Introduction

The HIV/AIDS Network Coordination (HANC) project works with the six NIAID HIV/AIDS Clinical Trials Networks 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), the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), and the Microbicide Trials Network (MTN).

The HANC project 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 Work Plan outlines cross-network coordination objectives and activities for the period of June 1, 2011 - May 31, 2012. 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>
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<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Working Group</td>
<td>Create 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 full group F2F.</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 &quot;topics of interest&quot; 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 WG</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>Provide broad input and recommendations to DAIDS for upcoming Network restructuring.</td>
<td>Provide DAIDS with input from community. Provide community with the opportunity to impact the upcoming restructuring.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Recommendations Working Group</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. After completion of training materials, assess the value of materials and determine whether additional priority topics will be addressed 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.</td>
<td>Common community member understanding of basic concepts in HIV, TB, Malaria, and Hepatitis C, 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 EMTF. Revise the CP site staff and site CAB survey.</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 designs.</td>
<td>Solicit feedback regarding ethical considerations and provide recommendations to DAIDS</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Site-Level Funding Working Group</td>
<td>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. 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>Q2</td>
</tr>
<tr>
<td>Area</td>
<td>Group Responsible</td>
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<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.</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 DMCs.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group</td>
<td>Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization</td>
<td>Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group, Lab PI/Manager and Training Committees</td>
<td>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.</td>
<td>Inform training plans and ensure that sites receive the data management training necessary to participate in clinical trials.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Harmonization Working Group</td>
<td>Harmonize data definitions and standards for compatible all network use.</td>
<td>Formalize expectations among network and DMC staff and reduce duplicative systems.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation Measurement Task Force Planning Group</td>
<td>Determine if and how harmonized processes and collaboration are contributing to improved communication, information sharing, and study implementation across the HIV/AIDS networks.</td>
<td>Identify similarities and differences in the management, funding and performance of multi- vs. single network NIAID clinical research sites</td>
<td>Q3 2012</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation Measurement Task Force Planning Group</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>Q4 2012</td>
</tr>
<tr>
<td>Area</td>
<td>Group Responsible</td>
<td>Objective</td>
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<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 LTC</td>
<td>Update SOPs that make up 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>Completion target end Q4 (June 2012)</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>HANC Staff/LFG</td>
<td>Develop laboratory training listings on the HANC public website and distribute comprehensive communications to the laboratories on a regular basis</td>
<td>Increase laboratory knowledge of and access to relevant trainings.</td>
<td>Q1 Develop listing on HANC public website; Q1-4 Distribute notices/reminders to labs</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>HANC Staff</td>
<td>Expand HANC Lab DB to include query capabilities.</td>
<td>Provide cross-network means of collecting and sharing results of laboratory surveys; reduce redundancy and the demand on laboratory time.</td>
<td>Q1-2 Develop proof of concept; Q3 Test; Q4 Complete and launch</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>HANC Staff</td>
<td>Replace Proficiency Test Performance Tracking System with an EQA DB.</td>
<td>Provide a cross-network database for collecting and analyzing EQA data for increased efficiency of network oversight of laboratory EQA performance.</td>
<td>Q1-2 Develop proof of concept; Q3 Test; Q4 Complete and launch</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>PBMC SOP WG</td>
<td>Complete and implement version 3 of Cross-Network PBMC SOP.</td>
<td>Consistent PBMC processing at network labs.</td>
<td>Q1 Complete v3 of SOP; Q2 (Nov 09) Require SOP at all English speaking sites and request translations; Q4 Require SOP at all sites</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Continue and increase 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 participation of disparately impacted populations in HIV clinical research.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Influence the creation of scientific agendas and science that is responsive to community priorities. Conduct and support primary research on community engagement and clinical trial participation and the relationship between them</td>
<td>Increased enrolment of representative populations in HIV clinical research studies and identify practices to achieve this objective.</td>
<td>Ongoing</td>
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## HANC Work Plan Year 6.pdf

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<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 Disclosure Working Group</td>
<td>Consider creating a cross-network web database and submission form.</td>
<td>Eliminate redundant reporting requests and reduce the network’s reporting costs.</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.</td>
<td>Address issues of common concern and harmonize policies and procedures regarding site-level operations.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Site Management and Clinical Trials Logistics</td>
<td>Pluripotent Configuration Study Working Group</td>
<td>Convene a sub group of site coordinators to consult on the Pluripotent Configuration Study project (see evaluation objective #2)</td>
<td>Identify similarities and differences in the management, funding and performance of multi- vs. single network NIAID clinical research sites</td>
<td>Q3 2012</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>Training Committee in collaboration with the Community Training WG</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. After completion of training materials, assess the value of materials and determine whether additional priority topics will be addressed 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.</td>
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### 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 group as they put in the time and sustained effort to complete the work, acknowledging that members participate in working groups and take on cross-network tasks voluntarily, above and beyond their full-time 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 in some cases bring them to the Network Leaders and DAIDS and form new working groups or 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 website.
- 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 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.

