Office of HIV/AIDS Network Coordination

2014 Semiannual Report

December 1, 2013 – May 30, 2014

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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 outlined cross-network coordination objectives and activities for the period of December 1, 2013 – November 30, 2014. The objectives, strategies and activities were 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.

This report is the semi-annual report based on progress made on the objectives, strategies and activities by all the HANC-facilitated work groups from December 1, 2013 through May 31, 2014. Progress reports are in bold.

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 website.
- 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.

Be the Generation HIV Prevention Research (HPR) Training Module.

Information for researchers interested in proposing behavioral studies to each of the NIH funded HIV/AIDS clinical trials networks and other affiliated research groups.

Network presentations from CROI 2014 which took place from March 3-6, 2014 in Boston, MA were posted to the HANC website. Also ongoing maintenance including posting of updated laboratory certificates and documents to the ACTG/IMPAACT Laboratory Manual as noted in the Laboratory Coordination section on page 18.

The HANC Collaborator Portal

The HANC portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC portal includes document libraries; document development and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory linked to the DAIDS-ES Master Contact system. As of July 21, 2014, 1,345 individuals have active HANC portal user accounts and 74 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 provided 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.
- Created 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.

During the first half of this year all of the activities listed above were ongoing.

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. The HANC newsletter is published 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 provides individualized trainings for networks and affiliated partners as requested. HANC has a YouTube page (youtube.com/officeofhanc) to broadcast and share network videos. HANC uses Google Analytics to track the most used resources and pages on both the HANC public and portal websites.

As of June 1, 2014, HANC had 219 friends on Facebook and is being followed by eleven people. HANC is following 308 accounts on Twitter and is being followed by 230. HANC had 340 connections on LinkedIn. During the six-month period, HANC’s public website had 3,756 unique visitors with nearly 19,000 page views. The average user spent 2’49” on the website. There were a total of 308 unique visitors that used the HANC portal during the same time frame with a total of 13,070 page views. The average user spent 9’14” on the HANC portal.

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.

During the first half of 2014 HANC submitted one CRS funding request to translate the HANC PBMC SOP v5.0 into three languages, but due to CRS budgetary constraints the request could not be accommodated.

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”.

The Behavioral Science Working Group conducted five teleconferences during the first half of the fiscal year.

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 held six teleconferences during the first half of the fiscal year.
- The BSCG held a conference call with MTN leadership.
- The BSCG Co-chairs held an additional planning call re: face-to-face meeting at CROI 2014.
- The BSCG met face-to-face at CROI 2014. Members unable to attend in person attended by conference call. Sharon Nachman (Chair of IMPAACT) attended the meeting as well.
- The BSCG planned a face-to-face meeting to convene at the conclusion of IAPAC in June, 2014.
- The BSCG has provided feedback to the HVTN, IMPAACT, and MTN networks. The BSCG specifically helped HVTN by providing feedback on HVTN 915. The BSCG is continuing to help IMPAACT evaluate their adherence measures. The BSCG has been vital in providing feedback for a conditional economic incentive protocol. The work is ongoing.
- The BSCG has developed a core competencies document to denote the areas of expertise of the BSCG members.
- A library of adherence forms has been created on the BSCG site on the HANC portal.
The BSCG network representatives presented an overview of each network presentation to the SWG meeting convened by NIAID in January 2014 to review the scientific agendas of the refunded networks for the next 7 year funding period.

BSCG network representatives assisted with the planning of a pre-conference symposium at the IAPAC 9th Conference on Treatment and Prevention Adherence held in June 2014.

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: Facilitate 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.

- This is an ongoing activity. The BSWG has started to discuss potential topics for two possible subject matter expert consultations to be held later in 2014. The BSWG will continue to propose topics for network meetings and facilitate planning as requested and able. Discussions for future meetings are ongoing.

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”.

