



# Office of HIV/AIDS Network Coordination

## 2015 Semiannual Report

December 1, 2014 – May 30, 2015

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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, laboratory and behavioral sciences, including: scientific leadership; site management and research logistics; laboratory operations; training information dissemination; data management; sharing 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 2015 Work Plan outlined cross-network coordination objectives and activities for the period of December 1, 2014 – November 30, 2015. 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 28-29.

**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, 2014 through May 31, 2015. 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](http://www.hanc.info)) contains a calendar of events, network newsletters, general information about HANC’s coordination activities, training resources, laboratory resources, and other resources for collaborators, research sites, and the general public, including:

- A dynamic calendar of scientific conferences, network meetings, community events, training opportunities, and more.
- Some of the Division of AIDS’ Office of Clinical Site Oversight Clinical Research Policies and Standard Operating Procedures that are not listed on the DAIDS website and a link to the official versions of all current DAIDS Clinical Research Policies that are posted on the NIAID/DAIDS web site.



- A dynamic announcement section on the home page for posting important notices, such as recent major study results and DAIDS policies.
- An HIV News section with the most recent HIV news and research findings via RSS feeds.
- Information for community members interested in supporting HIV/AIDS research as a community advisory board member.
- Links to [clinicaltrials.gov](http://clinicaltrials.gov) for individuals interested in participating in a clinical research study.
- Free online Good Clinical Practice, Human Subjects Protection and Responsible Conduct of Research Training through the Collaborative IRB Training Initiative (CITI), and DAIDS-ES Applications Training Information.
- A dynamic, searchable map showing locations of networks and research sites around the world.
- Information for laboratories, including PNL Contact Assignments, a Laboratory Certification Library, and laboratory training videos.
- Resources and links to direct site and network staff regarding who to contact or where to find the information they are looking for, updated DAIDS organization charts, and OCSO SOPs.
- Library of all the network publications cataloged in one central location for ready access on the HANC public website, including network press releases and responses to study results such as iPrEx.
- A library of centralized laboratory certifications (i.e. CAP and CLIA) for sites.
- Links to Network websites and social media communication resources.
- Community training resources including the Basic Scientific Literacy and the Be the Generation HIV Prevention Research (HPR) Training Module. In addition, the Recommendations for Community Engagement in Clinical Research document and Native American Engagement in Clinical Research Best Practices are available on the website.
- 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 2015 which took place from February 23-26th were posted to the HANC website.
- Ongoing maintenance including posting of updated laboratory certificates and documents to the ACTG/IMPAACT Laboratory Manual.

### 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 June 1, 2015, 2,426 individuals have active HANC portal user accounts and 79 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 2015 Work Plan include:

- Ongoing improvements to the HANC Portal and team site content to better support the objectives of the working groups in 2015.
- 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.
- 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 and 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](http://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, 2015, HANC had 223 friends on Facebook and is being followed by 55 people. HANC is following 312 accounts on Twitter and is being followed by 256. HANC had 454 connections on LinkedIn. During the six-month period, HANC’s public website had 3,955 unique visitors with over 18,000 page views. The average user spent 2’38” on the website. There were a total of 253 unique visitors that used the HANC portal during the same time frame with a total of 13,714 page views. The average user spent 8’58” on the HANC portal.**

### Clinical Research Support Contract

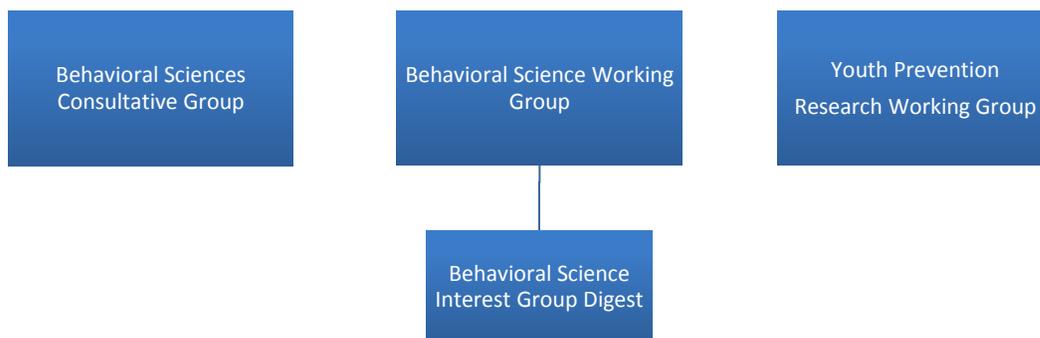
The HIV Clinical Research Support (CRS) contract between DAIDS and the contract research organization can be accessed by the networks to fund a variety of clinical research support tasks, from monitoring study conduct to providing simultaneous translation services for meetings. Networks request network-specific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

