Office of HIV/AIDS Network Coordination
Year 7 Extension Work Plan

June 1, 2013 – December 31, 2013

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Introduction

The Office of HIV/AIDS Network Coordination (HANC) works with the NIH HIV/AIDS Clinical Trials Networks primarily funded by the Division of AIDS (DAIDS) of 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: 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 Year 7 Extension Work Plan outlines cross-network coordination objectives and activities for the period of June 1, 2013 - December 31, 2013. The objectives, strategies and activities detailed herein have been developed in consultation with each of the relevant work groups. The document is intended to communicate and guide
coordination efforts at a high level. Progress in meeting objectives will be monitored and communicated on a regular basis by HANC staff, as outlined on page 32.

### Major Cross-Network Projects

<table>
<thead>
<tr>
<th>Area</th>
<th>Group Responsible</th>
<th>Objective</th>
<th>Intended Impact</th>
<th>Timeline and Completion Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Working Group</td>
<td>Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science.</td>
<td>Endeavor 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.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Working Group</td>
<td>Maintain a repository of measures, data forms, and standardized core elements of interventions</td>
<td>Facilitate sharing of information and state-of-the-science practices.</td>
<td>Ongoing</td>
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<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Working Group</td>
<td>Collaborate on shared, permanent products such as white papers or manuscripts, meetings, and workshops.</td>
<td>Leverage experiences and “lessons learned” from research for integration into network protocol planning. WG to host one F2F meeting in June 2013.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Behavioral Science</td>
<td>HANC staff</td>
<td>Maintain “Behavioral Science Interest Group” alias and resource center for network-affiliated behavioral and social scientists.</td>
<td>Circulate notice of important tools, measures, CRFs, meeting notices, and articles. Host “topics of interest” webinar series.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Communications</td>
<td>Communications WG</td>
<td>Leverage network experience and expertise; collect communications tools and measures; and harmonize elements of the networks communications plans.</td>
<td>Increased coordination and consistent messaging.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Communications</td>
<td>IT Infrastructure Task Force</td>
<td>Provide opportunity for networks to share IT expertise, address challenges, and harmonize elements of websites</td>
<td>Provide the networks a forum to discuss IT issues and new technology; Improved navigation of network public sites.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Partners</td>
<td>Gather and collate information on community engagement mechanisms that are best practices across sites and share this with Networks, including posting CAB newsletters on the HANC Website.</td>
<td>Share information across Networks</td>
<td>Ongoing</td>
</tr>
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<tr>
<td>Community Coordination</td>
<td>Community Partners</td>
<td>Revise CP’s values and mission, develop a series of goals or organizational status statements which will describe and define the work of CP over the next three years and identify key strategies to reach the identified goals and address key issues.</td>
<td>Guide CP’s work over the next three years as part of the Network restructuring.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Partners</td>
<td>Utilize CP to provide broad input and recommendations to DAIDS for upcoming Network restructuring.</td>
<td>Improve the quality of engagement with DAIDS, across Networks and with other Infections Disease groups.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Training Working Group</td>
<td>Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Develop a strategy to measure dissemination and promotion across networks. Access the value of materials and determine additional priority topics. Develop cross-network guidance document for staff working directly with CABs. Gather and catalogue available training resources on the HANC website. Work to make CP training modules on the DAIDS LMS available in an open access forum</td>
<td>Common community member understanding of basic concepts in HIV, TB, Malaria, and Hepatitis C, scientific literacy and clinical trials methodology, and CAB role. Improved training quality and consistency.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Evaluation Working Group</td>
<td>Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact. Serve as advisory group to HANC’s evaluation projects.</td>
<td>Use CP Guidelines and other clear measures to demonstrate the value of Community Partners. Data to identify opportunities to increase CP effectiveness.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Ethics Working Group</td>
<td>CP will provide cross-network input to DAIDS to support the development of ethical guidelines and considerations into trial design and conduct.</td>
<td>Solicit feedback regarding ethical considerations and provide recommendations to DAIDS</td>
<td>Ongoing</td>
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<tr>
<td>Community Coordination</td>
<td>Community Site-Level Funding Working Group</td>
<td>Review site-level CAB funding and support to identify areas where funding and support mechanisms are working well and areas where there are opportunities for improvement. Provide information/input to DAIDS and Network Leadership and develop recommendations pertaining to site-level CAB funding based on survey findings and other information and community experiences.</td>
<td>Identify expectations for CAB support and funding that can tie into cross-network community evaluation and make recommendations that are actionable to the Network Leaders and DAIDS.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group</td>
<td>Implement Information Technology Best Practice Standards at DAIDS Clinical Trials study sites and affiliated laboratories and monitor infrastructure changes. Coordinate with SDMCs on changing IT best practices and electronic data capture guidelines.</td>
<td>Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems used by the DMCs.</td>
<td>Version 2.0 issued. Annual revisions anticipated.</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group</td>
<td>Maintain and update Safety &amp; Reconciliation Policy statement developed with OPCRO and RSC; identify and implement useful fields in DAERS (e.g., onset date); review and harmonize adherence to DAIDS Term Selection Guidelines..</td>
<td>Improve communication across SDMCs, DAIDS, and RSC; minimize unnecessary reporting; increase efficiency by moving to electronic sign-off; improve SAE/EAE data collection and analysis; advance common definition of terms and processes.</td>
<td>Ongoing review of systems and processes. Safety &amp; Reconciliation policy will be upversioned in Year 7 Extension Q1.</td>
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<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group</td>
<td>Harmonize data definitions and standards for compatible all network use; e.g., respond to CDISC requirements in the SDMC FOA, monitor electronic data capture best practices and Federal guidance; coordinate anticipated two-way reconciliation across SDMC and RSC data systems.</td>
<td>Formalize expectations among network and DMC staff and reduce duplicative systems.</td>
<td>Ongoing. Develop two-reconciliation plan by Year 7 Q2 for implementation in new award cycle.</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation Committee</td>
<td>Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks.</td>
<td>Identify streamlined reporting processes.</td>
<td>Dec 2013</td>
</tr>
<tr>
<td>Evaluation</td>
<td>HANC Staff</td>
<td>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.</td>
<td>Identify evaluation methodology and the impact of community participation on the Networks’ scientific agenda and protocol development process</td>
<td>Dec 2013</td>
</tr>
<tr>
<td>Infrastructure and Admin Support</td>
<td>HANC staff</td>
<td>Review website and portal user statistics and member survey data to inform HANC programmatic and portal improvements.</td>
<td>Improved communication and access to information to support decision-making and completion of cross-network objectives. Increase awareness of ongoing HANC coordination activities and potential new opportunities.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>ACTG/IMPAACT Lab Technology Committee</td>
<td>Update SOPs in the ACTG/IMPAACT Laboratory Manual</td>
<td>Consistent processing and testing at ACTG/IMPAACT laboratories; sharing of useful SOPs with other networks and extra-network organizations.</td>
<td>Ongoing</td>
</tr>
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<tr>
<td>Laboratory Coordination</td>
<td>PBMC SOP WG</td>
<td>Complete and implement version 5 of Cross-Network PBMC SOP.</td>
<td>Consistent PBMC processing at network labs.</td>
<td>Q1 Complete v5 of SOP; Q2 (Nov 13) Require SOP at all English speaking sites and request translations; Q1 2014 Require SOP at all sites</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>LFG, IQA CD4 WG, ICAG</td>
<td>Complete review and revision of EQA Monitoring SOPs and Investigation Report Procedures</td>
<td>Consistent and defined practices for monitoring EQA and investigating/reporting on root cause analysis for overall quality of laboratory processing and testing.</td>
<td>PBMC Cryo: June 2013; Flow Cytometry: Sept 2013; Patient Safety Testing December 2013</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>Malaria Lab Network</td>
<td>Plan and conduct advanced microscopy certification opportunity</td>
<td>Certification of advanced microscopists for participation in network and non-network clinical studies.</td>
<td>November 2013</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Establish and or enhance partnerships and collaborations with government agencies, scientist, CBOs and ASOs, medical/academic institutions, specialized institutions/networks, experts/advisors.</td>
<td>Increased awareness of critical need to improve support for, and participation of disparately impacted populations in HIV clinical research.</td>
<td>Ongoing</td>
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<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Influence the creation of scientific agendas and research that responds to community priorities. Conduct and support primary research on community engagement, clinical trial participation and the relationship between them. Develop innovations, models and/or strategies that promote enhanced, active and strategic collaborations that yield improved capacity at the individual, organizational and community level.</td>
<td>Increased enrollment of representative populations in HIV clinical research studies and identify best practices to achieve this objective.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Build the capacity of communities and researchers to equally partner in the research enterprise.</td>
<td>Increased research literacy in communities most impacted by HIV and increased cultural awareness and responsiveness of research staff and sites.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>Financial Disclose/Conflict of Interest Working Group</td>
<td>Work closely with network staff and DAIDS to review the harmonized network Conflict of Interest/Financial Disclosure requirements, and maintain the cross-network web-based reporting interface.</td>
<td>Coordinated solicitation will minimize burden on sites, operation center staff, and investigators required to report. Continue to improve and adapt the SOP and secure online system for ease of use and clarity, and to ensure concordance with federal regulations</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>Network Leaders, OCSO, OPCRO, HANC Staff</td>
<td>Work closely with network staff, OPCRO, OCSO and other DAIDS offices to identify and address priority site management issues.</td>
<td>Improve communication and site operations.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>Site Coordinators Working Group</td>
<td>Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks’ core operations centers.</td>
<td>Address issues of common concern and harmonize policies and procedures regarding site-level operations.</td>
<td>Ongoing</td>
</tr>
<tr>
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<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>Site Coordinators Working Group</td>
<td>Facilitate collaboration with the WG, OCSO and relevant members of the new networks to harmonize reporting requirements and increase transparency.</td>
<td>Improve budgeting and reporting processes while dealing with multiple networks at the site level.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>HANC Staff</td>
<td>Create a mapping table defining operating elements such as roles and procedures across the networks and core/operations centers.</td>
<td>Providing staff a quick reference point for clarity around different terms with synonymous meaning.</td>
<td>Dec. 2013</td>
</tr>
<tr>
<td>Training</td>
<td>Training Committee</td>
<td>Identify and provide access to cross-network standardized training for high priority topic areas.</td>
<td>Provide training support to the sites.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Training</td>
<td>HANC staff</td>
<td>Partner with the DAIDS Training and Safety Branch on development and deployment of training resources.</td>
<td>Serve as a liaison between the networks and external collaborators on training needs.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Training</td>
<td>Training Committee</td>
<td>Identify potential administrative/fiscal training materials needed at the site level.</td>
<td>Educate experienced and non-experienced sites on the new administrative/fiscal requirements.</td>
<td>Dec. 2013</td>
</tr>
</tbody>
</table>

