/or general distribution to network operation centers as requested.
- Hold monthly calls with HANC and OCSO leadership to facilitate communication and coordination of site-level activities.
- 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:

- Hold monthly site coordinator teleconferences dedicated to address significant site issues common across the networks.
- Discuss issues that emerge from the Site Coordinator WG with the network leaders, core/operations centers, OCSO and/or the OD as appropriate.
- Provide site-level perspective to DAIDS and or core/operations centers on new or revised policies and procedures.

Training Resources

Training Resources Objective for 2014

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 will inform our partners of cross-network activities undertaken, progress made and challenges encountered. HANC progress reports will be shared with stakeholders via:

- Semi-annual HANC progress reports posted on the HANC portal and sent to Network Leadership and DAIDS.

- An annual HANC progress report provided to NIAID Grants Management and posted on the HANC portal.
- 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 will evaluate HANC efforts and inform HANC of any changes needed. The next survey is scheduled for 2014.
 - 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.
 - Create topic-specific webpages (e.g., network presentations at prominent scientific conferences, “Network Responses to the iPrEx trial” or “Network Responses to the 30th Anniversary of the First Reported Case of HIV in the US”) on the HANC public website.
- 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 Quick Summary.
 - DAIDS Master Contact System.