- The HANC blog as well as an easily updated program spotlight applet on the homepage: featured links to AIDS.gov “Future Directions for NIAID HIV Research” blogs

- A library of centralized laboratory certifications (i.e. CAP and CLIA) for sites.

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. Year 6 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 Year Six, approximately 1,013 individuals have active HANC portal user accounts and 64 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 2011-2012 include:
● Reviewing user statistics and member survey data collected in Q4 of Year 5 to inform improvements to the HANC Portal and team site content to better support the objectives of the project in Year 6.

● 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 Y6 Q1) allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.

● Expansion of the lab database to include equipment and platform inventories.

● Continued optimization of the Proficiency Testing Performance Tracking tool which captures laboratory proficiency testing data and manages work flows so that appropriate contacts are notified of proficiency testing failures, multiple network responses to a failure are collected, and sites are notified in a single communication.

● HANC program staff provides programmatic updates on the “Daily Dose” announcement box.

● In Year 5 the Communications Working Group developed the Communications Resource Center, a repository of tools, presentations, articles, guides, best practices, and evaluation measures. In Year 6 HANC staff and working group members will continue to curate content for the site.

**Social Networking & Information Sharing**

HANC has Twitter (search for “Hancprograms”) and Facebook (search for “Hanc Programs”) 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.

**Clinical Research Support Contract**

The HIV Clinical Research Support (CRS) contract between DAIDS and contract research organization PPD 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 services from PPD 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, PPD staff, and the networks involved. Tools on the HANC Portal streamline CRS Request submission, tracking and status communication. Nineteen cross-network CRS requests have been submitted since the CRS contract was initiated. In Year 5 HANC submitted two new CRS requests. 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**

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.

**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:** Create a repository of measures, data forms, and standardized core elements of interventions accessible to partnering networks. The documents and links will be housed on the HANC public website and/or the HANC portal.

**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 host a face-to-face behavioral science meeting in Year 6.

**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.
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.

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 Working Group 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 WG meets bi-monthly, and topic-specific trans-WG calls are scheduled as needed.

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

- Create a “Network Study Results & Publications” page and library on the HANC public website.
- Create topic specific webpages (e.g., “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.

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 website 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 400 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.

**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:

- Partnering with AIDS.gov and DAIDS-ES to create a dynamic map of all network sites.
- Partnering with AVAC on a dynamic “HIV/AIDS Clinical Trials Protocol Timeline” calendar.
- Review existing website usage tools.
- Share experiences using social network sites such as Facebook 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”

**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:** Consider coordinating a one day face-to-face meeting. Network and partner representative 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
- Data management related contact list
- Cross-network collaborator list
- Network newsletter library
- Archive of network meeting agendas
- Network press releases and study results

**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 NIAID 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 NIAID 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 NIAID HIV/AIDS Clinical Trials Networks research sites.
Community Partners Structure
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 Year 6**

**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.

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.

Strategies and activities to support this objective:
- Develop a clear written outline of the project scope, intent, and timeline.
- Gather and organize existing network CAB newsletters to post on the HANC Website.
- CP will provide cross-network input to DAIDS to support the development of ethical guidelines and considerations into trial designs.

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
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 monthly teleconferences, and is charged with mapping CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-DMC use.

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

**DMC Coordination Objectives for Year 6**

**DMC Coordination Objective #1:** Implement Information Technology Best Practice Standards developed in Year 3 at DAIDS Clinical Trials study sites and affiliated laboratories and monitor infrastructure changes.

- The IT Best Practice standards document developed in Year 3 will be made available to all DAIDS Clinical Trials study sites and affiliated laboratories.

- 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 to establish understanding of how the organization will work with the networks.