- This is an ongoing activity. The portal library has been created and is updated weekly. To date, there are over 1,600 documents that have been added to the site. A Behavioral and Social Science library with links to PubMed abstracts has been created on the HANC public website. The BSIG members are encouraged to submit their work, funding opportunities, and relevant research.

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.

- This is an ongoing activity. At the end of each call, the BSWG partakes in a round-robin to discuss current on goings within the networks. HANC also created the “BSIG Rx Connect” which allows researchers to pose behavioral and social science questions via email.
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.

- This is an ongoing activity. The BSWG has discussed ongoing network behavioral and social science activities. The Working Group has been discussing potential topics of subject matter expert consultations.

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.

- This is an ongoing activity. Following a key recommendation of the 2012 BSWG meeting, HANC has explored ways to address key network priorities. Important topics such as risk assessment, adherence (A)CASI utility, etc. are being pursued on related WGs and focus groups. The BSWG is currently discussing potential topics for up to two subject matter expert consultations.

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.

- This is an ongoing activity. HANC has created the BSIG list serve, portal-based resource center, and publications library on the public website. HANC circulates a weekly digest of newly published BSS articles, CRFs, funding opportunities, job openings, blog posts, etc. HANC launched the “BSIG Rx Connect” allowing BSIG members to pose research questions and develop relationships in a mediated email setting. Nearly 400 behavioral and social scientists have joined the BSIG since its inception. HANC hosted a webinar on January 13, 2014 with Robert Gross who discussed “Partner-based intervention for adherence to second-line ART: A multinational RCT (ACTG A5234). HANC will also be hosting a webinar with Barbara Friedland of Population Council in July, 2014 and is planning on a webinar with Dr. Lisa Eaton on her work in Atlanta, GA around BMSM.

Behavioral Science Objective #7: Collate and analyze behavioral data elements across network studies for analysis by scholars/fellows in network mentor programs and other junior investigators.

- This is an ongoing activity. The library has been created and is updated as needed. The “Behavioral, Adherence and Neurocognitive Measures” table is updated on an as needed basis. The group has reviewed network CRFs and BSS elements, statistical modeling, validating qualitative measures, and (A)CASI on calls/webinars.

Youth Prevention Research Working Group Coordination Objectives for 2014

The group held six teleconferences during the reporting period. The group developed and administered a survey in April 2014 to 150 Clinical Research Sites for the purpose of assessing site-level experience and interest in conducting research with adolescents within the NIH-sponsored networks. Analysis of the responses from almost 60% of the sites is ongoing in the second half of the year. The group also was asked to issue the survey to the 29 newly funded NICHD sites in June 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.

- This survey was successfully developed and implemented using SurveyMonkey, with the survey closing date of April 18th and results being compiled in early June. Much work and review went into developing a concise, relevant set of questions that were representative of the group’s interests and goals.
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.

- This goal was accomplished during various meetings. Sample articles of discussion included the research ethics and implementation surrounding patient adherence to experimental protocols, harmonizing protocol templates across sites, and site-level training techniques for best implementation practices.

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.

- Limited attention has been paid to the database due resource constraints. Several members are still involved, however.

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.

- This goal was also accomplished throughout various meetings—sharing of trial designs, progress, goals, etc. such as but not limited to PrEP, a study utilizing vaginal swabs to test for HIV exposure as well as mobile phone updates, and an adolescent TB trial.

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.

- This was accomplished throughout the meetings, supported by robust multi-network attendance and discussion of protocols and objectives from various networks.

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

- A variety of adolescent studies were discussed as mentioned above, though protocol development was slow during this period due to the refunding and re-evaluation of network research agendas and priorities given resource constraints.

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

- The YPRWG continues to maintain diverse network representation among its members and move forward with its goals including survey implementation, research awareness, protocol development and collaboration.

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.
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- 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.

The group held three teleconferences during the reported period. On February 11, 2014, the group invited Kay Marshall with AVAC to present and Kay provided updates to the Communications WG on the results of social media focus groups with researchers and trials site staff at the HVTN and MTN meetings in Cape Town in October 2013 to discuss if and how social media is used around HIV prevention trials in Africa.