**No requests were submitted during this reporting period.**

## 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.**
- **The Behavioral Science Working Group also planned a subject matter expert consultation on qualitative research and the methods and tools used to collect qualitative data. The volunteer planning committee held eight planning calls during the first half of the fiscal year planning for the June 5, 2015 consultation.**

**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 376 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.**
- **Co-chairs of the BSCG held a conference call with Dianne Rausch to discuss next steps for the group.**
- **Available BSCG members met face-to-face for a lunch session during CROI 2015 in February, 2015 in Seattle.**
- **The BSCG planned a face-to-face meeting to convene at the conclusion of IAPAC in Miami, FL on July 1, 2015.**
- **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 provide feedback for MTN 031. The BSCG is also**

started providing feedback to HPTN for HPTN 083. A separate ad-hoc volunteer committee has been put together to continue assisting HPTN on the qualitative components of HPTN 083.

- The BSCG has started collecting information on how the networks share data. The BSCG is considering creating a data sharing chart.

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 2015

Behavioral Science Objective #1: Members of the BSWG will report back from plenary sessions at network annual meetings to discuss new developments and their implications for network science, take stock of lessons from related domains, provide new and ongoing adherence counselor training, elicit community working group input on adherence measurement and counseling, etc.

- **This is an ongoing activity. BSWG members are encouraged to report back from network and non-network meetings to discuss new developments.**

Behavioral Science Objective #2: Convene a subject matter expert consultation to discuss qualitative data by looking at the most effective and the most efficient methods used in large prevention studies and develop a best practices/recommendations document. The subject matter expert consultation will be held in Q1 or Q2 of 2015.

- **The BSWG hosted “Qualitative Research: Best Practices Informed by Study Design, Data Collection, and Analysis” subject matter expert consultation on May 5, 2015. There were a total of 32 participants in the one-day subject matter expert consultation.**

Behavioral Objective #3: 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 April 14, 2015 on HPTN 077 titled,**

**“Moving forward with development of GSK1265744 (cabotegravir) for long-acting injectable PrEP in men and women”. Raphy Landovitz presented to a group of nearly 50 webinar participants.**

Behavioral Science Objective #4: 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 activity within the networks. HANC also created the “BSIG Rx Connect” which allows researchers to pose behavioral and social science questions to their colleagues via email.**

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.**

Behavioral Science Objective #6: Collaborate on shared products such as white papers or manuscripts, conference proceedings, and workshops.

- **The BSWG has discussed ongoing network behavioral and social science activities. The BSWG will likely work together to write a paper from the qualitative research subject matter expert consultation.**

Behavioral Science Objective #7: 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 library has been created and is updated as needed.**

Behavioral Science Objective #8: Collate and analyze behavioral data elements across network studies for analysis by scholars/fellows in network mentor programs and other junior investigators.

- **This has not been done.**

## Youth Prevention Research Working Group

Major accomplishments during this reporting period:

- **The group held five teleconferences during the reporting period. During this period, the YPRWG planned a 3-hour Adolescent Combination HIV Prevention workshop at the annual HPTN/IMPAACT conference on June 17, 2015. Four speakers agreed to present, two from the MP3 protocols (Linda-Gail Bekker and Ann Kurth), one from the PEPFAR DREAMS initiative (Heather Watts) and a methodologist with adolescent prevention research and MP3 design experience (Jim Hughes).**
- **In addition, the group is planning two webinars later in the year on topics of interest including adolescent engagement and community advisory boards, and IRB/Ethics Board training in adolescent research topics.**
- **The group also developed and administered a survey in mid-2014 to 150 Clinical Research Sites, and again to 29 recently funded NICHD IMPAACT 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 was completed and shared with YPRWG leadership and with relevant HANC work group members.**

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 18, 2015 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. The resulting report was distributed to OCSO and DAIDS leadership as well as relevant HANC work groups.**

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.

- **Though the group email alias is occasionally used for information and resource sharing, this goal, upon early 2015 review, was found to be a challenge due to inadequate resources and possible redundancy.**

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. There is still interest in pursuing this objective.**

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 objective is addressed on an ongoing basis during the monthly YPRWG group call—sharing of trial designs, progress, goals, etc. in protocols focusing on PrEP, vaginal swabs to test for HIV exposure, cash transfer in adherence, a dapivirine ring, and combination prevention strategies, among numerous other adolescent research projects.**

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 detailed in Objective #4 above.**

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. However, while the group membership is representative of the diverse interests, attendance on the monthly calls is not always representative. The group has discussed a survey of the YPRWG members to determine their ongoing interests and highest priority topics or projects. This will be discussed further in the second half of this year.**

## 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.

- **The group held three teleconferences during the reported period. In December, 2015, the group provided reports/updates from various meetings, including HIVR4P.**
- **During the February 2015 call, the group discussed the results from VOICE. During the April 2015 call, the group discussed the CROI 2015 highlights, in particular: Proud and Ipergay, Partners PrEP Demonstration Project and FACTS 001.**

### 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 2015

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.

