HIV/AIDS Network Coordination

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Strategic Work Plan for HIV/AIDS Network Coordination

June 1, 2007 – May 31, 2008

I. Executive Summary

The HIV/AIDS Network Coordination (HANC) Office is responsible for facilitating coordinated research activities across the six Division of AIDS (DAIDS) funded HIV/AIDS clinical trials networks. 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 office focuses its coordination efforts on the following major activities: scientific leadership; research logistics; laboratory activities; development and distribution of training modules that apply across organizations; harmonization of data collection processes and optimization of statistical analyses; development and application of consistent standards of performance evaluation; and facilitating effective community engagement in the research process.

This Strategic Work Plan outlines cross-network coordination objectives and activities proposed by the current cross-network committees and working groups and the HANC office for the period of June 1, 2007 - May 31, 2008. The document is intended to communicate and guide these coordination efforts at a high level. The details and schedule for how strategies and activities will be developed and implemented to support the objectives outlined at a high level in this document will be determined by HANC staff in coordination with the cross-network committees and working groups. Progress in meeting these objectives and will be monitored and communicated on a regular basis by HANC staff, as outlined in section V. Table 1 contains an overview of the current objectives proposed for each area of cross-network coordination.

Table 1. Coordination Objectives by Topic Area

Topic Area	Coordination Objectives
Laboratory Objective 1:	Maintain a structure and processes for consistent communication and access to critical information across the Network Core Laboratory Programs
Laboratory Objective 2:	Establish standard quality assurance across networks and other partners through the further development and implementation of a Total Quality Management Program.
Laboratory Objective 3:	Harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.
Community Objective 1:	Develop and implement Community Partners membership and operations.
Community Objective 2:	Develop recommendations on providing community input into the planning and implementation of research activities.
Community Objective 3:	Utilize the Community Training Working Group to coordinate and develop cross-network CAB training materials.
Community Objective 4:	Identify, articulate and communicate scientific priorities of communities that are developed within the network community groups, areas of divergence from scientific researchers' priorities, and unaddressed issues or unmet community needs.
Training Objective 1:	Develop and enhance common safety training modules.
Training Objective 2:	Develop a modular fiscal and administrative training program to help research administrators meet minimum NIH standards.
Training Objective 3:	Develop a centralized communication process for scheduled domestic and regional trainings and managing training requests.
Training Objective 4:	Develop and provide access to cross-network standardized training for high priority

Topic Area	Coordination Objectives
	topics including risk reduction counseling, research methodology, GCP and HSP.
Training Objective 5:	Develop a long-term plan for implementing standardized training across the networks.
Site Mgmt & Clinical Trials Logistics Objective 1:	Develop a Cross-Network Committee focused on Site Management and Clinical Trials Logistics Coordination.
Site Mgmt & Clinical Trials Logistics Objective 2:	Identify and prioritize site management and clinical trials logistics coordination activities to pursue that will add value for the networks, sites and DAIDS.
SDMC Objective 1:	Establish information technology "Best Practice" standards at DAIDS clinical trials study sites and affiliated laboratories
SDMC Objective 2:	Establish an "Input/Output transmission Standards" book that describes the necessary structure for data interchanges of assays, inventories, and manifests
SDMC Objective 3:	Complete Laboratory Data Management Systems harmonization
SDMC Objective 4:	Harmonize of MedDRA coding
SDMC Objective 5:	Coordination of Resource Allocation for DMC Activities with DAIDS Study Sites
Evaluation Objective 1:	Work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.

II. Introduction

Background

In November 2004 the National Institute of Allergy and Infectious Diseases (NIAID) and collaborating Institutes and Centers of the National Institutes of Health (NIH) released a Request for Applications (RFA) to establish the Leadership of three to six HIV/AIDS clinical trials networks. These networks carry out the NIAID research agenda in the following areas: Vaccine Research and Development; Translational Research/Drug Development; Optimization of Clinical Management, Including Co-Morbidities; Microbicides; Prevention of Mother-to-Child Transmission (MTCT) of HIV; and Prevention of HIV Infection. Clinical Trial Units were solicited in a subsequent, linked RFA. Each network is expected to give high priority to collaborations with the other DAIDS-sponsored networks funded through this RFA, other NIH HIV/AIDS clinical research programs, and other HIV research entities in order to effectively develop and implement a clinically relevant, interdisciplinary and cost-efficient research program.