**Infrastructure and Administrative Support**

**HANC Staff Role**

HANC staff serve an administrative and project management role on each of the cross-network committees and working groups. As a working group or committee identifies areas of need or opportunity, HANC staff are responsible for developing and monitoring an action plan and documenting progress and challenges. HANC staff identify individuals to take on each task and encourage the relevant working group to sustain the effort to complete the work, acknowledging that members participate in working groups and take on cross-network tasks voluntarily, above and beyond their responsibilities within their primary organization. HANC staff are responsible for setting call and meeting agendas, drafting and distributing materials, coordinating logistics for and chairing teleconferences and meetings, taking minutes and ensuring that action items are communicated, tracked and completed. HANC staff manage HANC portal team sites as a collaborative space for each working group, develop web-based tools and train group members how to utilize them. HANC staff are an important conduit of information between different groups with potential shared interest or overlap in activity (e.g. ensuring that staff involved in Training coordination communicate regularly with those involved in Laboratory Operations coordination regarding plans for Good Clinical Laboratory Practice training). Additionally, HANC staff are continuously considering opportunities for cross-network coordination and collaboration. When they become aware of such opportunities they present them to the relevant working group, or bring them to the Network Leaders and DAIDS and form new working groups or ad hoc task forces as needed.
The HANC Public Website

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

- A dynamic calendar of scientific conferences, network meetings, community events, training opportunities, and more.
- Some of the Division of AIDS’ Office of Clinical Site Oversight Clinical Research Policies and Standard Operating Procedures that are not listed on the DAIDS website and a link to the official versions of all current DAIDS Clinical Research Policies that are posted on the NIAID/DAIDS web site.
- A dynamic announcement section on the home page for posting important notices, such as the iPrEx and CAPRISA 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.
- The HANC blog as well as an easily updated program spotlight applet on the homepage.
- A library of centralized laboratory certifications (i.e. CAP and CLIA) for sites.
- Links to Network websites and social media communication resources.