**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:**

- **CP SWG representatives attended the January 2015 SWG meeting on behalf of CP.**
- **The CP Ethics WG invited co-chairs, Annet Davis-Vogel and Liz Barr from the Women’s HIV Research Collaborative (WHRC) to the call to share information with the WG based on discussions with Katy Godfrey, DAIDS Medical Officer, regarding the issue of contraception guidelines for women enrolled in clinical trials**
- **CP sent a letter to the NLG, and copied to DAIDS, concerning community input into co-enrolling protocols among networks.**

- As part of the collaboration with the TB Community Research Advisory Group (CRAG), to help educate TB community members and researchers about HIV, and to help educate HIV community members and researchers about TB and how the two diseases are connected, CP created a TB Resources Page on the HANC Public Site.
- CP and CRAG submitted abstracts to United States Conference on AIDS 2015, the CDC Prevention meeting and the Lung Meeting in South Africa later this year. CP presented at the TBTC CRAG meeting in Atlanta on May 4, 2015. The joint TB/HIV abstract, *TB/HIV International Community Partnership*, was accepted as a workshop presentation by the United States Conference on AIDS 2015.
- CP, in collaboration with a local partner, Gay City Health Project, conducted a field test of the basic scientific literacy learning module on May 2, 2015. The module and activities were well received. Minor revisions will be made based on the testing.
- CP invited Melissa Austin, HANC Lab Coordinator, to the May 2015 CP call to discuss TB infection control site surveys developed by the TB Lab Diagnostic Group.
- CP hosted a Webinar focused on TB/HIV on May 27th. Presenters included Sharon Nachman, Amita Gupta, Anneke Hesselning and Lindsay McKenna.
- Sam Garner discussed the paper that he co-authored, *Testing the waters: Ethical consideration for including PrEP in a phase IIb HIV vaccine efficacy trial* during a CP Ethics call.
- CP received and discussed the response from the Network Leadership regarding community engagement and meaningful input in the multi-network protocol development process.
- CP initiated SWG representatives solicitations/elections in May 2015.
- CP Training and Ethics WGs initiated development of Informed Consent slide deck for community and site staff.

### Data Management Center Coordination

The network Statistical and Data Management Centers (SDMCs) have identified key areas in which the sharing of expertise, resources, and procedures will strengthen the capacity and increase the efficiency of data management operations.

The DMC Working Group includes representatives from FSTRF, SDAC and SCHARP, and meets on monthly teleconferences to carry out activities to address cross-network data management coordination objectives.

AIDS Defining Events Working Group includes representatives from SCHARP, SDAC, FSTRF, DAIDS and clinicians and meets semi-annually. The group is charged with mapping adult and child CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use when MedDRA is updated.

- **The ADE Working Group includes SDAC representatives, HANC, and 3 clinicians. As of October 2014, HANC has taken on more responsibilities with the process including reviewing list of new Proposed Terms and PT promotions and demotions, as prepared by SDAC, call coordination and moderation, and preparing the ADE updates in formats for easy upload by SDAC into their system.**
- **Upversioning for the HIVSTAGE MedDRA v18.0 was completed April 2015. Over 500 new PTs were reviewed and the relevant revisions were made to the programming of the HIVSTAGE macro in collaboration with SDAC colleagues.**

The IT Best Practices Task Force includes representatives from the DMCs, OCICB, and DAIDS, and meets biannually via teleconference calls, to review and revise the IT Best Practices Guidance Document.

- **The biannual review is ongoing with the first call of the ad hoc group conducted in May 2015. It is anticipated there will be major revisions to the guidance document with the increased use of cloud and web-based and electronic data entry.**

### DMC Coordination Work Group

**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 SDMCs and sites. The comments will be discussed in future meetings.**
- **The working group formed a subgroup (the Electronic Data Capture Working Group) to convene with OPCRO representatives and provide input on the redrafting of the Essential Documents and Source Documents SOPs. Jeff Schouten provided a walk-through of the FDA EDC guidelines mentioned above. Subsequently, DAIDS issued a clarification of electronic data capture, in May 2015. Ongoing are the discussions of the revisions to the Essential Documents and Source Documents SOPs.**
- **Ulana Bodnar of Safety and Pharmacovigilance at DAIDS provided regular updates on the DAIDS Toxicity Grating Table and Cross-Center Consistency Check, among other Pharmacovigilance and data-related projects.**

### 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. **No significant activity on this objective occurred in this reporting period.**
- Liaise with DAIDS Enterprise System (DAIDS ES) team to identify areas for collaboration and enhanced data sharing across DAIDS ES and the SDMCs. **HANC representatives participate in the monthly DAIDS-ES all collaborators call.**
- Share 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. **The SDMCs provided monthly updates on their work with the DAIDS CDISC consultant.**

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

Strategies and activities to support this objective:

- **The group reconvened and calls polls were conducted in April-May 2015.**
- **This document is currently in the review process as of the May 21, 2015 teleconference, per biannual schedule.**
- **Both EDC and DMC members were invited to comment, in addition to international and domestic colleagues for EDC Work Group members.**
- **A follow-up call was scheduled for June 11, 2015 to discuss proposed changes to the standards.**

DMC Coordination Objective #3: Harmonization of MedDRA coding and revisions of the HIVSTAGE coding program.