Prior to the release of the RFA, NIAID and the applicant HIV/AIDS clinical trials networks recognized the need for effective leadership of cross-network coordination efforts. In October 2004, Dr. James Kublin opened the HIV/AIDS Network Coordination (HANC) office based at the Fred Hutchinson Cancer Research Center and began working with applicant networks and DAIDS staff to identify priority areas and activities for coordination, increase communication across networks, and identify opportunities to improve processes that would lead to greater efficiency.

In June 2006 NIAID announced that six awards had been issued for leadership of the restructured HIV/AIDS clinical trials networks, with total funding expected to reach $285 million during the first year of the awards. The HANC Office is responsible for facilitating coordinated research activities in the new grant period across the six DAIDS funded HIV/AIDS clinical trials networks, which include the ACTG, HPTN, HVTP, IMPAACT, INSIGHT, and the MTN.

Mission

The HANC mission is to support the science and operations of the DAIDS-funded global HIV/AIDS clinical trials networks by increasing efficiency and resource-sharing through cross-network coordination of critical activities.

Coordination Focus

The HANC office focuses its coordination efforts on the following major activities:

- Scientific leadership, including Principle Investigator advancement of optimal collaborative clinical trials research activities within the networks, and the Network Leadership Operations Group's consideration of crucial operational and scientific questions to drive collaborative efforts among the networks and other research partners;
- Research logistics including site management, protocol development and implementation, and study conduct;
- Laboratory activities including specimen collection and processing, repository utilization, and quality assurance;
- Development and distribution of training modules that apply across organizations;
- Harmonization of data collection processes and optimization of statistical analyses;
- Development and application of consistent standards of performance evaluation;
- Facilitating effective community engagement in the research process.

III. General Cross-Network Support

HANC Staff Role

HANC staff are a cohesive force in each of the cross-network committees or working groups, serving in both an administrative and project/management role as well as a restrained leadership role.

HANC staff are tasked with the challenge of providing tactful leadership and direction to collaborative workgroups whose members are diverse and often reflect the different goals and perspectives of their research networks. The HANC staff person must gently help the group identify areas of need or opportunity and develop consensus around objectives and tangible tasks to address them. Members participate in working groups and agree to take on cross-network tasks voluntarily, above and beyond their full-time responsibilities within their primary organization. For a working group to be successful , HANC staff must help the group clearly identify the work to be done, consistently articulate the value to the networks and individuals in completing it, identify and persuade appropriate individuals to take on each task, and encourage the group and build momentum so that they do not lose heart or interest, especially when activities take time and sustained effort to complete.

As a working group or committee develops consensus on their objectives, HANC staff are responsible for developing and monitoring an action plan and documenting progress. Most of the project management work is done by the HANC staff person. Administrative and project management responsibilities usually include: setting call and meeting agendas, drafting and/or collecting and distributing materials, coordinating logistics for teleconferences or meetings, chairing conference calls or meetings, taking and

distributing minutes and ensuring that action items are communicated, tracked and completed. HANC staff also update information and manage the HANC Portal teamsites as a collaborative space for each working group, develop web-based tools to meet working group needs and train group members on how to utilize them. Considering the voluntary nature of working group participation as previously described, it is not surprising that HANC staff are often tasked with creating initial drafts of work group documents for review and comment. HANC staff also serve as an important conduit of information between different groups with potential shared interest or overlap in activity (e.g. ensuring that Network and DAIDS staff involved in Training communicate regularly with those involved in Laboratories regarding plans for Good Clinical Laboratory Practice or IATA training for lab staff at research sites).

Communication and the Collaborative HANC portal

An online collaborative portal environment is used as a platform for communication and information exchange and a virtual home for cross-network activities. The secure HANC Portal environment includes: a document management system; discussion and collaborative areas like blogs, wikis, and discussion boards; calendaring and announcements; master contact system; meeting workspaces, work-team collaboration areas and the ability for custom web page and sub-site development by collaboration partners.

