Introduction

The Office of HIV/AIDS Network Coordination (HANC) 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 treatment, 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).

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; behavioral/social science research facilitation; 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, 2012 - May 31, 2013. 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 34.

### 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>
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<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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<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. BSWG to host one full group F2F meeting annually.</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, RFAs 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. Increase dissemination of ongoing study information and recent study results.</td>
<td>Ongoing</td>
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<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>
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<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 with Networks, including posting CAB newsletters on the HANC Website.</td>
<td>Share information across Networks</td>
<td>Ongoing</td>
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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 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. 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, developed 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, and Hepatitis C clinical trials methodology, and role of the CAB. Improved training quality and consistency.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Community Coordination</td>
<td>Community Evaluation Working Group</td>
<td>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 in trial design and conduct.</td>
<td>Solicit feedback regarding ethical considerations in trial design and conduct 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>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.</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 SDMCs.</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>Q2</td>
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<tr>
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<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>
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<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 key characteristics, processes, and interactions in pluri-potent sites and units. Determine how well HANC is supporting and facilitating cross-network coordination, both within and across network harmonization projects.</td>
<td>Ongoing, complete in Q3</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation Measurement Task Force Planning Group</td>
<td>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.</td>
<td>Objective evaluation of the impact of the research output of the NIAID HIV/AIDS Clinical Trials Networks.</td>
<td>Ongoing, complete in Q4</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>Begin in Q1, complete in Q4</td>
</tr>
<tr>
<td>Infrastructure and Administrative 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. Increased 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 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>Completion target end Q4 (June 2012)</td>
</tr>
<tr>
<td>Area</td>
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<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 Database 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>Update version 4 of Cross-Network PBMC SOP as needed.</td>
<td>Consistent PBMC processing at network labs.</td>
<td>Review annually and update as needed with translations</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Continue and increase partnerships and collaborations with government agencies, investigators, CBOs and ASOs, medical/academic institutions, specialized institutions/networks, and experts /advisors.</td>
<td>Increased awareness of critical need to improve participation of disparately impacted populations in HIV clinical research in the U.S.</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 enrollment of representative populations in HIV clinical research studies and identify 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>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>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>
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</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 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 the 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 present 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 web site.
- A dynamic announcement section on the home page for posting important notices, such as major recent 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), DAIDS-ES Applications Training Information and access information to the DAIDS Learning Management System (LMS).

A dynamic, searchable map showing locations of networks and research sites around the world.

Information for laboratories, including PNL Contact Assignments, a Laboratory Certification Library, and laboratory training videos.

Resources and links to direct site and network staff regarding who to contact or where to find the information they are looking for, updated DAIDS organization charts, and OCSO SOPs.

Library of all the network publications cataloged in one central location for ready access on the HANC public website, including network press releases and responses to study results such as iPrEx.

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. Year 7 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 Seven, approximately 1,030 individuals have active HANC portal user accounts and 72 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 2012-2013 include:

- Reviewing user statistics and member survey data collected in Q4 of Year 6 to inform improvements to the HANC Portal and team site content to better support the objectives of the project 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 approved protocol documents (to be implemented in Y6 Q4) allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.
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- Expansion of the lab data base 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 7 HANC staff and working group members will continue to curate content for the site.
- HANC staff created the Youth Prevention Research Working Group team site and will continue to develop and add resources to that site in Year 7.

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 provides individualized trainings for networks, working groups and affiliated partners as requested. HANC now has a YouTube page (youtube.com/officeofhanc) to broadcast and share network videos.

Clinical Research Support Contract

The HIV Clinical Research Services Support (CRSS) contract between DAIDS and the contract research organization Westat 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 Westat through their designated point of contact at DAIDS. Requests for CRSS services that apply across networks are made through HANC. HANC coordinates the development of cross-network CRSS requests, submits them to the CRSS project officer, tracks their progress, and liaises with DAIDS, Westat staff, and the networks involved. Tools on the HANC Portal streamline CRSS Request submission, tracking and status communication. Twenty two cross-network CRSS requests have been submitted since the CRSS contract was initiated. In Year 6 HANC submitted three new CRSS requests. Details of CRSS requests can be viewed at https://portal.hanc.info/crs/default.aspx.