Strategies and activities that supported this objective:

- **This project was completed per schedule, under the HANC Laboratory Coordination group, led by Melissa Austin.**

## 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 2015

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**
- **Creation of cross-network Community Indicator question library to enhance cross-network awareness of methods and strategies for community evaluation in their site evaluation processes.**

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 that supported this objective:

- **Discussion and sharing of Community Indicator surveys, creation of a combined Community Indicator library, and subsequent selection of cross-network question set consisting of common questions revised to a cross-network standard.**

## 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:

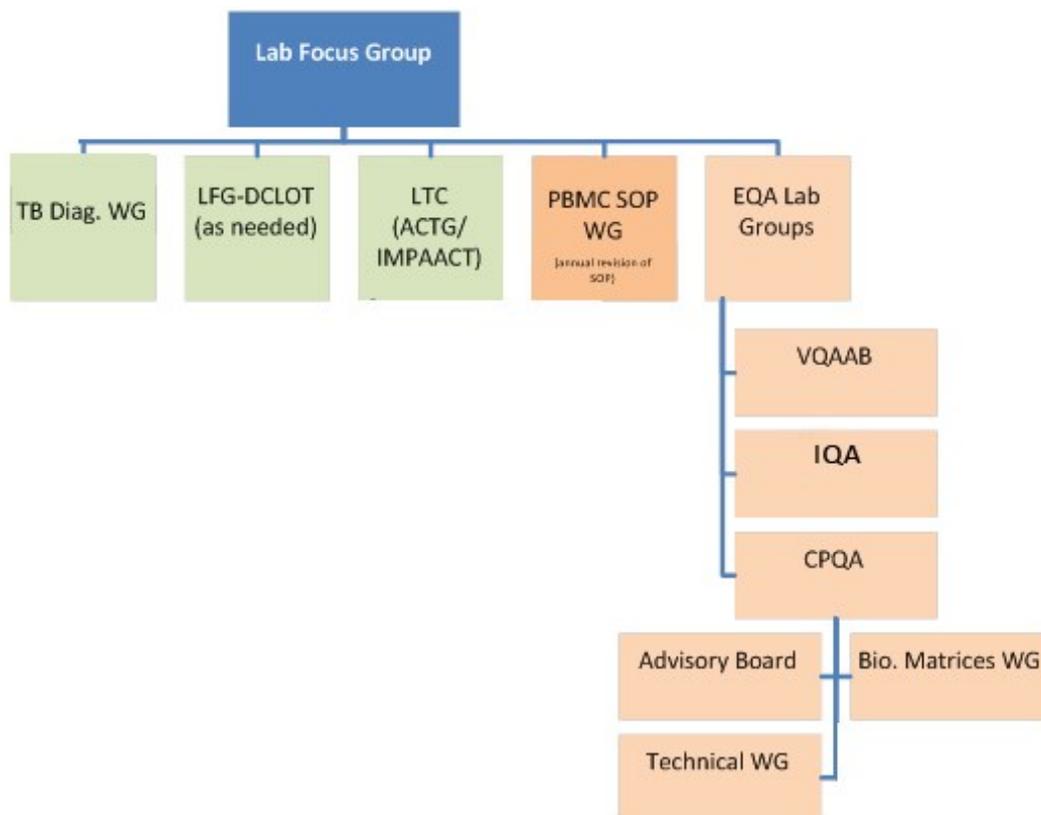
- **Continue to review U.S. Health and Human Services financial disclosure regulations and audit requirements.**
- **Provide feedback to DAIDS and product sponsor's FDA-specific financial disclosure requirements and SOPs.**
- **Consult network grantee institutions on matters of financial disclosure requirements, 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 has updated the SOP as well as the solicitation language for the upcoming 2015 annual solicitation.

## 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.

**Four 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:

- **Fetal Bovine Serum (FBS)-** Members are discussing more economical methods of distributing IQA approved FBS to international sites, especially ones located in the African continent. Issues include country specific mandates of allowable imported FBS.