In June 2010, HANC completed a total redesign and upgrade of the public website in a SharePoint 2010 environment. The project involved a thorough reorganization of the site, improved navigation and ease of content modification by project managers, a new logo, and refreshed content. DAIDS and network staff provided feedback throughout the process. The Year 7 Extension will see ongoing adjustments, additional resources, and improvements to the new design.
The HANC 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. At the beginning of Quarter 4, Year Seven, approximately 1,137 individuals had active HANC portal user accounts and 81 secure team sites were 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 Year 7 Extension include:

- Ongoing improvements to the HANC Portal and team site content to better support the objectives of the working groups in Year 7.
- 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 (to be implemented in the Year 7 Extension allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.
- HANC program staff provides programmatic updates on the “Daily Dose” announcement box.
- HANC staff and working group members will continue to curate content for the Communications Resource Center site.
- Create portal accounts for all CTU site leaders and coordinators.
- Continued optimization of HANC “Contact Management System” which integrates the portal permissioning, email aliases, and contact lists.

Social Networking & Information Sharing

HANC has Twitter (search for “Hancprograms”), Facebook (search for “Hanc Programs”), and LinkedIn accounts to share general programmatic updates with a broader audience. Due to the interest in the resources shared in the HANC newsletter, HANC staff has increased the publication frequency from quarterly to monthly. “HANC Portal 101s” are now offered on a monthly basis. HANC members are invited to participate in a walk-through of portal/website resources and given the opportunity to learn more about SharePoint technology. HANC will provide individualized trainings for networks and affiliated partners as requested. HANC now has a YouTube page (youtube.com/officeofhanc) to broadcast and share network videos. HANC has started using Google analytics to track the most used resources and pages on both the HANC public and portal websites. HANC is exploring further customization of the reports generated by Google analytics in order to be able to track trends.

Clinical Research Support Contract

The HIV Clinical Research Support (CRS) contract between DAIDS and the contract research organization can be accessed by the networks to fund a variety of clinical research support tasks, from monitoring study conduct to providing simultaneous translation services for meetings. Networks request network-specific Clinical Research Support contract through their designated point of contact at DAIDS. Requests for CRS services that apply across networks are made through HANC. HANC coordinates the development of cross-network CRS requests, submits them to the CRS project officer, tracks their progress, and liaises with DAIDS. Tools on the HANC Portal streamline CRS Request submission, tracking and status communication. Twenty-two cross-network CRS requests have been submitted since the CRS contract was initiated. Details of CRS requests can be viewed at http://portal.hanc.info/crs.
Objectives and Activities by Area of Coordination

Behavioral Science Coordination Objectives and Activities

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 hosts a “Technologies and Measures Task Force” pursuant to a recommendation emerging from the Year 7Q2 “Electronic Behavioral Data Capture Focus Group”.

- **Behavioral Science Interest Group (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 500 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.

- **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, 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 the Year 7 Extension**

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

**Behavioral Science Objective #2:** Maintain a repository of measures, data forms, and standardized core elements of interventions accessible to partnering networks. The documents and links are housed on the HANC public website under “Behavioral Science Publications” and/or the HANC portal’s “Behavioral Science Interest Group Resource Center”.

**Behavioral Objective #3:** Collate and analyze behavioral data elements across network studies.

**Behavioral Science Objective #4:** Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings, and workshops. The Working Group will explore hosting face-to-face meetings and topic-specific focus group.

**Behavioral Science Objective #5:** Study and promote the development and implementation cross-network/trans-Institute studies and/or behavioral data elements in network studies. Analyze funding and scientific review procedures. Convene a group of experts, the “Cross-Network Behavioral Science Advisory Group” (BSAG) in coordination with the National Institutes of Mental Health (NIMH). This group will include approximately eight investigators, four affiliated with the NIH HIV/AIDS Clinical Trials Networks and 4 unaffiliated investigators, who will meet by teleconference monthly and face-face bi-annually. This group will provide expert opinion to the NIH HIV/AIDS Clinical Trial Networks on the behavioral components of their research studies: including, but not limited to, advice on protocol design, protocol implementation and methodology for data collection and evaluation.

**Behavioral Science Objective #6:** Improve information exchange among network-affiliated behavioral and social scientists. 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.

**Behavioral Science Objective #7:** Facilitate discussions and meetings to develop a cross-network behavioral science scientific agenda. Build on the discussions and recommendations considered at the 2012 and 2013 BSWG meeting considering this objective. Address questions in topic-specific focus groups as needed.

**Behavioral Science Objective #8:** Convene a BSWG Technologies and Measures Task Force to consider the networks’ adoption of novel technologies, provide expert advice on implementation of these tools in studies, and consider the extent to which the intervention enhances study objectives and provides accurate behavioral data.

**Behavioral Science Objective #9:** Interface with ongoing behavioral science projects such as the Youth Prevention Research Working Group, the DAIDS Risk Assessment Best Practices Working Groups, and intra-network behavioral research committees.
Youth Prevention Research Working Group Coordination Objectives for the Year 7 Extension

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

Youth Prevention Research Working Group Objective #2: Identify key metadata terms; expand a custom robust and searchable database of relevant materials; and identify search parameters to identify research gaps. The database lives on the HANC portal and be available to the research community.