During the April 8, 2014 call, the group discussed a potential Communications WG Symposium and decided not to have a symposium in 2014.

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.
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- 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.

The group held a total of twelve teleconferences during the reporting period, including the WG calls. The group accomplished the following during the reporting period:

- In December 2013, the group developed a Community Engagement slide deck for site closure purposes. The slides contain recommendations intended to address some of the issues expressed by CABs/CAGs and communities around site closures. These slides were shared with the Office of Clinical Site Oversight and some of the points included in the slides were included in letters sent to PIs of closing sites.
- The CP Research Priorities WG identified the transgender population as a priority for DAIDS-funded clinical trials and research and in May 2014, submitted a memo to DAIDS regarding transgender inclusion in DAIDS-funded clinical trials.
- In February 2013, CP initiated work on revising the Recommendations for Community Engagement in HIV/AIDS Research.
- In March 2013, CP submitted two abstracts to the 2014 United States Conference on AIDS.
- The CP Ethics WG invited Liza Dawson, DAIDS Team Leader, Research Ethics Team on the April 2014 CP Ethics WG call for a DAIDS ethics grants presentation to discuss collaboration and input opportunities
- Ray Chung with ACTG provided an overview of HCV and the liver to CP members during the March 2014 CP call to help educate CP members regarding viral hepatitis and HCV infection and treatment.
- Initiated and formalized collaboration with TB Community Research Advisory Group (CRAG) and invited CRAG representatives on the February 2014 CP call to discuss TB research issues and CP members presented on a April 2014 CRAG call and discussed CP activities. CP and CRAG are working to advocate for TB and HIV joint presentations.
In May 2014, CP representatives were invited to present an interactive training for IMPAACT ICAB members at the IMPAACT annual meeting in DC.

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

Five teleconferences were held during this reporting period.

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:

- The working group discussed and reviewed newly issued FDA guidelines for Electronic Data Capture (EDC) such as eCRFs beginning in January of this period, extending to April due to the significance of this event, with the intention of facilitating understanding of the new guidelines across sites. The comments will be discussed in future meetings.
- FSTRF is reviewing new possibilities in monitoring including Clinical Trial Management Systems (CTMS) for the possibility of remote site monitoring/data monitoring.
- DAIDS released proposed changes to Toxicity Tables and a new Data Dictionary. Review will be through June 27, 2014.
- A CDISC programming consultant was hired by DAIDS (Jane Dieffenbach), and announced on the April 24, 2014 meeting.

Objectives Addressed:

- 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:

- Continued attention to and review of new FDA electronic data capture recommendations and its SDMC and site implications.

**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.
- 281 new MedDRA PT codes were reviewed by clinicians in April 2014 by the HANC-facilitated AIDS Defining Event work group.
- The HIVSTAGE programming tool was updated by SDAC according to the MedDRA reviews in April 2014.

**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.

Two teleconferences were held during this reporting period.

**Evaluation Coordination Objectives for 2014**

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

Strategies and activities that supported this objective:

- Completed cross-network evaluation calls to facilitate communication, site evaluation, evaluation development and analysis of site data
- Review & presentation via Webinar of community recommendations document for strategic harmonization of site personnel across the network (February 12, 2014)

**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:

- Surveying and analyzing site response led to the publication, “Assessing the Challenges of Multi-Scope Clinical Research Sites: An Example from NIH HIV/AIDS Clinical Trials Networks” (Epublished November 14, 2013)
- Early development and planning of a centralized Network Community Indicator Survey to remove burden from CABs and assist in evaluating relationships and enhancing communication and involvement with communities.
- Opened discussion of a centralized cross-network community survey with the networks.
**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.

The Financial Disclosure Working Group conducted three teleconferences during the first half of the fiscal year. The Working Group developed a user guide for the all-network financial disclosure system.

**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.
December 1, 2013-May 31, 2014 accomplishments:

Five teleconferences were held during this reporting period.