**Harmonize Lab Processes:**

- **Updated HIV Diagnosis Guidelines to version 4.0** reflecting the updated CDC laboratory guidelines for diagnosis of HIV published in June 2014 and any network specific changes regarding HIV testing.
- **Acute HIV diagnosis:** Topic will be a continuous discussion to possibly develop a cross-network standard of diagnosis and process for acute HIV infection.
- **Updated PNLs as necessary.**
- **Discussions have been initiated regarding harmonization of PBMC Thawing procedures.**
- **Reviewed DAIDS proposed Audit Shells for TB-AFB laboratories and PBMC processing laboratories.**

**Assist EQA :**

- **Reviewed Dec 2014 and March 2015 PBMC Cryopreservation PT reports.**
- **Reviewed QC results for A5315 sample submissions.**
- **Recommended additional data to be included in Laboratory Results Report for PBMC Cryopreservation PT program** such as number of samples thawed to meet QC requirement.
- **Members formulated a group response to DAIDS's recommendation regarding uhCG pregnancy kits from a specific manufacturer in reference to performance issues with low concentrations, after analyzing performance and previous results. In addition, each network developed a plan to track and monitor future data using a new source for the low concentration sample.**
- **Lab leaders harmonized the required minimum amount of samples needed for HIV rapid test validations.**

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.

**One Ad-hoc teleconferences was held during this reporting period.**

- **LFG, DCLOT, and SMILE discussed the low end concentration testing results concerns and possible contributing factors, as well as further investigation and resolution.**

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. *Next revision period is 2016.*

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

**Eleven teleconferences were held during this reporting period.**

- **Initiated SOP/Documents for harmonization:**
  - **Cobas Ampliprep**
  - **Shipping notice for ambient, refrigerated and frozen shipments- Finalized**
  - **Shipment Evaluation Form**
  - **Female Genital Secretion SOP**
  - **Male Genital Secretion SOP**
  - **Category B Shipment Instructions**
- **Prioritized Documents for edits and revisions**
- **Assist FSTRF with LDMS operation- optimizing implementation in labs and creation of LDMS codes.**
- **Discussed issues and/or complexity in upcoming protocols.**
- **Collaborated information about TB procedures**
- **Developed an Orientation and Training booklet for LTC Protocol Support Members**

**One Ad-hoc Call for Shipping Documentation Working Group:**

**Updating shipping forms and documents 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, 2014-May 31, 2015 accomplishments:**

Five teleconferences were held during this reporting period.

**Resource:**

- Reviewed DAIDS Proposed Audit Shell for TB Laboratories
- BARC lab agreed to accommodate Community Partners request for lab demonstration of specimen destruction process.
- Provide forum of expertise with members from ACTG/IMPAACT LTC, TBTC, CDC, FSTRF, and NHLS

**EQA:**

- Reviewed updates to the program and results for GeneXpert EQA program: 2014 3<sup>rd</sup> panel and 2015 1<sup>st</sup> panel
- SMILE EQA Program- reviewed results from Round 2 of 2014
- Reviewed potential EQA program for Line Probe Assay using the same samples for the current GeneXpert PT program

**Infection Control Checklist (ICC):**

- ICCs from 2 sites were reviewed with for a total of 36 sites to date
- Discussions regarding data to be collected for the next round of ICC survey and revision to the checklist were initiated
- Members reviewed manuscript written by Katy Godfrey, Gail Tauscher, et al regarding analyzed data from ICC survey results. A manuscript was submitted for publication in May 2015.

**TB Lab Assays**

- Reviewed results of Culture Isolates Microbank Study Thaws (week 1- Month 9 thaws)
- Provide resources and communication channels for Mylab Group/ TB Core Team for SOP harmonization and process questions.

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.

- **Circulated two 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, 2014-May 31, 2015 accomplishments:**

**Two teleconferences were held during this reporting period (CNLG-Tech).**

**Advisory Board and Bio-Matrices: Call Meetings have been cancelled until further notice**

**CNLG-Tech:**

- **Provided Technical guidance for Round 33 Proficiency Testing**
- **Technical Support of PK techs from CPQA Labs**

**Pilot 3: Testing for Interlaboratory Accuracy and Precision of Intracellular Measurements of FTC-TP and TFV-DP in PBMCs**

- **Three to four labs have volunteered to participate in Pilot 3 Study of this on-going project. One call meeting.**

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

**Six teleconferences were held during this reporting period.**

- **Committee provided oversight for 5 proficiency testing programs: DNA DBS, DNA, RNA, HIV Genotyping and HIV Integrase.**
- **Reviewed data and approved alternative methods for constructing a consensus sequence to evaluate data generated for VQA genotypic drug resistance proficiency testing panels using internally developed assays (In-house). WG will continue to monitor multiple rounds using similar strategy to assure that same trends continue. Alternative methods were developed in response to discontinuation of the TruGene Assay.**
- **Approved switching the ranges of the VQA200 control based on the log shift occurring in the Roche assays in comparison to Abbott RealTime assays after numerous data reviews. New range for the Roche TaqMan assay was set to start in April 2015.**
- **Committee reviewed the changes in lab statuses.**
- **Provided input to Validation/Proficiency Testing program being developed by VQA for Hepatitis Testing.**