Youth Prevention Research Working Group Objective #3: Analyze the existing research imperatives, trial results, and protocols in development to identify gaps in the scientific enterprise.

Youth Prevention Research Working Group Objective #4: Working Group members will liaise with their respective Network Leadership and protocol team members to share the assessment of the ongoing research and consider ways to address the gaps.

Youth Prevention Research Working Group Objective #5: Ensure cross-network/trans-Institute communication around research in the youth population.

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

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

Youth Prevention Research Working Group Objective #8: Engage network community representatives and experts in the field. At-large participants could be engage to address technical considerations such as data management and protocol design models.

Communications Objectives and Activities

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 IT Infrastructure Task Force provides a forum for network operations center staff, community liaisons, and data managers to share experiences with existing IT systems, share opinions about emerging technology, and to consider the changing IT landscape and its implications for managing complicated international clinical trials. The Communications WG has monthly calls, the IT Infrastructure Task Force meets ad hoc, and topic-specific trans-WG calls/webinars are scheduled as needed.

Communications Objective #1: Develop cross-network strategic message guidelines and recommendations for study results dissemination.

- Maintain the “Network Study Results & Publications” page and library on the HANC public website.
- 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.
- Expand the “Network Press Release” page and library on the HANC public website.
- Maintain and add functionality to a dynamic web-based map of all DAIDS network sites.
Communications Objective #2: Consider ways to harmonize network communications strategies and external relations policies. Areas of interest include:

- Review and identify points of commonality across network websites.
- Network policies regarding posting protocol documents on public websites.
- Network online recruitment strategies.
- Links to outside parties including all other networks.
- Share 508 compliance information for network websites.

Communications Objective #3: 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.

Communications Objective #4: Share IT- and Communications-related developments across all areas of coordination. Possible areas of coordination include:

- The IT Best Practices document developed by the SDMC Harmonization Working Group.
- Community Partners and the Site Coordinators Working Group concerns about IT needs at resource-challenged sites.
- Implementation and use of DAIDS-ES web services.
- Privacy and IT security issues.
- Novel technologies for communications and behavioral data capture.
- Explore cross-network/SDMC “single sign-on” account federation in collaboration with InCommon.

Communications Objective #5: Review existing methods of evaluating communications efforts and consider which practices could be employed within the networks. Activities to support this objective include:

- Share video production tools and experiences.
- Review existing website usage tools.
- Share experiences using social network sites such as Facebook, LinkedIn, and Twitter and document web traffic generated from new media sites.
- Discuss focus group guidelines and outcomes.
- Collation of these resources for network use.
- Community engagement strategies.

Communications Objectives #6: Review and make recommendations about communications best practices and evaluate available resources such as Microbicide Media and Communications Initiative “Clinical Trial Handbook”. Develop news tools such as a “Social Media Best Practices for HIV/AIDS Clinical Trial Networks”. Explore methods to evaluate the effectiveness of network communications practices.

Communications Objective #7: Invite key stakeholders, opinion-makers, and experts in the field to present on working group calls. Areas of expertise could include: journalists, advocates, bloggers, and communications professionals.

Communications Objective #8: Pursue recommendations emerging from the third NIH HIV/AIDS Clinical Trials Networks’ Communications Symposium in May 2013 and consider coordinating a follow-on face-to-face meeting.
Network and partner representatives will use the time to discuss upcoming communications priorities, network restructuring and consider additional areas of coordination.

**Communications Objective #9:** Identify, implement, and maintain tools to improve cross-network communication. At present, 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

**Community Coordination Objectives and Activities**

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** 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 Partners Structure

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Community Partners; and continued community participation. CP members are representative of the global NIH HIV/AIDS Clinical Trials Networks research sites.
The Community Partners Executive Committee is drawn from the general membership of Community Partners and is empowered to make decisions on behalf of and in the best interests of CP and its general membership in accordance with CP Organizational Guidelines.

The Community Training Working Group considers areas of community training common across networks and standardizes or develops materials that have broad application to community issues around HIV/AIDS clinical research and participation in trials.

The Community Site-Level Funding Working Group reviews site-level CAB funding and support to identify areas where funding and support mechanisms are working well and areas where there are problems or opportunities for improvement.

The Community Evaluation Working Group considers evaluation of Community Partners efforts and activities and develops and implements mechanisms to evaluate Community Partners progress and impact and serves as an advisory group to the EMTF.

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 the Year 7 Extension

Community Partners Objective #1: Develop a community research priorities agenda.

Strategies and activities to support this objective:
- 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 to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups.
- Develop a strategy to measure dissemination and promotion across networks.
- After completion of the training materials, the standardization process and impact of the initial cross-network CAB training module will be assessed and presented to CP. If there is consensus on the value added the working group will select additional priority topics to address using the same process.
- In partnership with DAIDS, develop eLearning modules based on the CP Training Materials.
- Gather and catalogue available training resources on the HANC website

Community Partners Objective #3: CP will consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate our progress and impact and serve as an advisory group to the EMTF.

Strategies and activities to support this objective:
- Develop a continuous quality improvement process for CP.
- Identify objective metrics and mechanisms for evaluating the impact of CP activities.
- Revise the Site Staff and Site CAB Survey.
Disseminate survey results and use findings to help guide future CP activities.

**Community Partners Objective #4: Review site-level CAB funding and support in the current grant period to identify areas where funding and support mechanisms are working well and areas where there are problems or opportunities for improvement.**

Strategies and activities to support this objective:
- Research the current site/CAB funding structure to better understand how the system works.
- Partner with the network leadership to assess how site funding mechanisms have impacted community involvement at the network, CTU, and CRS levels.
- Based on analysis of that information identify expectations for CAB support and funding that can tie into cross-network community evaluation and make recommendations that are actionable to the Network Leaders and DAIDS.