Objectives and Activities by Area of Coordination

Behavioral Science Coordination Objectives and Activities

HANC supports three 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 NIAID HIV/AIDS 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/social science is integrated into clinical trials. The working group, formed in Q4 of Year 3, holds monthly teleconference calls and an annual meeting.

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/social science research within NIAID HIV/AIDS 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. Over 500 members receive a weekly digest of new library additions and are encouraged to participate in the BSIG Topics of Interest webinar series.

Youth Prevention Research Working Group (YPRWG): The cross-network/trans-Institute Youth Prevention Working Group (YPRWG) was formed in the Q3 of Year 6. Its creation was a key recommendation emerging from the NIH “Focused initiatives for Healthier Lifestyles by the Inter Network Advisory Group on Adolescent Prevention” meeting. The group consists of representatives from the DAIDS networks, the Adolescent Trials Network (ATN), DAIDS, NIAID, NIMH, NIDA, and NICHD. 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 will address 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 Year 7

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 host a face-to-face behavioral science meeting in Year 7.

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. 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.

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 BSWG meeting considering this objective.

Behavioral Science Objective #8: Interface with ongoing behavioral science projects such as the Youth Prevention Research Working Group and the DAIDS Risk Assessment Best Practices Working Groups.

Youth Prevention Research Working Group Coordination Objectives for Year 7

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 and develop a robust searchable database of relevant materials. The database will live 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 will be engaged as needed 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 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.

- Maintain the “Network Study Results & Publications” page and library on the HANC public website (e.g. CROI 2012 Network Presentations).
- 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.
• Maintain and add functionality to the map of all the NIAID HIV/AIDS clinical trial network sites, including the NICHD-funded IMPAACT sites and the ATN 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 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 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.

**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 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
- DAIDS Topic-specific Contact List
- Cross-network collaborator list
- Network newsletter library
- Network press releases and study results

Community Coordination Objectives and Activities

Since the 1990’s, community representatives associated with the NIAID HIV/AIDS clinical trials networks and research sites have been working together to identify common issues and learn new approaches and solutions from each other 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, the 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 and elected by their respective network global CABs.

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, and trial designs relative to guidelines, local standards of care and placebo arms in prevention and therapeutic trials.

**Community Coordination Objectives for Year 7**

**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: CP to provide input and disseminate information about network and site restructuring.

Strategies and activities to support this objective:
• Provide recommendations for community reviewers to DAIDS for Leadership Groups and CTU FOAs.
• Identify external domestic and international community groups and key stakeholders representing TB and HCV advocates in response to the broadened NIAID scientific agenda.

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 for trial designs.
• Identify opportunities for improvement and generate recommendations regarding placebo or standard of care 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 and collaboration, including the Adolescent Trials Network.
• 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 monthly teleconferences, and is charged with mapping CDC stage 3 and WHO stages 3 and 4 events into MedDRA codes for intra-SDMC use.

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

DMC Coordination Objectives for Year 7

**DMC Coordination Objective #1**: 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 to establish understanding of how the organization will work with the networks.
DMC Coordination Objective #2: Monitor 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 worked 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.
- Ongoing ad hoc calls and testing of manifest files to ensure proper system functioning.

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 is advantageous to ensure that a consistent MedDRA coding of adverse events (e.g., a single reported verbatim has one corresponding MedDRA term) is maintained across 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 achieve a high 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 MedDRA upversioning and related MedDRA issues.
- 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. The working group conducts conference calls at least once per month, and will meet face-to-face as needed.

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-annually 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 are resolved 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.
- Understanding and planning for CDISC requirements in the leadership group recompetition.

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 DIADS staff regarding the development and requirements of the (DAERS).
- Share experiences interfacing with the DAERS system on monthly DMC conference calls and DAIDS-ES Collaborator 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.

DMC Coordination Objective #10: The DMCWG will keep abreast of related HANC activities (e.g., behavioral science and IT Infrastructure Working Group discussions).