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

**During this reporting period:**

1. **Provided information regarding TB/HIV lab issues that have been discussed in TB Lab Diagnostics Working group to Community Partners Working Group.**
2. **Re-designed HANC Portal Sites for LFG and ACTG-IMPAACT LTC.**
3. **Created site for LTC Protocol Support Members.**
4. **Created Graphic Poster version of ICC (Infection Control Checklist) parameters suggested to TB/HIV study sites for implementation. Poster was presented to Community Partners and shared with TBLD-WG and LTC.**
5. **Provided support for ad-hoc calls including, but not limited to, FSTRF-CPQA calls.**
6. **Gathered user needs regarding HANC lab websites to improve usability.**
7. **Provide software support for documentation formatting using Photoshop, Visio, Excel, Word, and Adobe Acrobat.**
8. **Developed tracking methods for various activities such as the infection control checklist (ICC).**
9. **Re-designed HANC Portal Site for CPQA and TBLD-WG.**
10. **Updated HANC Public Sites for Lab Coordination as needed.**
11. **Updated HANC Portal Sites for Lab Coordination as needed.**
12. **Provided technical and communication support for Lab Coordination Working Groups and external collaborators.**

## 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 five teleconferences during the reporting period.**
- **HANC and HVTN Legacy staff held three internal meetings during this period met to discuss and clarify focus of the Legacy 2014 Work Plan and activities.**

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 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: Facilitate community, site and network involvement throughout the research process in the NIH HIV/AIDS clinical research networks.

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

- **An ad hoc group of the WHRC met twice to discuss potential new research projects for the group.**
- **The WHRC Co-Chairs met with the Community Partners Ethics Working Group to discuss partnering on promoting issues regarding women in HIV clinical research.**
- **Katie Godfrey presented on a WHRC call regarding the upcoming changes to the FDA Guidelines regarding women and contraceptives in package labeling.**

*Collaborate with all of the NIH HIV/AIDS clinical research networks and sites to raise awareness among high-risk populations (Black and Latino MSMs, Transgender persons, House Ball community, Black gay pride attendees, Women, etc.)*

- **Actively participated on HPTN 073 protocol team (participated in five meetings between December 2014 and May 2015).**
- **Actively participated on HPTN Black Caucus (participated in 5 meetings between December 2014 and May 2015, and attended face to face meeting during NAESM Conference in Atlanta, GA in January 2015).**
- **Actively participated on HPTN Global Community Working Group (participated in four meetings between December 2014 and May 2015).**
- **Engaged HPTN site in Los Angeles to build and enhance relationships with house ball community and Black gay pride attendees.**

- Engaged MTN core regarding a Black MSM consultation in conjunction with MTN 017.
- Participated in an MTN community consultation to provide guidance on the future direction of rectal microbicides in March 2015.
- Attended and facilitated a conversation of network staff and community members at the HVTN Annual Meeting in May 2015.
- Participated on HPTN 065 community working group (participated in 1 meeting between December 2014 and May 2015, but had multiple interactions with protocol team and protocol PI during this timeframe).
- Participated in community sessions at CROI 2015 in Seattle, WA.
- Cosponsored “The Future of ARV-based HIV Prevention: A Community conversation on understanding new HIV prevention data and what it all means” at CROI on February 25, 2015 with AVAC, SisterLove, US Women and PrEP Working Group
- HANC/Legacy Project staff met with Meico Whitlock from NASTAD to provide consultation on engaging YBMSM in prevention efforts.
- Legacy Project was invited to present the HIV Prevention Research Module 4-hour training at the 2015 HPTN/IMPAACT Annual Meeting.

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

- This is an ongoing collaborative effort to ensure that the BTG website remains current and accurate.

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

- Network staff participated on the Legacy Project Work Group and Women’s HIV Research Collaborative calls. Staff prepared for the presentation of the HIV Prevention Research Module at the HPTN/IMPAACT meeting in June 2015.
- HANC/Legacy staff were actively involved in the Community Engagement Working Group for the HVTN 703/HPTN 081 trials. The Legacy Project proposed several projects to foster increased community engagement in anticipation of the HVTN 703/HPTN 081 trial, in addition to the HPTN 083 trial.

Legacy Project Objective #2: Utilize the Legacy Project to provide information exchange to enhance collaboration and identify further engagement topics/issues.

*Maintain collaborations/partnerships with former BTG partners and select CBOs and ASOs across the US*

- Legacy Project provided technical assistance as requested by former partners.
- Promoted increased literacy of HIV clinical research through emails, enewsletters, and community trainings.