**DMC Coordination Objective #2:** Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization

The three unique LIMS systems in use in the HVTN network (site affiliated labs use the Laboratory Data Management System (LDMS) as provided by FSTRF; the NICD lab in South Africa and an endpoint lab use the HVTN LabWare LIMS; and the DAIDS Repository (BBI/SeraCare) uses the DAIDS Repository BSI-II LIMS)
were designed to generate system-specific barcode label formats and shipping manifest file formats. Following successful efforts to modify LDMS to accept, import and export manifest files between HVTN LabWare and DAIDS BSI-II LIMS systems, SCHARP and FSTRF propose to work with BBI/SeraCare and HVTN Labware to make additional changes to the manifest format, in order to complete Manifest Harmonization efforts.

Strategies and activities to support this objective:

- SCHARP and FSTRF will maintain code mappings across the LIMS systems as needed; and modify the specimen inventory data elements as requested by the SCHARP Data Management Center to appropriately track and QA the data.
- SCHARP and FSTRF will work with each individual collaborating partner to ensure that previously identified common data elements are included and supported in electronic manifest files which can be read across multiple systems and reported back to SCHARP as part of an inventory data feed.

DMC Coordination Objective #3: 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.

Strategies and activities to support this objective:

- The DMC Harmonization working group will collaborate with the cross-network Training Committee to identify and address data management training needs.

DMC Coordination Objective #4: Harmonization of MedDRA coding.

It would be advantageous in the long run to ensure that a 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 (DMIWG) 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 will map CDC and WHO stages into MedDRA codes for intra-DMC use.
  - Each network 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 MedDRA working group, which is currently chaired by the DAIDS MedDRA consultant. Eventually it will be chaired by one of the lead coders, at which time the chair will be rotated annually. The working group conducts conference calls at least once per month, and will meet face-to-face at least once per year, rotating between network locations.
  - The DMWG members developed a DAIDS MedDRA Terms Selection Guidelines document that is a supplement to the MSSO Terms Selection document. The group also developed the MedDRA Versioning Policy for DAIDS that outlines the procedures for updating the network databases with bi-yearly MSSO releases.
The members of this working group will periodically exchange lists of MedDRA codes used for the first time which will be reviewed by the other coders in light of DAIDS enterprise coding policies. Disagreements in coding will be reported to the chair. The chair will collate the responses and redistribute to the entire working group for discussion and resolution during the monthly conference call. This group is also responsible for reviewing any nominations for the DAIDS-ES synonym list, collecting and reviewing change requests for possible submission to the MedDRA Maintenance and Support Services Organization (MSSO), as well as discussing other MedDRA-related issues and issue consensus statements as appropriate.

DMC Coordination Objective #5: 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, FSTRF, University of Minnesota 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.

DMC Coordination Objective #6: Implement clinicaltrials.gov results reporting requirements.

Strategies and activities to support this objective:

- Identify policies and mechanisms for affected studies and existing data management systems.
- SCHARP and FSTRF will continue to communicate challenges and requests to DAIDS and Network Leaders. Experiences will be reported to the full DMC working group as needed.

DMC Coordination Objective #7: Harmonize Clinical Event Collection policies and procedures to make recommendations on Adverse Events Reporting.

Strategies and activities to support this objective:

- Working group members will review vigilance reporting (FDA requirements and CTA agreements), pregnancy outcomes, the collection of non-AIDS defining events, and toxicity tables, and develop in consultation with DAIDS recommendations for standardized cross-network policies and procedures.

DMC Coordination Objective #8: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).

Strategies and activities to support this objective:

- Explore the formation of an Adverse Events Reporting Taskforce with representatives from the networks, SCHARP, FSTRF and DAIDS Office of Safety and Pharmacovigilance.
- Maintain ongoing dialogue with DAIDS staff regarding the development and requirements of the (DAERS).
Share experiences interfacing with the DAERS system on monthly DMC conference calls.

DMC Coordination Objective #9: Consider hosting a one day DMC face-to-face meeting. DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination.