**Community Partners Objective #5: Utilize CP to provide input and recommendations to DAIDS for upcoming network restructuring.**

Strategies and activities to support this objective:
- Develop a clear, written outline of the project scope, intent, and timeline.
- Identify external domestic and international community groups and key stakeholders willing to provide input and recommendations to DAIDS for the network restructuring.
- Collaborate with networks to identify the most effective methods to solicit external community input.
- Gather and organize community input from existing network CABs and external groups regarding the restructuring and make actionable recommendations to DAIDS.
- Share CP FOA recommendations with CABs and Site staff

**Community Partners Objective #6: Gather and collate information on community engagement mechanisms that are best practices across sites and share across networks and with DAIDS to address these 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.
- Collect, review and analyze information related to management of pregnancy and contraception on study to identify and generate related cross-network tools and guidelines/recommendations.
- 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.

**Community Partners Objective #7: 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
- Increase awareness of CP training materials
- Promote CP training materials at full network group meetings
- Gather and organize existing network CAB newsletters to post on the HANC Website.
Data Management Center Coordination Objectives and Activities

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.

DMC Committees and Working Groups

HANC supports three active data management related working groups:

- **DMC Harmonization Working Group** includes representatives from FSTRF, University of Minnesota and SCHARP, meets on monthly teleconferences, and carries out activities to address cross-network data management coordination objectives.

- **AIDS Defining Events Working Group** includes representatives from SCHARP, SDAC, and FSTRF and meets on teleconferences, and is charged with mapping CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use.

- **IT Best Practices Task Force** includes representatives from the DMCs, OCICB, and DAIDS, meets on teleconference calls, and reviews and recommends possible applications of IT best practices at DAIDS-funded sites.

DMC Coordination Objectives for the Year 7 Extension

DMC Coordination Objective #1: Monitor various ongoing data quality assurance projects, identify areas for improvement, provide recommendations, and implement as appropriate. Current activities include:

- Monitor Laboratory Data Management Systems / Multi-LIMS Manifest harmonization. Coordinate upversionings and systems changes as needed.

- Identify site DMC training and support needs and in collaboration with the cross-network lab and training groups develop recommended funding and implementation suggestions to address them.

- Share clinicaltrials.gov results reporting requirements with Network Leaders and DAIDS; identify policies and mechanisms for affected studies and existing data management systems.

- Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS); maintain ongoing dialogue with DAIDS staff regarding the development and requirements of the (DAERS), and share experiences interfacing with the DAERS system on monthly DMC conference calls.

- 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. HANC will coordinate the SDMCs’ monthly DAIDS ES Collaborator call agenda items and follow-up on action items associated with discussions.

• Ongoing consideration and exploration of project management software applications.

**DMC Coordination Objective #2:** Monitor Information Technology Best Practice Standards finalized in Year 6 at DAIDS Clinical Trials study sites and affiliated laboratories and monitor infrastructure changes. Strategies and activities to support this objective:

  • Ongoing monitoring to ensure that infrastructure changes made by one group would not negatively impact the systems used by another IT will be done with monthly DMC Harmonization calls as a forum for discussing any proposed changes.
  
  • Continue the dialogue with OCICB and DAIDS' OCSO to establish understanding of how the organization will work with the networks.
  
  • Annual upversioning and dissemination of the Best Practices to accommodate changes in IT needs and standards.

**DMC Coordination Objective #3:** Harmonization of MedDRA coding.

It would be advantageous in the long run to ensure that consistent MedDRA coding of adverse events (e.g., a single reported verbatim has one corresponding MedDRA term) is maintained across our studies. The SDMC working group will work with the DAIDS MedDRA consultant and DAIDS-facilitated MedDRA Implementation Working Group (MIWG) towards harmonization of MedDRA coding. These efforts will also achieve a higher standard of MedDRA coding. Strategies and activities to support this objective:

  • The HANC-facilitated AIDS Defining Events Working Group (ADEWG) has mapped CDC and WHO clinical stages into MedDRA codes for intra-DMC use. The ADEWG will consult with the MIWG on the semi-annual MedDRA up-versioning and related MedDRA issues. Document and share MedDRA mapping tool utility and application across DAIDS-funded studies.
  
  • Each data center will designate a lead coder who will have completed formal training in MedDRA. This individual may be shared across networks.
  
  • The lead coders are organized into the MIWG, which is chaired by a DAIDS representative. The working group conducts conference calls at least once per month, and will meet face-to-face as needed.
  
  • The MIWG members have developed a DAIDS MedDRA Terms Selection Guidelines document that is a supplement to the ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use) Terms Selection document. This document supports consistent MedDRA coding amongst the MIWG members. The group also developed the MedDRA Versioning Policy for DAIDS that outlines the procedures for updating the network databases with the semi-annual MSSO MedDRA dictionary version releases.
  
  • The DAIDS MedDRA Consultant conducts semi-annual cross-center consistency reviews to ensure the coding correctness and consistency of MedDRA coded data across the SDMCs and RSC. Members of the MIWG submit MedDRA coded data sets that are reviewed for consistency and correctness. Each organizations submitted data is reviewed separately to ensure the coding is
correct and that it follows the rules set forth in the DAIDS Term Selection document. Comments from this review are documented and shared with the individual organization. The data sets, from each organization, are then merged and a review of the data for consistency across the organizations is performed. The outcome of this review is shared with the MIWG for discussion and action if required.

- The MIWG identifies needed MedDRA dictionary updates and changes. The MIWG then reviews and submits MedDRA dictionary change requests to the MSSO.
- Assist in the communication of MedDRA upversioning coordination across SDMCs and RSC. The window has been narrowed to one month with exceptions made in the event of DSMB review, etc.