Economies of Scale: List of concerns that were discussed and possible search for more economical avenues than the present:

1. IATA Shipping Training in South Africa - members took inventory of their sites to determine the needs and current funding status for the face-to-face training as part of the new requirements for South Africa. Currently, many of the sites are funding their own training. The group is open to developing a collaborative solution if the network operations begin to fund the IATA training for South Africa. Status: Group will track the needs of their sites.

2. World Courier - members discussed the challenges they are having with World Courier as well as ways of decreasing costs. They also discussed the issues with a cross-network account. While this topic is given a lower priority, network operations will be contacted to determine if an infra-structure to handle a cross-network account can be feasibly developed and requirements that would be addressed.

3. FBS - members will look into more economical distribution of FBS for their international sites, specifically Africa.

Harmonize Lab Processes:

1. PBMC SOP v5.1: Overlooked and reviewing the changes made in the Cross Network PBMC SOP from version 4 to 5.1

2. LDMS Mandates/ FSTRF: Monitoring LDMS mandates now actively tracked by FSTRF. Providing guidance to FSTRF in some of the site communications to increase compliance, as well as addressing any serious concerns.

3. Acute HIV diagnosis: Topic will be a continuous discussion to possibly develop a cross-network standard of diagnosis and process for acute HIV infection.

4. APL/CDC HIV Algorithm: members initiated the discussion while the new algorithm was in draft form to possibly address issues that may arise in the final version.

5. Clarification was established that PNLs are still in effect and protocol for existing channels.

Assist EQA:

1. LFG will be taking over the disbanded ICAG’s responsibility of addressing minor concerns with the PMBC Processing Proficiency Testing program. They will determine if ICAG members would need to be re-called for Ad hoc meeting of serious concerns.

2. Teleconference provided a good arena for discussion regarding communications with DCLOT versus inter-networks in reference to a site that was not in full compliance of certain process requirements of a study.

3. Clarification was established regarding Heme auto-differential reporting for SMILE.

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.

December 1, 2013-May 31, 2014 accomplishments:

Ad-hoc Teleconference Calls

1. Call gave the LFG members opportunity to voice out their thoughts regarding the recent methodology of DAIDS site audits, as well as provide constructive suggestions for the auditors. DAIDS and SMILE were able to respond and discuss the challenges they face in these audits with the constraint of time and budgets. Everyone agreed that audits are not designed to fail the sites, but rather to increase performance in preparation for FDA audits.

2. LFG participated in the review of a new audit shell. DCLOT will be incorporating some of their suggestions for future audits.
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.

December 1, 2013-May 31, 2014 accomplishments:

One teleconference was held during this reporting period.

The Working Group finalized the steps in the Cross-Network PBMC Processing SOP that can be harmonized among networks.

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

December 1, 2013-May 31, 2014 accomplishments:

Eight teleconferences were held during this reporting period.

1. Approved Cross-Network Documents:
   - 1 SOP: GALT Protocol and LPC Review Procedure and Checklist SOP
   - LPC Template
   - Standard Wording for Pediatric Immunology

2. Other Documents Initiated:
   - Initiated Sputum SOP
   - Revising Metabolic Standard Wording

3. Assist FSTRF
   - Establish LDMS codes
   - Reviewers of new training modules – such as LDMS Mandate and Installation Validation

4. Members participated in over 90 protocols as protocol team members

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

December 1, 2013-May 31, 2014 accomplishments:

Six teleconferences were held during this reporting period.

Resource:

1. Sent input regarding Biohazard Section for TB for the DAIDS Control Policy Change

EQA:

1. Developed and Tracking GeneXpert EQA program
   Tracking status of sites: December: 11 approved and 13 concern sites
   May: 18 sites enrolled with 26 instruments submitted
   Updates on Methodologies and method standardization including Incidence Report documentations
2. SMILE EQA Program
   Updates received in January- most sites are doing well

Comparative Evaluation of TB Methods:

1. Vanometer Information was disseminated to sites for education in assessing room ventilation

Infection Control Checklist (ICC):

1. ICCs from 12 sites were reviewed with three with no deficiencies noted
2. ICCs were updated for two revisions
3. Processes for ICC communication channels were developed including flowchart of involved parties and tracking sheet recording sites and deficiencies.