**Evaluation Coordination Objectives and Activities**

The goal of this project is to carry out targeted, utility-focused evaluation studies of stakeholder-identified critical success factor domains for the DAIDS clinical research enterprise (i.e., including the Division of AIDS and its HIV/AIDS clinical trials networks) in order to identify systems, policies and practices that can be modified/improved for increased efficiency and effectiveness. The project is coordinated through the Office of HIV/AIDS Network Coordination (HANC) providing central leadership, in partnership with Concept Systems, Inc (CSI), the latter playing a pivotal role in the conception, design and conduct of the evaluation studies. Building from initial pilot study efforts in each of the four stakeholder-identified domains previously identified, these evaluation studies are expected to: a) yield detailed information about the current functioning of the network enterprise; b) identify areas for integration of data sets and analyses across areas of evaluation; c) indicate ways to improve processes and identify best-practices; and d) generate recommendations that can guide continuous improvement among the current networks, and inform future iterations of the NIAID clinical research networks.

Federal statutory and NIH mandates require DAIDS to conduct evaluations of its operations and programs. It has been posited that a comprehensive, integrated evaluation system will support DAIDS and its investigators in identifying critical success factors, defining and implementing best practices, and assessing progress towards achieving the mutual goals of scientific excellence, integration of therapeutics and prevention research, efficient use of resources, and effective collaboration.

**Evaluation Committees and Working Groups**

HANC is a member of the Evaluation Measurement Task Force and four related domains of activity.

The Evaluation Measurement Task Force (EMTF) Planning Group is comprised of representatives from each NIAID, CSI and HANC. The planning group provides detailed, technical input about potential measures, data sources and tools to be considered for use in the development of the evaluation system plan.

Operations, Policies and Resources Domain of Activity focuses on administrative policies, funder issues, process efficiency and site capacity. Included in the scope of this advisory group is how to evaluate: 1) the efficiency of policies and procedures in the conduct of high quality science; 2) the provision and use of resources; and 3) the capacity of clinical research sites.
Community and Participants Domain of Activity focuses on the importance of community involvement at all levels and at critical milestones in study development and implementation. Included in the scope of this advisory group is how to evaluate the ways the network research enterprise: 1) addresses questions of relevance to the communities and trial participants; 2) produces results (including answers to questions) that may lead to preventions and treatments that can practically and affordably be made available to the study participants and their communities; and 3) provides adequate support for community participation and education.

Scientific Agenda and Objectives Domain of Activity focuses on how the networks specifically, and the DAIDS HIV clinical research enterprise as a whole, identify their research priorities, how they identify prevention and treatment strategies for HIV/AIDS leading to fewer new infections, and how their efforts assure progress on the pathway to reduced morbidity and mortality. Included in the scope of this advisory group is how to evaluate aspects of the pipeline through which each study passes, starting with the setting of the scientific agenda, progressing through study implementation, dissemination and impact.

Communication, Collaboration and Harmonization Domain of Activity focuses on the collaboration and communication within and between networks and between DAIDS and the networks and sites. Included in the scope of this advisory group is how to evaluate: 1) collaboration activities at the scientific and operational levels; 2) the restructuring principles of efficiency, coordination, and integration; 3) the function of the HANC office; and 4) the coordination and maximization of research opportunities.

Evaluation Coordination Objectives for Year 6

Primary evaluation coordination objectives for 2010-2011 include:

Evaluation Objective #1: Understand the processes for protocol development and implementation in the DAIDS HIV/AIDS networks.

Strategies and activities to support this objective:

- Model time to event data across protocol development and implementation milestones, from concept proposal to study completion and publication of the primary analysis, in order to better understand the contribution to overall protocol timeline by each phase of protocol lifecycle;
- Determine the time duration for protocol milestones for domestic vs. international research protocols;
- Develop expected timing patterns for meeting milestones, based on protocol type (prevention, treatment), phase, size (number of patients, sites), network, and other factors (i.e. protocol monitoring level and complexity).

Evaluation Objective #2: Determine if and how harmonized processes and collaboration are contributing to improved communication, information sharing, and study implementation across the HIV/AIDS networks.

Strategies and activities to support this objective:

- Using a broad set of measures with which there is experience in the networks, as well as focus groups and structured interviews (e.g. CRS leaders, site coordinators) analyze the performance of single network vs. multi-network affiliated clinical research sites (CR5s)
- Assess the quality of, and extent to which HANC is supporting and facilitating cross-network coordination, through an analysis of the Annual HANC Collaborator surveys, interviews with
network leaders and NIH staff (NIAID and collaborating ICs) and cross-network working group members.

- Assess DAIDS policy development, communication and network and site interactions.

**Evaluation Objective #3:** Assess the scientific output and impact of the scientific the DAIDS networks relative to current scientific literature, practice guidelines, continuing medical education, and networks’ own scientific agendas.