DMC Coordination Objective #4:
Harmonize data definitions and standards for compatible all network use. Strategies and activities to support this objective:

- In consultation with DAIDS and network operation centers, SCHARP, SDAC, and FSTRF will collaborate to determine the feasibility of the project determine to whom, when, and how data elements should be harmonized.
- The group will solicit feedback for the networks and DAIDS. Developments and recommendations will be circulated to relevant parties.
- Developing a mapping rationale using the CDISC framework.
- Participate as HIV content expert on CDISC organization working groups.
- 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.
- Respond to CDISC requirements as outlined in the SDMC FOA for implementation with new award announcement and pursue areas of collaboration ongoing.
- Continue to monitor FDA guidance on electronic source data; consider implications for SDMC and network electronic data capture (EDC); liaise with DAIDS EDC and regulatory stakeholders; and provide a forum to discuss EDC best practices.
- Review researcher experience implementing and monitoring EDC-based interventions.
- Share electronic data sharing opportunities across DAIDS and SDMCs; e.g., discuss Regulatory Affairs Branch’s response to the FDA Electronic Technical Document requirements.

DMC Coordination Objective #5: Maintain and update Safety & Reconciliation Policy statement developed with OPCRO and RSC.

- Discuss SDMC approaches to the expected two-way reconciliation requirement undertaken by DAIDS.
- Coordinate Expedited Adverse Event (EAE)/Serious Adverse Event (SAE) data element definitions.
- Monitor reconciliation data element exceptions and change requests; e.g., onset date.
- Collaborate with Regulatory Support Center (RSC) on its development of useful reports to minimize discrepancies across SDMCs, RSC, and sites; e.g., redesigning the EAE line listing report.
- Review and harmonize adherence to the DAIDS Term Selection Guidelines.
- Provide feedback to RSC’s internal safety and reconciliation SOP currently under review.
Pursue RSC agreement to implement electronic documentation showing reconciliation review has occurred, discrepancies found, actions taken, finalization.

DMC Coordination Objective #6: Consider hosting a one-day DMC virtual meeting and continue to engage SDMC representatives on relevant HANC working groups and/or meetings. DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination.

DMC Coordination Objective #7: The DMCWG will keep abreast of related HANC activities and contribute expertise as appropriate (e.g., behavioral science, Site Coordinators Working Group, and IT Infrastructure Working Group discussions).

Evaluation Coordination Objectives and Activities

Evaluation Committee

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

Evaluation Coordination Objectives for the Year 7 Extension

Primary evaluation coordination objectives for 2012-2013 include:

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

Strategies and activities to support this objective:

- Monthly cross-network evaluation teleconferences will provide a forum to discuss and address opportunities.
- Determine how to reconfigure new reporting processes for new networks.

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

Strategies and activities to support this objective:

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

Laboratory Coordination Objectives and Activities

Laboratory Committees and Working Groups

HANC coordinates the Lab Focus Group, a TB and Malaria focused group, provides support to the ACTG/IMPAACT Lab Technologist Committee and co-facilitates the DAIDS EQA provider calls.
The Lab Focus Group (LFG) is comprised of Network Laboratory Leadership and management staff. It holds teleconferences once or twice per month 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 LFG-DAIDS Clinical Laboratory Oversight Team (DCLOT) Collaborative Working Group includes members of the LFG and DCLOT and serves as a forum for discussion of various laboratory matters that require input from all the networks and DAIDS. This group schedules ad hoc calls as necessary.

The 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 gives 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.

- The Data Availability Reports (DARs) Working Group is a working group of the ACTG/IMPAACT Lab Tech Committee, which is tasked with developing tools and processes for ensuring that processing laboratories are able to obtain, process, and store the specimens required by each protocol.

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.

- **The CPQA CNLG – Scientific** serves as a forum for the pharmacology specialty laboratory principal investigators to discuss various scientific issues, such as eradication, co-infection, prevention, microbicides on bimonthly webinars.

- **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.

The IQA PBMC Cryopreservation Proficiency Testing Advisory Group (ICAG) collaborates with the IQA to develop and implement a PBMC cryopreservation proficiency testing program for US and non-US laboratories, quality control of cryopreserved PBMC samples at the Biomedical Research Institute (BRI) repository, and considers other questions that affect the quality of PBMC samples on monthly teleconference calls. ICAG includes representatives of ACTG, HPTN, IMPAACT, DAIDS, FSTRF, Westat, NICHD, SDAC and the IQA.

The Malaria Laboratory Network (MLN) was convened by HIV/AIDS Network Coordination (HANC) in May, 2010 to serve as a forum for collaboration among the NIH HIV/AIDS clinical trials networks, DAIDS, and Patient Safety Monitoring in International Laboratories (SMILE) for the establishment and improvement of malaria diagnostics capabilities and procedures and quality assurance for participation in network studies with malaria diagnostics endpoints. The group quickly evolved and expanded to include researchers from other organizations with a shared interest in establishing infrastructure for the improvement of malaria diagnostics for use in both network and non-network studies.

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.

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

**Laboratory Coordination Objectives for the Year 7 Extension**

**Laboratory Coordination Objective #1:** Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.

Strategies and activities to support this objective:
A face-to-face meeting will be scheduled as needed to bring together the Network Laboratory Leadership, DAIDS Laboratory program staff, and key contractors/partners.

LFG teleconferences will 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.

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.

HANC staff will provide the Cross-Network Laboratory Interest Group with monthly updates from the other cross-network laboratory groups.

**Laboratory Coordination Objective #2**: 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.

**Strategies and activities to support this objective:**

- 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.

**Laboratory Coordination Objective #3**: Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.

**Strategies and activities to support this objective:**

- The LTC will review and revise the overall structure of the ACTG/IMPAACT Lab Manual itself and the standard operating procedures and resources that are part of it.

- The LFG will review and revise cross-network guidelines for diagnosis of HIV-1 infection in NIAID-funded network studies.

- HANC staff will continue to expand listings of laboratory training resources on the HANC public website.

- HANC staff and ACTG/IMPAACT network staff will continue to populate the Laboratory Certificate Library on the HANC public website.

- The LFG will 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.
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- HANC staff will work with network staff to coordinate the negotiation of memoranda of understanding and/or purchasing/service agreements with suppliers as necessary.

Laboratory Coordination Objective #4: Collaborate among the networks, HANC, DAIDS and SMILE to improve TB Laboratory, TB proficiency testing and participation of labs with TB diagnostic capacity in network protocols where TB is a component.