TB Lab Assays
1. MicroBank assay. ATCC Isolates have done well for three years. Culture isolates were delayed and were re-grown. Working Group is reviewing progress.

2. Other assays are considered and discussed for possible EQA programs such as LAM assay.

The Cross-Network Lab Interest Group (XNLI G) 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.

December 1, 2013-May 31, 2014 accomplishments:

Circulated three reports highlighting activities of the Cross-Network Lab Coordination Working groups.

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.

December 1, 2013-May 31, 2014 accomplishments:

Twelve teleconferences were held during this reporting period (two Advisory Board, four CNLG-Tech and six BioMatrices Working Group).

Advisory Board:
1. Provide oversight of the PK PT program and discussed results
2. Consulted for feedback regarding a studies involving adherence counseling and compliance of possible CLIA requirements
CNLG-Tech:
1. Collaborated on technical issues and results of Rifamycin testing
2. Provided Technical guidance for Round 33 Proficiency Testing
3. Technical Support of PK techs from CPQA Labs

Bio-Matrices
1. Four presentations of using various matrices for PK measurement: hair, liver, red blood cells, GALT, and dried blood spots
2. One presentation on technology for adherence- Intrauterine vaginal ring
3. Provided technical expertise for discussion with DAIDS and other external collaborators regarding development of PK assays as point-of-care tests for both preventive and treatment purposes and the possible regulatory issues that would need to be addressed.

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

December 1, 2013-May 31, 2014 accomplishments:

Six teleconferences were held during this reporting period.

1. VQA officially scoring the Geno-Integrase Proficiency Testing Program
2. Working group is providing oversight of five PT Programs: DNA DBS, DNA, RNA, HIV Genotyping
3. Discussion and researching the possibility of reducing the frequency of VQA HIV RNA PT Sample Testing. This has brought on discussion about using various statistical methods such as Westgard scoring
4. Discussions and feedback regarding differences in kits lots, kit controls versus external control.
5. Discussed and preparing for rising issues with discontinued 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.
HIV/AIDS Network Coordination 2014 Work Plan

1. Coordinate scheduled and ad hoc teleconference, providing continuity of information by providing minutes, tracking email discussions, and editing team sites for usability.
2. 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

December 1, 2013-May 31, 2014 accomplishments:
1. Provided support for ad-hoc calls and FSTRF-CPQA calls
2. Provide Email correspondence and communication channel support between Working groups and external collaborators.
3. Gathering user needs regarding websites and developing to improve usability
4. Provide software support for documentation formatting using Photoshop, Visio, Excel, Word, and Adobe Acrobat
5. Develop tracking methods for various activities such as the infection control checklist (ICC)

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.

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 held four teleconferences during the reporting period.
- An ad hoc group, the Legacy Project Planning Group, held three teleconferences to discuss the development of the 2014 Legacy Project Work Plan.
- HANC and HVTN Legacy staff met to discuss and clarify focus of the Legacy 2014 Work Plan.

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.

- The WHRC conducted three bimonthly teleconferences during the reporting period.
- The Co-Chairs and HANC staff met monthly to coordinate the activities and updates of the group.
- The WHRC white paper, “Gendered Violence, HIV Acquisition, and Clinical/Behavioral Research,” was accepted for publication in The Journal of Health Disparities Research and Practice.

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

Engagement & Collaboration

Facilitate community, site and network involvement throughout the research process

Collaborate with network partners, the Women’s HIV Research Collaborative and Community Partners to identify community research priorities. Maintain collaborations/partnerships with former BTG partners and select CBOs and ASOs across the US

- An ad hoc group of the WHRC met twice to discuss potential new research projects for the group.