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

- Conduct a five-year bibliometric data analysis for longitudinal assessment of translational scientific impact of network research.
- Conduct a retrospective analysis of select protocols and their respective results to model a discovery to utilization timeline.
- Assess the alignment between network and enterprise scientific agendas, scientific results, and impact of network studies.
- Determine the impact of network research on the practice of HIV medicine by surveying HIV specialists and collaborating with HIV medical educators.
- Analyze network results dissemination by determine the time to publication of primary results following trial completion analysis of time to publication of study primary results following study.

**Evaluation Objective #4:** 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 to identify and profile best practices in community involvement across networks.
- Conduct an analysis of network CAB characteristics and site performance variables.
- 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 supports 13 active laboratory working groups.
The Laboratory PI/Manager Committee includes Network Lab PIs, Lab Managers and DAIDS Clinical Laboratory Oversight Team (DCLOT) members, NICHD, statistical data management center, and quality assurance contractors who meet on ad hoc teleconferences to serve as a central communication center for the other laboratory working groups and committees. The Lab PI/Manager Committee receives updates from the various laboratory working groups and discusses issues raised by them.

The ACTG/IMPAACT Laboratory Technologist Committee is a joint ACTG/IMPAACT committee. 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 clinical sites and laboratories. HANC support staff coordinate specific projects and give technical support to the committee’s team site and work load 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 Clinical Pharmacology Quality Assurance (CPQA) Advisory Board serves as a forum for the networks to communicate their pharmacology quality assurance needs to the PQA 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 discussion of scientific and policy issues that affect the pharmacology laboratories, and for the discussion of potential collaborations and efficient use of resources during bimonthly teleconferences.

The Immunology Quality Assurance (IQA) CD4 Working Group addresses CD4 proficiency testing issues at non-US laboratories, quality management, instrument validation, and integrity of CD4 data to protect patient/study populations. This is accomplished through monthly teleconferences, which include representatives from ACTG, IMPAACT, HPTN, HVTN, MTN, NICHD, DAIDS, SMILE, UK NEQAS and the IQA.

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, and quality control of cryopreserved PBMC samples at the Biomedical Research Institute (BRI) repository on monthly teleconference calls. ICAG includes statisticians and representatives of ACTG, IMPAACT, DAIDS, FSTRF, Westat, NICHD, and the IQA.

The Lab Focus Group (LFG) includes the network laboratory and operations staff and meets once or twice per month to do much of the detailed background, document development, and follow-up work to complete projects and tasks that address laboratory training, operations, and support issues that apply across Networks.

The LFG-DCLOT Collaborative Working Group includes members of the LFG and DCLOT in order to facilitate communication on specific topics as needed. Calls are held on an ad hoc basis.

The Malaria Laboratory Working Group includes DAIDS, SMILE, ACTG, IMPAACT, HPTN, NICHD, DMID and other external collaborators, and first convened in May 2010 to discuss and address questions regarding malaria diagnosis within network protocols.

The PBMC SOP Working Group is charged with developing, implementing, reviewing, and revising the Cross-Network PBMC Processing SOP. The PBMC SOP WG includes representatives of ACTG, IMPAACT, HPTN, HVTN, MTN, DAIDS and the IQA and meets during ad hoc teleconferences.

The TB Laboratory Diagnostics Working Group includes SMILE, DAIDS, NICHD, CDC, IMPAACT and ACTG members and identifies and evaluates international TB diagnostic laboratories for participation in clinical trials with TB diagnostic endpoints, and develops standards for specimen collection and transport and TB diagnostics for network protocols.

The Virology Quality Assurance Advisory Board (VQAAB) addresses virology proficiency testing issues identified by Virology Quality Assurance (VQA) and other VQAAB members during monthly teleconferences. The VQAAB includes representatives of ACTG, IMPAACT, HPTN, HVTN, MTN, DAIDS, the VQA, and sub-contractors.

**Laboratory Coordination Objectives for Year 6**

**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 Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners.
Cross-Network Laboratory PI/Manager Committee and 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.

LFG/DCLOT teleconferences will facilitate communication among Network Laboratories and DCLOT regarding DAIDS policies and procedures that apply to network laboratory activities.

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 further developed to contain additional parameters useful to the Network Laboratories until such time that they are captured in the DAIDS-ES system.