*Conduct capacity building and HIV scientific literacy training with faith leaders to increase culturally appropriate messengers who value research environments and support clinical trial participation. Activities will be evaluated on their ability to provide opportunities to remove obstacles to spiritually-informed HIV education*

- Presented at the Intersection of Faith and Health Conference sponsored by African American Reach and Teach Health Ministries on April 25, 2015 in Seattle, WA.

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 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 Dallas Black Pride with hosting the 4<sup>th</sup> annual Ball House and Pageant Conference. The overall goal of the B/HAP Conference is to reduce health disparities across the southern region of the United States by promoting health equity and improving leadership capacity among sexual minorities and members of the GLBT community.

*Develop strategies to establish and/or enhance linkages/partnerships with other Legacy stakeholders*

- Reviewed grant opportunities to conduct additional formative work that expands on this project's findings regarding the level of research literacy, HIV/STI knowledge and clinical research awareness on HBCU campuses.
- Submitted an abstract for the qualitative data (student focus groups and faculty interviews) to the CDC National HIV Prevention Conference in December 2015 in Atlanta, GA.

*Host webinars focused on raising awareness about recent discoveries and progress on HIV prevention and treatment clinical research advances in collaboration with all of the NIH HIV Clinical Trials Networks among high risk populations. See below.*

*Maintain the BTG Google Group to facilitate communication among the former BTGB partners*

- E-mails were regularly sent to former BTGB Partners to promote developments in HIV prevention research.
- E-mails were sent to the BTG Google Group to encourage awareness of:
  - National Black HIV/AIDS Awareness Day
  - National Women and Girls HIV/AIDS Awareness Day
  - National Native HIV/AIDS Awareness Day
  - National Youth HIV/AIDS Awareness Day

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

- Engaged HPTN sites in 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.
- Legacy Project staff has been invited to take part on a planning committee for the Arts, AIDS, America exhibit at the Tacoma Art Museum (TAM). This is a continuation of the work begun through Legacy's Creating Awareness Through Art (CATA) Initiative. A letter from DAIDS was provided to the TAM for inclusion in the exhibit catalog.

Legacy Project Objective #3: Utilize the Legacy Project to share and disseminate information, training materials and resources.

*Coordinate dissemination and promotion of the BTG HIV Prevention Research and Basic Scientific Literacy Modules*

- **Disseminated weblinks and promoted BTG HIV Prevention Research and Basic Scientific Literacy Modules in presentations during NAESM Conference in January 2015, at the community consultation held by MTN in May 2015, and to community participants at the HVTN annual meeting in May 2015.**

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 79 members representing 28 BTG partner organizations.**
- **An abstract entitled “Improving Knowledge of HIV Prevention Research Methods among Native American/Two-Spirit Communities” was submitted and accepted as a seminar for the 2015 USCA conference.**
- **An abstract on the same topic was submitted to the 2015 CDC Prevention Conference.**

*Host community-focused webinars on HIV prevention and treatment clinical research advances in collaboration with the HIV/AIDS Clinical Trials Networks*

- **On December 10, 2014 the Legacy Project hosted a webinar entitled “Native American Engagement in HIV Clinical Research (NAEHCR) Project Guidance & Best Practices: Lessons Learned and Resources for Working with Urban Native Communities” outlining our collaboration with the National Native American HIV Prevention Center.**
- **On April 2, 2015 the Legacy Project hosted a webinar, “Stuck: Contextualizing the US HIV epidemic among black MSM,” in collaboration with Greg Millett from amfAR.**

*Disseminate a guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project*

- **The NAEHCR Guidance Document was promoted through the above mentioned webinar and on the HANC website.**

*Host workshops/presentations at the National Pow Wows, NAESM, USCA 2015 and other meetings/events aimed at improving community research literacy and support for the NIH HIV Clinical Trials Networks*

- **Legacy Project staff co-authored two abstracts on the house ball community that were approved/facilitated as a workshop and poster presentation at the 2015 NAESM Conference in Atlanta, GA in January 2015.**
- **Legacy Project staff participated on a panel discussion that examined health disparities in the house ball community from a socio-ecological and ethnographic framework.**
- **Legacy project staff presented a workshop at the NAESM 2015 conference on the HIV Prevention Research Module in collaboration with staff from the HPTN, MTN, AVAC, and HVTN.**

*Host or co-host community-focused workshops/presentations on ongoing network research including Cure, PrEP, microbicides and vaccines among high risk populations at meetings/events*

- **Legacy Project staff facilitated a community workshop on HPTN 065, specifically focusing on the impact of financial incentives, with the ACTU Community Advisory Board in April 2015.**

*Host workshops/presentations on the HBCU Lincoln Project and submit abstracts to present findings at NAESM and USCA*