Collaborate with network and sites to raise awareness about PrEP and HPTN 073 among Black MSMs, including House Ball community and Black Gay Pride attendees

- Participated on HPTN 073 protocol team meetings (six meetings between December 2013 and May 2014)
- Engaged HPTN, HVTN, and ACTG sites in Atlanta and Los Angeles to build and enhance relationships with house ball community and Black gay pride attendees.
- Engaged MTN core regarding to partner in a Black MSM consultation in conjunction with MTN 017.

Manage BTG website content and updates in collaboration with the HPTN, HVTN and MTN

- Managed the transition of the Be the Generation website from FHCRC to HANC.
- Through the combined efforts of project partners, FHI360, the BTG website was relaunched for public use in February 2014.

Coordinate editing and completion and dissemination of the BTG HIV Prevention Research Module

- Coordinated with Cranmer Communications to edit and complete the BTG HIV Prevention Research Module.

Assist WHRC leadership in developing new research projects focused on women and PrEP acceptability in collaboration with the HPTN 076 and 077 protocol teams

Maintain relationships with network communications and community engagement staff in collaboration with Community Partners and the HANC-facilitated Communications Work group

Oversee publication of quarterly BTG e-newsletter in collaboration with the HPTN, HVTN and MTN

- The BTG eNewsletter was published and distributed to the BTG listserv in December and March. The BTG listserv has 1,045 recipients. The eNewsletter is now being produced quarterly.
- Staff coordinated with HIV prevention networks to solicit articles for the BTG eNewsletter.

Maintain the BTG Google Group to facilitate communication among the former BTG B partners
Increase the number of formal partnerships with Historically Black Colleges and Universities (HBCUs) to raise awareness and support for HIV/AIDS Clinical Research

- All data collection activities, including faculty interviews, were finalized. All of the faculty interviews have been coded and are set to be analyzed soon.

Establish and/or enhance site-level linkages/partnerships with specialized institutions/networks by continuing engagement with the house/ball community.

- Engaged HPTN, HVTN, and ACTG sites in Atlanta and Los Angeles to build and enhance relationships with house ball community. This engagement occurred through email and phone communication, as well as on the ground contact, and will be ongoing to provide strategic community engagement tools and strategies to enhance site-level linkages/partnerships between researchers and community-based organizations and groups. House ball communities organized town hall meetings in Atlanta, GA and New York, NY and there are additional activities being considered for other regions.

Establish and/or enhance site-level linkages/partnerships with specialized institutions/networks by continuing engagement with Black Gay Prides (Atlanta, Dallas and LA)

- Engaged HPTN, HVTN and ACTG sites in Atlanta and Los Angeles to build and enhance relationships with Black gay prides. This engagement occurred through email and phone communication, and will be ongoing to provide strategic community engagement tools and strategies to enhance site-level linkages/partnerships between researchers and community-based organizations and groups. Assisted Houston Black Pride via phone and email communication to develop a survey instrument that would assess pride attendees attitudes and perceptions of educational seminars during prides, as well as knowledge and attitudes towards PrEP.

Trainings/Capacity Building

Build the capacity of communities and researchers to partner in the research enterprise

Dissemination of training materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic

- The new BTG brochure developed under the leadership of our colleagues at FHI360 is available for download on the BTG website. This was communicated to partners through the Google Group. The Google Group has seventy-nine members representing twenty-eight BTG partner organizations.

Host community-focused webinars on HIV prevention and treatment clinical research advances in collaboration with the HIV/AIDS Clinical Trials Networks Disseminate a guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project

Provide resources and technical assistance to former BTG B partners and Community Based organizations

- The National Organization Leadership Briefing was held December 11, 2013, in Arlington, VA. National leaders engaged in a dialogue with Dr. Carl Dieffenbach, Director, Division of AIDS, NIAID.