The HANC Portal has the capacity for complex customization as requirements dictate. Activities around the HANC Portal in the next year will include building additional pages and team sites, user management, responding to support requests via a ticketing system, and developing increased functionality as requirements dictate. Some of the specific areas of portal development include:

- **Optimizing portal user experience -** In order to utilize technology tools necessary for effective collaboration, a minimum standard for client access points, including operating system, internet browser and productivity tools should be in place for individual HANC members. We will work to identify and document the current client access points each HANC portal member utilizes and make recommendations for both "minimum necessary" and "optimal" upgrades.
- **Optimizing portal access for mobile devices –** HANC IT staff will research and implement improvements to the portal to allow increased connectivity via mobile devices.
- **Providing web-conferencing capabilities via the HANC Portal -** Web-conferencing services facilitate real-time collaboration and represent cost-savings by decreasing the need for frequent face-to-face meetings. HANC staff are exploring options to make web-conferencing available to cross-network committees and working groups.
- **Training Coordination –** HANC staff continue to pursue new tools to increase awareness and accessibility for cross-network training opportunities. The portal will be used to capture training requests, inform users of available regional trainings, and offer a variety of resources to access on-line trainings. The portal will also provide a training module document library.
- **Developing portal user management tools –** HANC IT staff will develop and implement an efficient automated process for user management, to include: electronic form requests for new users, validation of affiliation with a network, and capture of all user contact information to populate and maintain a robust HANC Contact System.

Clinical Research Support (CRS) Contract

The HIV Clinical Research Management Support (CRS) contract between DAIDS and 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. PPD is a leading global contract research organization providing discovery, development and post-approval services. Networks request network-specific CRS services from PPD through their designated point-of-contact at DAIDS. Requests for CRS services that apply across networks are made through the HANC office. HANC coordinates the development of cross-network requests for CRS services, submits them to the CRS Project Officer, tracks their progress and liaises with DAIDS, CRS contractor staff and the networks involved. Tools on the HANC Portal are in development to streamline CRS Request submission, tracking and status communication.

IV. Focused Areas of Priority Coordination

Network Leadership and Oversight of Coordination Activity

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) and the AIDS Clinical Trials Network Strategic Working Group (SWG) are cross-network bodies established by DAIDS that the HANC office participates in and helps support. The SWG is a working group of ARAC that is intended to provide strategic review and planning for the coordinated research efforts of the NIAID-funded 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 periodically to review and discuss cross-network issues as well as specific scientific plans, progress and opportunities. Although the SWG is facilitated and supported by DAIDS, Dr. Kublin is an active participant, working with DAIDS leadership and the Network Principle Investigators (PIs) before and after each SWG meeting to encourage productive discussion when the group is officially convened.

The NLOG is charged with implementing and advancing optimal collaborative clinical trials research activities among the NIH-sponsored HIV/AIDS clinical trials networks. This group considers crucial operational and scientific questions to drive collaborative efforts among the networks and other research partners and oversees the coordination of common activities across the networks. The NLOG makes recommendations to NIAID and DAIDS regarding resource allocation that would improve efficiency within and across networks. HANC convenes the NLOG via bi-monthly teleconferences to consider Leadership-level coordination issues and provide oversight to the overall coordination activity. HANC staff are responsible for working collaboratively with DAIDS and the Network PIs to set NLOG agendas, lead the calls and meetings, and ensure that any tasks or issues that arise from NLOG discussions are addressed.

HANC staff also convene monthly conference calls with the Network PIs to address issues that are best dealt with on a small-group level. HANC staff keep the PIs appraised of cross-network coordination activities, opportunities and challenges. Although this work plan does not include specific objectives related to Network Leadership, cross-network interactions at the leadership level are critical for informing all areas of cross-network activity. Ideas and issues raised within the three leadership forums often become activities or objectives that the various coordination area specific committees or working groups are then tasked with.

Laboratory Coordination Objectives and Activities

A Cross-Network Laboratory Committee comprised of the Lab PIs and Lab Managers from each DAIDS-funded network, DAIDS staff, HANC staff and other individuals as appropriate has existed since early 2005. Laboratory coordination across the networks is currently focused on three major objectives.

A. Laboratory Coordination Objective #1: Maintain a structure and processes for consistent communication and access to critical information across the Network Core Laboratory Programs.