Strategies and activities to support this objective, the TB Laboratory Diagnostics Working Group will:

- 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
  - Draft/compile and implement standard guidelines for sample collection, transport and diagnostics
- Coordinate comparative evaluations of TB Laboratory methods.
- Support institution of cross-network international specialty and regional TB laboratories
- Explore opportunities for the development and validation of point-of-care TB Laboratory assays.

Laboratory Coordination Objective #5: Collaborate among the NIH HIV/AIDS networks, DAIDS, NICHD, Patient Safety Monitoring in International Laboratories (SMILE) and other organizations to establish and improve malaria diagnostics capabilities, procedures and quality assurance for participation in network and non-network studies with malaria diagnostics endpoints.

Strategies and activities to support this objective, the MLN will:

- Serve as a forum for NIH-funded and collaborative investigators to share information about malaria diagnostics and recommend information for dissemination and training.
- Be a resource to network and non-network protocol teams:
  - Inform the choice and implementation of malaria diagnostics methods for use in clinical trials.
  - Propose relevant EQA and QC approaches to ensure the quality of study data.
  - Review malaria component of study-specific procedures to include guidance on sample acquisition and processing prior to shipment to testing laboratories as requested.
- Develop a list of malaria diagnostics resources, such as training opportunities and reference standards.
- Offer an advanced microscopy certification opportunity at a major conference.

Legacy Project

The Legacy Project works to increase the participation of historically underrepresented communities most impacted by the domestic HIV epidemic in HIV prevention and treatment clinical research by building on the efforts and successes of the ongoing HIV Vaccine Trials Network (HVTN) Legacy Project. The Legacy Project focuses on partnership and relationship development, both internally among NIH-funded HIV/AIDS Clinical Trials Networks and externally. The Legacy Project is committed to capacity building and infrastructure development within the communities and populations most disparately impacted by the domestic HIV epidemic.

The Legacy Project focuses on establishing and maintaining relationships with key organizations/partners in and among the populations most impacted, private and public that is characterized by trust and respect. The Legacy Project has a national stakeholder engagement program which includes the following stakeholders groups: faith-based
community, historical civil rights and political groups/organizations, academic institutions and professionals, diverse forms of media and the organizations and individuals that drive media, old and new, for-profit businesses, organizations and individuals, and the arts and entertainment industry. The Legacy Project collaborates with external and internal partners in development of creating culturally appropriate and responsive social marketing and communication materials that enhance and support community education.

**Legacy Project Working Groups and Committees**

The Legacy Project Advisory Group is comprised of external experts in public health, community engagement, and research that address health disparities. They provide guidance and direction for the project, and advise HANC leadership on program direction. The members agree to act as ambassadors for the broad HIV research agenda in a manner that heightens awareness and increases the visibility of HIV clinical research with the target populations. Legacy Project’s long-term strategy is to build upon existing relationships and partnerships and make new connections with leaders who have the power and influence to expand the reach of HIV prevention, care and treatment to those communities that are most impacted by HIV/AIDS. This Advisory Group is critical to those connections and relationships.

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

The Women’s HIV Research Collaborative (WHRC), a subcommittee of the Legacy Project Working Group, provides culturally appropriate guidance and leadership in development, implementation and dissemination of information about HIV researched focused on and responsive to the needs of women and girls in the United States. The WHRC works to raise the visibility of issues related to HIV in women in the U.S. and promote awareness of scientific research to women in disproportionately impacted communities. The WHRC focuses on advocating for HIV research with women living in the United States, but operates with a comprehensive awareness of the potential for women in America to benefit from HIV research that is being conducted internationally. To that end, WHRC’s focus is domestic, but its interests are both global and optimistic.

Legacy Project partners and collaborators include representatives from NIH Institutes/Centers, 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.

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

**Legacy Project Objectives and Activities**

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

Strategies and activities to support this objective:

- The Legacy Project will increase the number of formal partnerships with United States Department of Health and Human Services funded agencies, including but not limited to state and local Health Departments through the US.
- The Legacy Project will increase the number of formal partnerships with CBOs and ASOs across the US.
The Legacy Project will enhance formal partnerships with all the NIH funded HIV clinical research networks.

- The Legacy Project will increase the number of formal partnerships with Historically Black Colleges and Universities (HBCUs).
- The Legacy Project will establish and/or enhance partnerships with specialized institutions/networks by continuing engagement with faith-based organizations, the house/ball community, Black and Gay Prides and the arts and culture sector.

**Legacy Project Objective #2:** Influence the creation of scientific agendas and research that responds to community priorities. Conduct and support primary research on community engagement, clinical trial participation and the relationship between them. Develop innovations, models and/or strategies that promote enhanced, active and strategic collaborations that yield improved capacity at the individual, organizational and community-level.

**Strategies and activities to support this objective:**

- The Legacy Project Social Scientist will conduct two meta-analyses on enrollment in HIV prevention and treatment clinical research versus HIV incidence/prevalence at clinical sites, and examining barriers/challenges to enrollment in HIV prevention and treatment clinical research.
- The Legacy Project Scientific Director will submit two abstracts at national conferences for peer-review on evaluation activities from the Legacy Project.
- The Legacy Project Scientific Director will submit one-two grant proposals for program expansion activities and research initiatives.
- The Legacy Project Scientific Director will submit two manuscripts and/or journal articles.
- The Legacy Project will work with the Research/Evaluation Workgroup and the Women’s HIV Research Collaborative to identify community research priorities.

**Legacy Project Objective #3:** Build the capacity of communities and researchers to equally partner in the research enterprise.

**Strategies and activities to support this objective:**

- The Legacy Project will develop fact sheets, frequently asked questions (FAQs), brochures, posters and other educational and promotional materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic.
- The Legacy Project will host webinars on HIV prevention and treatment clinical research advances among its stakeholders.
- The Legacy Project will host workshops/presentations at conferences and other meetings that are aimed at improving community research literacy and the capacity of HIV prevention and treatment clinical research sites, community advisory boards (CABs), and/or researchers.