  Disseminated information about network-hosted webinars, research updates and other related biomedical HIV clinical research information to house ball communities, black pride organizers, and other groups of Black MSM nationally through email list-serves, Facebook, and Twitter.

Conduct workshops/presentations at the Tulsa National Pow Wow and USCA 2014 aimed at improving community research literacy and support for HIV/AIDS Clinical Trials Networks

- The BTG HIV Prevention Research Module was presented by Bertram Johnson at the Tulsa Two-Spirit Gathering on April 26, 2014, in collaboration with leadership from the Northeast Two Spirit Society.
Conduct workshops/presentations on the HBCU Project at USCA 2014 and submit abstract to present at NASEM 2015

- An abstract was submitted and accepted for workshop presentation at USCA on the HBCU collaborative project with Lincoln University.
- Legacy staff assisted in writing the, *Improving Scientific Literacy among communities interested in HIV Prevention and HIV/AIDS Clinical Trials Globally*, abstract submitted on behalf of HANC for the 2014 US Conference on AIDS, which was accepted as a combined workshop presentation.

### Analysis, Publication & Dissemination of Data

Publish and disseminate results of the NACHER Project and the HBCU Lincoln Project

- The NAEHCR Project Guidance and Best Practices Document was finalized, posted to the HANC web site and distributed through the BTG listserve, eNewsletter, and HANC website on May 19, 2014.
- Legacy Project presented at the 2014 NAESM MSM Leadership Conference on HIV/AIDS and Other Health Disparities. The session was entitled “Strengthening Researcher-Community Ties in HIV Biomedical Research within Communities of Color: Lessons from the Legacy Project”. This conference was held in Orlando, Florida January 16th – 19th, 2014. The session was well attended by general community members, and site/core representatives from HPTN and HVTN. The session provided an overview of the Legacy Project and its initiatives, as well as a clinical research overview. The discussion was highlighted by a significant discussion on community engagement, research literacy among communities of color, and PrEP adherence.
- Stephaun Wallace of the Legacy Project also participates in the National Black Gay Men’s Advocacy Coalition (NBGMAC) in a leadership role.

### 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.

HANC attended the January 28-29, 2014 SWG meeting during which each of the refunded networks presented an in-depth review of their new network structure, research priorities and protocols in development.

#### 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.

The NLG had four calls in this reporting period. A significant amount of time and effort was spent on prioritization of HANC activities in light of the reduced resources in 2014 and a draft HANC work plan was reviewed and finalized in June 2014.

DAIDS-HANC leadership had three calls during this reporting period. As with the NLG, conversations focused on prioritization of HANC work group activities for 2014.
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

Four teleconferences were held during this reporting period.

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:

- The Site Coordinators WG met on a (generally) monthly basis to discuss issues relevant to site management and coordination. The group worked with the Youth Prevention WG to complete site surveys addressing site issues, scope of practice, and other areas of interest, and was made aware of survey results in April.

- The paper entitled "Assessing the Challenges of Multi-Scope Clinical Research Sites: An Example from NIH HIV/AIDS Clinical Trials Networks" was accepted for publication in Journal of Evaluation in Clinical Practice and published online in November 13, 2013.

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:

- Monthly calls were held to facilitate this goal, with a variety of discussions. One example of site harmonization resources and training was the DAIDS Learning Portal, a training resource for sites to become more knowledgeable with respect to regulatory policy, documents, and training. A demo was provided for group members.

- Site-level perspective was available to DAIDS and or core/operations centers on new or revised policies and procedures such as new .

The Site Coordination Work Group saw a change in coordination (Morgan Weaver replaced Christie Villa as host) and a solicitation for new members was planned to be sent in June 2014 to the newly funded 37 CTU PIs and CTU site coordinators. The Site Coordinators WG will continue to work towards completing the above stated goals in its newly expanded capacity in the second half of this year.

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.

All these HANC communication activities are ongoing and resources updated in a timely manner. However, HANC decided to delay the HANC Annual Collaborator Survey until 2015 to allow the new collaborators some time to begin their work with HANC.