Various laboratory working groups will coordinate the development of questionnaires for collecting laboratory information for cross-network use.

HANC support staff will maintain a team site on the HANC portal for each working group for information sharing and collaborative document development.

HANC support staff will continue to solicit and publish HANC member profiles to support working group rapport and communication.

**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 development and implementation of a Total Quality Management (TQM) Program. The TQM Program will improve 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 on regular teleconference calls.

- Cross-network QA working groups and the LFG (for safety QA) will develop, review, and/or modify as needed guidelines for laboratory quality management including performance criteria and mechanisms for restricting protocol testing based on poor proficiency testing performance and guidelines for data and communication flow.

- ICAG will complete, test and implement plan for quality control of cryopreserved PBMC that are sent to the Biomedical Research Institute (BRI) repository.

- The ICAG will consider using Day 2 viable recovery in the proficiency testing program and implement a decision as appropriate.

- The ICAG will consider differences, if any, between manual and ViCell counts.

- The LFG will continue to utilize online portal tools to review and track proficiency testing results and coordinate feedback to network site-affiliated laboratories for international laboratories.

- HANC support staff will continue to upgrade and modify these online tools as necessary.
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:

- Identify where economies of scale can be achieved by sharing resources, technician training opportunities, laboratories, etc. and address this opportunities in existing or new working groups.
- Facilitate utilization of the DAIDS Learning Management System (DLMS) to deliver and/or track laboratory training modules and manage training at the site levels.
- Complete revision of the Cross-Network PBMC Processing SOP for utilization at network laboratories and request translations.
- Coordinate the negotiation of memoranda of understanding and/or purchasing/service agreements with suppliers as necessary.
- Continue to expand listings of laboratory training resources on the HANC public website.
- Continue population of the Laboratory Certificate Library on the HANC public website.

Laboratory Coordination Objective #4: Continue collaboration 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:

- 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.
- Explore opportunities for the development and validation of point-of-care TB Laboratory assays.

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

Strategies and activities to support this objective:

- 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 protocol teams:
Maintain a list of US and non-US labs with reliable malaria diagnostic capacity as a resource for networks and their partners when conducting studies malaria diagnostics endpoints

Recommend laboratories for participation in studies

Propose and implement relevant EQA and QC approaches to ensure the quality of study data

Review proposed methods and draft/compile and implement standard guidelines for sample collection, processing, transport and diagnostics

Review malaria component of study-specific procedures to include guidance on sample acquisition and processing prior to shipment to testing laboratories as requested

- Identify, evaluate and support malaria laboratories that can:
  - Perform malaria testing in network and non-network clinical studies
  - Conduct evaluations of malaria diagnostic methods for use in HIV-positive study participants
  - Serve as regional training resources

**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 NIAID 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 maintaining and developing relationships with key organizations/partners in and among the populations most impacted, private and public. The Legacy Project has a national stakeholder engagement program which includes the following stakeholders groups: the Faith-based community, historical Civil Rights and political groups and organizations, social and fraternal organizations, academic institutions and professionals, diverse forms of media and the organizations and individuals that drive media, old and new, a host of professional and business organizations and individuals, and the arts and entertainment industry. The Legacy Project collaborates with external and internal partners in development of creating culturally competent and responsive social marketing and other communication materials that enhance and support community education.

**Legacy Project Working Groups and Committees**

The HANC Legacy Project Work Group (LPWG) is comprised of members from HANC, Community Partners, network core/operations centers, clinical research site representatives, DAIDS, Office of AIDS Research and other NIH Institutes and Centers. The LPWG ensures that the HANC Legacy Project assist the NIAID HIV/AIDS Clinical Trials Networks to achieve increased inclusion of historically underrepresented communities most impacted by the domestic HIV epidemic in HIV prevention and therapeutic research. Setting program objectives and monitoring progress toward those objectives are the fundamental tasks of this group.

The HANC 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.

The Women’s HIV Research Collaborative (WHRC), formed in June, 2010, focuses on advocating for HIV research with women living in the United States, but operates with a comprehensive awareness of the potential for women in America to benefit from HIV research that is being conducted internationally. To that end, WHRC’s focus is domestic, but its interests are both global and optimistic.

The Legacy Project Working Group and Legacy staff completed a three year strategic plan in Year 5 Q4. The Year 6 objectives are based on the Legacy Project goals outlined in that plan.