**Legacy Project Objective #4:** Enhance the internal and external operations of the Legacy Project.

**Strategies and activities to support this objective:**

- The Legacy Project will develop a comprehensive communication plan.
- The Legacy Project will develop a comprehensive staff professional development plan.

**Network Leadership**

**NLOG**

The Network Leadership Operations Group (NLOG) was originally charged with implementing and advancing optimal collaborative clinical trials research activities among the NIH-sponsored HIV/AIDS clinical trials networks. NLOG members include representatives from 18 NIH Institutes and Centers and provide a venue for cross-network as well as cross-institute information sharing and discussion. HANC solicits information from the networks, NIH representatives.
and other partners to bring forward and organizes and had facilitated quarterly teleconferences. In Year 7 it was decided to have ad hoc calls as needed rather than regularly scheduled quarterly calls.

**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 2013.

**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.

**Seroconverters Study Group**

The Seroconverters Study Group was an ad hoc group first convened at the request of the Network Leaders Group in February, 2011. The purpose of this group is to first compare and contrast the objectives and schedules of events of the various network and non-network protocols that follow study participants who seroconvert during HIV prevention trials. The group will also consider the feasibility of harmonizing the approach to following seroconverters across networks and develop recommendations for the Network Leader’s Group. The recommendations were published in AIDS in May 2013, completing the work of this group.

**Site Management & Logistics Coordination Objectives and Activities**

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 the OCSO and OPCRO offices 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 and Clinical Trials Logistics Coordination Objectives for the Year 7 Extension**

Site Management and Clinical Trials Logistics Objective #1: Work closely with network staff and DAIDS officers to review the harmonized network Conflict of Interest/Financial Disclosure requirements, and maintain the cross-network web-based reporting interface developed in Year 6.

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, INSIGHT, and PHACS.

Site Management and Clinical Trials Logistics Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS offices to identify and address priority site management issues.

Strategies and activities to support this objective:
- Network Leaders, OCSO, OPCRO and other stakeholders will identify an evolving list of site management issues and opportunities to better coordinate their respective efforts. Topics may include such issues as: SDMC issues; reducing confusion around site monitoring by clarifying site new performance monitoring policies; clarifying DAIDS and networks respective responsibilities and harmonizing site establishment processes.
- HANC to disseminate OPCRO and OCSO policies, memos, SOPs for comment and/or general distribution to network operation centers as requested.
- Hold monthly calls with HANC and OCSO leadership to facilitate communication and coordination of site-level activities.
- Hold bimonthly calls with HANC and OPCRO leadership to facilitate communication and coordination of site-level activities.
- Convene topic-specific working groups on an ad-hoc basis to address site-level issues.

Site Management and Clinical Trials Logistics Objective #3: Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks core operations centers.

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

Site Management and Clinical Trials Logistics Objective #4: Facilitate collaboration with the WG, OCSO and relevant members of the new networks to harmonize reporting requirements and increase transparency.

Strategies and activities to support this objective:
- Utilize the monthly site coordinator teleconferences to address significant fiscal issues common across the networks with network fiscal representatives and OCSO.
- Create a diagram outlining the new fiscal structure reporting requirements.
- Hold ad hoc calls as necessary with network fiscal representatives.

Site Management and Clinical Trials Logistics Objective #5: Create a mapping table defining operating elements such as roles and procedures across the networks and core/operations centers.

Strategies and activities to support this objective:
- HANC to work with the networks and compile a table defining common terms across networks.
Training Coordination Objectives and Activities

**Training Committee**

The Training Committee identifies and addresses cross-network core operations center and clinical trial unit training needs. The committee serves as the main point of contact for training related requests and issues, and consists of network training representatives and members from DAIDS, Westat, FSTRF, and each network.

**Training Coordination Objectives for the Year 7 Extension**

**Training Objective #1:** Identify and provide access to cross-network standardized training for high priority topic areas.

Strategies and activities to support this objective:

- Monthly cross-network training committee teleconferences provide a forum for identifying and discussing training needs and ways to provide access to trainings. This forum also allows the network training representatives to share information about upcoming trainings and inquire about additional training opportunities available for staff.
- The HANC public website provides CTU/CRS staff with information on upcoming training events and training resources available in various formats.
- DAIDS to continue sharing evaluation reports on training courses and events and update the committee as new trainings are modified or become available.
- HANC will facilitate communications about training options available on the DAIDS LMS.
- HANC will work collaboratively with DAIDS to transition the HIV Risk Reduction Counseling Training modules to AIDS.gov to allow broader access. HANC will also provide access to the accompanying Training Resources Manual on the HANC public website.

**Training Objective #2:** HANC to partner with the DAIDS Training and Safety Branch (TSB) on development and deployment of training resources.

Strategies and activities to support this objective:

- HANC to hold weekly check-in calls with the TSB to discuss on-going training related items.
- HANC to join working groups as requested by DAIDS on training related topics.
- HANC to serve as the liaison between CITI, DAIDS and the networks regularly updating all with new courses that become available and provide access as requested.
- HANC to assist with the development, expansion and access to curriculums available in the DAIDS LMS such as the HRCT curriculum, community modules.
- HANC to assist as needed on training resources in development and keep the training resources section of the HANC website updated with current information available.
- HANC to bring identified priority training topics needing input (i.e. genetics training materials) to relevant monthly calls such as the Training Committee and/or Site Coordinators WG.

**Training Objective #3:** Identify potential admin/fiscal training materials needed at the site level.

Strategies and activities to support this objective:

- Utilize the monthly cross-network training committee teleconferences to identify common training topics across the networks such as, budgeting, protocol costing and budget management.
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:

- Quarterly HANC progress reports posted on the HANC portal and sent to each Network Leadership and DAIDS.
- An annual HANC progress report provided to NIAID Grants Management and posted on the HANC portal.
- HANC produces a 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.
- HANC staff are available to provide updates or presentations as requested at all network group meetings or any other meetings.