Strategies and activities to support this objective:

- An annual face-to-face meeting will be held to bring together the Laboratory PIs, Laboratory Managers, DAIDS Laboratory program staff, and key contractors/partners. The first of these annual meetings was held in August 2006 in Washington D.C. to focus on Laboratory Management and standard quality assurance. To minimize travel costs, the annual face-to-face meeting in 2007 will

be held in conjunction with network meetings if possible. A clear purpose and intended outcome for the meting will be defined and communicated in advance.

- A Cross-Network Laboratory PI and Manager Committee comprised of the Lab PIs and Lab Managers from each DAIDS-funded network, DAIDS staff, HANC staff and other individuals as appropriate will meet monthly via teleconference. This Committee was first convened in March 2005 and is intended to guide the working groups and participants responsible for the implementation of the cross-network laboratory activities including proficiency testing coordination under the Total Quality Management (TQM) Program. It will also focus on many of the operational and implementation issues around laboratory coordination.
- The HANC Portal laboratory coordination teamsites will continue to be developed and new functionality implemented as a platform for communication and a tool for the coordination of laboratory activity. The laboratory committees and working groups intend to increasingly utilize the HANC Portal for communication, review and tracking of laboratory issues, such as the proficiency testing results and associated corrective action described in Objective #2.
- A laboratory database integrated with the DAIDS-ES master contact system may be developed and accessed through the HANC Portal. This would contain additional parameters useful to the Network Core Laboratories, such as an inventory of laboratory equipment, assays conducted, and access to operating procedures.

B. Laboratory Coordination Objective #2: Establish standard quality assurance across networks and other partners through the further development and implementation of a Total Quality Management (TQM) Program.

The validity of diagnostic and monitoring tests used by a laboratory is entirely dependent on the quality of the measures employed before, during, and after each assay. The consistent production of valid results from studies conducted by the networks and other partners (CIPRA and HIV-related research programs funded by other NIH Institutes and Centers) is more likely to occur when an overall program that includes Quality Assurance (QA) and Quality Control (QC) is utilized. In the fall of 2006 the Cross-Network Laboratory PI and Manager Committees initiated the development of a TQM Program that will provide quality management for all of the protocol-specified assays conducted in DAIDS-sponsored network clinical trials. The goal of the TQM program is improve the transparency and responsiveness of decision-making regarding issues around the results of proficiency testing at DAIDS-funded site laboratories by improving communication and access to timely relevant information. The scope of the TQM Program is broad and will respond to the needs of the networks as the field of HIV research evolves.

Strategies and activities to support this objective:

- The Total Quality Management system developed in late 2006 will continue to be implemented, including the formation and facilitation of Quality Assurance Working Groups for each of the areas of laboratory quality assurance that involve the networks.
- The cross-network committees and working groups will develop, review, and modify as needed guidelines for laboratory quality management including but not limited to performance criteria and mechanisms for restricting protocol testing based on poor PT performance.
- TQM program documentation includes delineation of roles and responsibilities that should lead to standardization of international lab assessment and initiation.

- Tools on the HANC Portal will be developed and utilized for review and tracking of proficiency testing results and associated corrective action for international laboratories. This will allow for timely coordinated responses to potential problems, transparent tracking of issue resolution, and the ability to track and respond to trends over time.

C. Laboratory Coordination Objective #3: 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 making recommendations to the NLOG about how to implement changes to achieve these efficiencies.
- Develop consensus protocols for assays that are shared across the networks. A consensus PBMC processing SOP is currently in development and comparative studies are being conducted to determine if there are critical differences between the consensus SOP and that used by external partners such as CHAVI for specific procedures involved.
- Determine whether there is value in pursuing standardization of evaluation metrics for laboratories working with multiple networks. This would include collection of the evaluation measures used by the networks in evaluating their affiliated laboratories and establishment of some common evaluation metrics. If this is pursued it would likely involve engaging the Cross-Network Evaluation Committee and DAIDS contract resources (e.g., VQA, IQA, SMILE).
- Work with the Cross-Network SDMC Committee on LIMS-LDMS issues such as standardizing common data items used to identify specimens across networks.

Community Coordination Objectives and Activities

Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the DAIDS-sponsored HIV/AIDS Clinical Trials networks conduct research. CP will harmonize community-related practices within the networks as well as with external stakeholders to facilitate coordination of community-based activities. HANC staff serve as non-voting members of CP and provide group facilitation, project coordination, fiscal oversight, and administrative support.