- **The Legacy Project submitted an abstract for workshop presentation to the CDC National HIV Prevention Conference to be held in Atlanta, GA in December 2015. Abstract highlights the qualitative data collected from the HBCU project and recommendations for next steps for engagement of HBCUs in HIV clinical research.**

*Host workshops/presentations on the House Ball Project and submit abstracts to present findings at NASEM and USCA*

- **The Legacy Project submitted an abstract for a workshop presentation to the CDC National HIV Prevention Conference to be held in Atlanta, GA in December 2015. The abstract is a collaborative session that will highlight the cumulative impact and best community engagement practices of several house ball community projects from CBOs and research centers around the country.**

*Publish and disseminate results of the HBCU Lincoln Project and the House Ball Project*

- **Completed the executive summary for the survey data associated with the Lincoln University-Legacy Project HBCU Project and provided to DAIDS and network leadership.**
- **Started drafting a manuscript examining how successful the project was by the inclusion of community-based participatory research principles in the engagement of the HBCUs and recruitment of the study participants (students and faculty).**
- **Started drafting another manuscript, highlighting the quantitative student survey data collected during the project, for submission to the American Journal of Public Health.**
- **Held discussions regarding additional potential publications that will focus on the focus group and interview qualitative data specifically.**
- **Re: House Ball Initiative- Coalition members, including Dr. Sheldon Fields, met in April 2015 in Los Angeles to discuss proceeding with another data collection effort that could serve as the primary data reported out in a publication. Stephaun Wallace will lead in the new data collection effort. To expand on the initial work done with the house ball community from the April 2012 face to face community consultation held in DC, the National House Ball Community Change Coalition (a body that organized in response to the 2012 consultation) will be distributing a survey to house ball members around the country (anticipated n>500) in order to assess the level of health and research literacy, HIV/AIDS knowledge and awareness, and clinical research awareness. It is expected that this survey will be distributed before the end of 2015. The data collected from this survey will be used as primary data for a manuscript to be developed that focuses on this project and outcomes.**

*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.**

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

*Collaborate with DAIDS, WHRC, Community Partners and the NIH HIV/AIDS clinical research networks to address transgender culturally competency and inclusion in network protocols*

- **Legacy Project staff actively participated on the DAIDS Cross-Network Transgender Working Group (participated in three meetings between December 2014 and May 2015), and assisted with developing and editing the memorandum that went out to DAIDS leadership, network and site principal investigators, and coordination centers about the inclusion of transgender and non-binary gender demographic variables in data collection efforts. The memorandum went out in April 2015.**

*Pursue funding opportunities in collaboration with Lincoln University to build on the findings and recommendations of the Historically Black Colleges and Universities (HBCUs) project to increase awareness and support for HIV/AIDS Clinical Research among HBCU faculty and students*

- **Reviewed funding opportunities as they became available.**

*Pursue funding opportunities in collaboration with House Ball Project community partners to build on the findings and recommendations of the National House Ball Community Change Project to increase awareness and support for HIV/AIDS Clinical Research among House Ball communities nationally*

- **Reviewed funding opportunities as they became available.**

## 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 January 2015.

**Russell Campbell attended the January 28-29, 2015 SWG meeting during which the HVTN presented an update of the P5 Southern Africa vaccine trials. Russell also attended the NIAID meeting focused on prevention research in special populations.**

### **Network Leaders and DAIDS**

HANC organizes focused monthly and ad hoc conference calls with the network Principal and Co-Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also hold bimonthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a monthly call with the leadership of OCSO leadership.

**The NLG had four calls in this reporting period.**

**DAIDS-HANC leadership had three calls during this reporting period.**

**OCSO Leadership-HANC had two calls in this reporting period in addition to a face-face meeting March 18, 2015 to discuss the OCSO Site Resource Catalog.**

## 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 2015**

**Four teleconferences were held during this reporting period, with a fifth, abbreviated call's summary sent as an email message.**

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.

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 and site-related updates. Topics included training opportunities and coordination, cross-work group updates, site monitoring policies and regulations, group project brainstorming, and other items as described below.**
- **Guest speaker Larry Allen of DAIDS attended two calls to speak about and provide a walk-through of the DAIDS Toxicity Table v2.0 and its associated training webinars and resources, and to respond to inquiries from the group.**
- **The group also was regularly informed by HANC of developments in the Electronic Data Capture Work Group and OCSO Site Resource Catalog projects as these areas pertain to site operations.**

### **Training Resources**

#### **Training Resources Objective for 2015**

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 staff regularly update the training resources library on the HANC website and post new training information as requested by DAIDS and the networks.**

### **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 was scheduled for 2014, but this was deferred due to the refunding of the network and sites.

- **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 30<sup>th</sup> 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 2014 HANC Biannual Collaborator Survey post recompetition to allow the new collaborators some time to begin their work with HANC. This issue will be readdressed with the Network Leadership Group in the second half of 2015.