Legacy Project Objectives and Activities

**Legacy Project Objective #1:** Continue and increase 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 governmental agencies, including but not limited to, six Health Departments through the US.
- The Legacy Project will increase the number of formal partnerships with twenty-four CBOs and ASOs, specifically collaborating with 14 African-American and 10 Latino-focused organizations within the US.
- The Legacy Project will increase the number of formal partnerships with two additional NIAD networks, specifically MTN and HPTN.
- The Legacy Project will increase the number of formal partnerships with four Historically Black Colleges and Universities (HBCUs).
- The Legacy Project will establish formal partnerships with specialized institutions/networks by continuing engagement with the faith-based and initiating formal relationships with the house/ball community and the arts and culture sector.
- The Legacy Project will establish two new subcommittees of the Legacy Project Working Group, specifically a Membership Workgroup and Research/Evaluation Workgroup.
- The Legacy Project will host two face-to-face meetings, including the Legacy Project Workgroup and the Women’s HIV Research Collaborative.

**Legacy Project Objective #2:** Influence the creation of scientific agendas and science that is responsive to community priorities. Conduct and support primary research on community engagement and clinical trial participation and the relationship between them.

Strategies and activities to support this objective:

- The Legacy Project will hire a Social Scientist at .5FTE.
• 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 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 establish a speaker’s bureau that will include six scientists to disseminate advances in HIV prevention and treatment clinical research.

• 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 and pilot test a cultural awareness and community engagement curriculum and/or tool kit for HIV/AIDS clinical research sites, scientist and community groups.

• The Legacy Project will develop two fact sheets, one focusing on overcoming barriers with racial ethnic groups and the second focusing on engaging transgender populations within the US.

• The Legacy Project will host four webinars on overcoming barriers to HIV prevention and treatment clinical research, engaging MSM, and identifying women’s research priorities and new prevention techniques.

• The Legacy Project will host a minimum of 12 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 rebrand to include: logo re-design, letterhead and product design.

• The Legacy Project will develop a comprehensive staff professional development plan.
Network Leadership

NLOG

The AIDS Clinical Trials 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 calls include the participation of 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 facilitates quarterly teleconferences.

SWG

The AIDS Clinical Trials Network 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 NIAID HIV/AIDS Clinical Trials Networks. The SWG provides input on strategic issues that cut across all six 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 3-4 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.

Network Leaders and DAIDS

HANC organizes focused monthly and ad hoc conference calls with the six 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 is 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.

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 Year 6**

**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 evaluate the feasibility of developing a cross-network web-based reporting interface.

**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: reducing confusion around site monitoring by clarifying site new performance monitoring policies; clarifying DAIDS and networks respective responsibilities and harmonizing site establishment processes; and address issues relevant to site core budgets.

- 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.

- Discuss policies and procedures concerning CTU/CRS core and PIF funding with the Network Leadership Group, DAIDS and CTU/CRS PIs and site leaders to address efficient resource allocation and transparency.

- 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.

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.

- Share IT Best Practices document with the Site Coordinators Working group (DMC Coordination Objective #1).

**Site Management and Clinical Trials Logistics Objective #4:** Convene a sub group of site coordinators to consult on the Pluripotent Configuration Study project (see Evaluation Objective #2).

Strategies and activities to support this objective:
• Hold bi-monthly working group calls to discuss background information, areas of inquiry, review draft survey, finalize the implementation plan and discuss results.

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, PPD, FSTRF, MHRP.

Training Coordination Objectives for Year 5

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 portal provides a team site for the training committee and each working group which supports information sharing, lists training announcements, provides a training request mechanism for the network training representatives to submit on an as needed basis for their upcoming network meetings or based on a site request, contains a training documents library, training topics blog and allows for collaborative document development. Additional tools will be developed depending on the groups needs.

• 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 for past DRTEs and update the committee as new trainings are modified or become available.

• HANC will facilitate communications about training options available on the DLMS.

Training Objective #2: (See Community Coordination Objective #2)

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 Executive Committee.
• An annual HANC progress report provided to NIAID Grants Management and posted on the HANC portal.

• HANC to produce quarterly newsletters distributed to all portal users and posted on the home page of the HANC portal.

• HANC to distribute an annual survey to all of HANC’s collaborators which will evaluate HANC efforts and inform HANC of any changes needed.

• HANC staff are available to provide updates or presentations as requested at all network group meetings or any other meetings.