Evaluation Coordination Objectives and Activities

The goal is to carry out targeted, utility-focused evaluation studies of the stakeholder-identified critical success factor domains for the DAIDS clinical research enterprise (including the Division of AIDS and it’s HIV/AIDS clinical trials networks) in order to identify systems, policies and practices that can be modified/improved for increased efficiency and effectiveness. The evaluation projects are 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 the 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 Planning Group and four related domains of activity.
The Evaluation Measurement Task Force (EMTF) Planning Group is comprised of representatives from 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: 1) the contributions of 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/AIDS clinical research enterprise as a whole: 1) identify their research priorities; 2) how they identify prevention and treatment strategies for HIV/AIDS leading to fewer new infections; and 3) 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 7

Primary evaluation coordination objectives for 2012-2013 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 pluripotent clinical research sites (CRSs).
- 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 output of the DAIDS networks relative to current scientific literature, practice guidelines, continuing medical education, and the networks’ 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, potentially by surveying HIV specialists and collaborating with HIV medical educators.
- Analyze network results dissemination to determine the time to publication of primary results following trial completion and 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 coordinates eight active cross-network laboratory groups, four ad hoc groups, and provides technical and project management support to one group.

The Lab Focus Group (LFG) 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 ACTG/IMPAACT Laboratory Technologist Committee (LTC) is a joint ACTG/IMPAACT committee. Voting members serve on protocol teams and provide those teams with technical expertise in the development of the laboratory components of protocols as well as standardizing the handling, processing, labeling, and storage of clinical specimens across all ACTG/IMPAACT clinical sites and laboratories. HANC support staff coordinates specific projects and give technical support to the committee’s team site and 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 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 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 teleconferences.

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, IMPAACT, DAIDS, FSTRF, Westat, NICHD, SDAC and the IQA.

The Malaria Laboratory Network (MLN) includes DAIDS, Patient Safety Monitoring and International Laboratory Evaluation (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 and other clinical trials.

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 ACTG, IMPAACT, HPTN, HVTN, MTN, DAIDS, the VQA, and sub-contractors.

The Immunology Quality Assurance (IQA) CD4 Working Group addresses CD4 proficiency testing issues identified by the IQA and the United Kingdom National External Quality Assessment Service (UK NEQAS) at international network laboratories. The IQA CD4 WG is currently on hold, scheduling ad hoc calls as necessary. It is includes representatives from ACTG, IMPAACT, HPTN, HVTN, MTN, NICHD, DAIDS, SMILE, UK NEQAS and the IQA.

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 is currently on hold, scheduling ad hoc calls as necessary.

The PBMC SOP Working Group The PBMC SOP Working Group is charged with developing, publishing and annually reviewing the Cross-Network PBMC Processing SOP for all network-affiliated labs that process
PBMC. Version 4 of the SOP and its translations are posted, and this group is currently on hold until the next review begins in 2013.

The Cross-Network Lab Interest Group (XNLIN) 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 Year 7**

**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.
- LFG/DCLOT teleconferences will facilitate communication among Network Laboratories and DCLOT regarding DAIDS policies and procedures that apply to network laboratory activities, as needed.
- 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 proficiency testing and/or external quality assurance.

- The ICAG will investigate the feasibility of a plan for quality control of cryopreserved PBMC that are sent to the Biomedical Research Institute (BRI) repository by comparing specimens that are sent directly to the IQA and those that are sent via BRI and by determining feasibility of using viability/viable recovery/functionality data from researchers as indicators of specimen quality at BRI.

- The ICAG will investigate the effect of duration of storage at -70°C on viability and viable recovery of PBMC from HIV-infected individuals.

- The LFG will monitor the transition to the new audit provider(s)

**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, technician training opportunities, laboratories, etc. and address these opportunities in existing or new working groups as necessary.

- 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, storage 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 networks, HANC, NIAID, 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 protocol teams:
  - Inform the choice and implementation of malaria diagnostics methods for use in clinical trials:
    - Develop a manuscript for publication.
    - Develop a manuscript and blog for posting and feedback on the HANC public website.
  - 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.

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**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 precursor 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.

**Legacy’s Vision**

The Legacy Project envisions accurately informed communities actively engaged in clinical research with culturally sensitive research environments and processes.

**Legacy’s Mission**
The Legacy Project’s mission is to build trust and collaboration between historically underrepresented communities most impacted by the domestic HIV epidemic, researchers, and research institutions; enhance cultural competence; and initiate scientific investigation to increase clinical research participation.

**Legacy's Organizational Values**

**Inclusion:** Participants in HIV research should be proportionate to those populations most impacted by the epidemic.

**Leadership Diversity:** Cultivation of leaders among communities most impacted by the epidemic.

**Innovation and sense of urgency:** New ideas, scientific generation of knowledge, and recognizing the importance of expediently addressing the HIV epidemic.

**Justice & Equity:** Parity, inclusion, and representation of all.

**Collaboration:** The power of teamwork and cooperation.

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 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 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 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 Legacy 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 7 objectives are derived from 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 Health Departments through the US.
- The Legacy Project will increase the number of formal partnerships with CBOs and ASOs, specifically collaborating with African-American and Latino-focused organizations within the US.
- The Legacy Project will expand collaborations with all of the NIAID HIV/AIDS Clinical Trials Networks.
- The Legacy Project will increase the number of formal partnerships with 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 host face-to-face meetings, including the Legacy Project Workgroup and the Women’s HIV Research Collaborative.
- The Legacy Project will identify current collaborators/partners of the clinical research sites, in an effort to facilitate greater coordination and collaboration.

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 will be led by the Legacy Project Social Scientist and will include:

- Support of the evaluation needs of Legacy Project initiatives.
- Analyze outcome data from Legacy Project initiatives.
- Support the dissemination of process and outcome evaluations of Legacy Project initiatives.
- Secure funding for and conduct at least one (1) mixed method research study on community engagement, clinical trial participation, or factors associated with HIV health and research among priority populations.
- Submit an abstract to a national scientific peer-reviewed conference on a Legacy Project initiative outcome evaluation data.
- Provide leadership and oversight of the LPWG Research and Evaluation Subcommittee.

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 test cultural awareness and community engagement tools for HIV clinical research sites, investigators and community advisory boards.

• The Legacy Project will develop and disseminate educational materials that will improve basic HIV biomedical scientific literacy, improve understanding of NIAID network research priorities and/or translate HIV biomedical study results for lay community members.

• The Legacy Project will provide scientific education webinars, consultations and/or workshops designed to improve basic HIV biomedical scientific literacy, improve understanding of NIAID network research priorities and/or translate HIV biomedical study results among lay community members, groups and/or organizations.

• The Legacy Project will provide individual consultations as requested on effective engagement/collaboration strategies to HIV clinical research sites, investigators and community advisory boards.

**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 including: logo re-design, letterhead and product design.

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

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**Network Leadership**

**NLOG**

The HIV 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 ~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 NIAID.
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 was 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 also considered the feasibility of harmonizing the approach to following seroconverters across networks and developed recommendations for the Network Leader’s Group. The group is at work on a manuscript detailing their analysis and recommendations.

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 also 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 7

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.

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.
HIV/AIDS Network Coordination Year 7 Work Plan

- 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 DAIDS policies and procedures.
- 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 and revised policies and procedures.

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 Year 7

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 Training Committee to provide recommendations and feedback on new or existing trainings to be developed and/or expanded.
- 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, and contains a training documents library. Additional tools will be developed depending on group 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 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 Learning Management System (LMS).

**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 of curriculums available in the DAIDS LMS such as the HRCT curriculum, A5001 neuroscreen trainings and 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 Activity Updates**

Clear progress updates from the HANC office inform our partners of cross-network activities undertaken, progress made and challenges encountered. HANC progress reports are shared with stakeholders via:

- Quarterly HANC progress reports posted on the HANC portal and sent to Network and DAIDS leadership.
- An annual HANC progress report provided to the NLG, DAIDS and NIAID Grants Management, and posted on the HANC portal.
- HANC monthly newsletters distributed to all portal users and posted on the home page of the HANC portal.
- HANC distributes an annual survey to all of HANC’s collaborators which evaluates HANC efforts and informs HANC coordination direction and projects.
- HANC staff are available to provide updates or presentations as requested at all network group meetings or any other meetings.