A. Community Partners Objective #1: Develop and implement Community Partners membership and operations.

Strategies and activities to support this objective:

- Develop CP member internal communications through improved access to interactive online tools
- Develop relationships within cross-network leadership groups and increase awareness of CP within relevant community groups
- Identify CP activities that best support the mission and vision of the group

Objective #1 Activities and Methods	Expected Completion Date	Responsibility
Complete portal training for community member users; determine and develop additional site functions/options	July, 2007	HANC; CP
Identify additional objectives and specific activities for Year Two	July, 2007	CP
Draft and distribute introduction letter for CP reps serving on NLOG/SWG to PI's and network leaders	August, 2007	CP
Develop educational materials and/or briefing documents about CP. Determine appropriate audiences, distribution methods and goals, and related costs	September , 2007	CP; HANC
Begin discussion/planning for face to face meeting, if needed	October, 2007	CP; HANC

B. Community Partners Objective #2: Develop recommendations on providing community input into the planning and implementation of research activities.

Strategies and activities to support this objective:

- Complete community recommendations document and references.
- Involve community in review process of document.
- Distribute recommendations document to appropriate network leadership and community groups.

Objective #2 Activities and Methods	Expected Completion Date	Responsibility
Revise recommendations document	July, 2007	CRWG
Finalization and approval of document	August, 2007	CRWG; CP
Develop distribution goals and determine methods and costs	September, 2007	CRWG; CP

Distribute recommendations document	October, 2007	CP
Collect responses to document and provide final report	December, 2007	CRWG

C. Community Partners Objective #3: Utilize the Community Training Working Group to coordinate and develop cross-network CAB training materials.

Strategies and activities to support this objective:

- Develop CAB training materials that are relevant across the six DAIDS-funded HIV/AIDS clinical trials networks.
- Distribute CAB training materials to relevant network staff and community groups.

Objective #3 Activities and Methods	Expected Completion Date	Responsibility
Draft training modules	August, 2007	CTWG
Develop standard Community Advisory Board training materials	October, 2007	CTWG
Develop distribution goals and determine methods and costs	November, 2007	CTWG; CP
Distribute CAB training materials	December, 2007	CP
Collect responses to materials and provide final report	February, 2008	CTWG

D. Community Partners Objective #4: Identify, articulate and communicate scientific priorities of communities that are developed within the network community groups, areas of divergence from scientific researchers' priorities, and unaddressed issues or unmet community needs.

Strategies and activities to support this objective:

- Develop scientific priorities that reflect community needs and interests within the networks.
- Develop methods and processes for ongoing communication of scientific priorities to network leadership groups and researchers.

Objective #3 Activities and Methods	Expected Completion Date	Responsibility
Identify key scientific priorities; determine ongoing process for review of scientific priorities	July, 2007	CP
Collect/develop related reference materials to support priorities	September, 2007	CP
Determine process for communication of priorities with scientific community (i.e. as part of CP reps activity within SWG/NLOG; as a presentation at a particular conference, etc.)	November, 2007	CP
Present current scientific priorities; establish ongoing relationships for providing CP scientific priorities	January-March 2007	CP

Training Coordination Objectives and Activities

Training coordination includes compiling and sharing the vast library of training materials already developed within networks, identifying common Core Competencies, and collaborating on the development of new standardized training modules that are applicable across networks. The following working groups were put in place by the Cross-Network Training Committee to actively develop specific cross-network training: Safety and EAE Working Group, Admin-Fiscal Working Group and (in conjunction with Community Partners) the Community Training Working Group. The Cross-Network Training Committee continues to identify high priority areas that will address network and Clinical Trial Unit (CTU) training needs. Two additional working groups, the Risk Reduction Counseling working group and Research Methodology working group, are currently being formed to begin moving these curricula forward.

A. Training Objective #1: Develop and enhance common safety training modules.

Strategies and activities to support this objective:

- The Safety and EAE working group is focusing on safety evaluation and reporting including broadening safety assessment training with a focus on EAE, attribution and case studies.
- A standardized web-based EAE training module will be developed. Networks will have an opportunity to make sections of network-specific EAE content available online to supplement the standard module.
- A generic Attribution Training module will be developed for networks to modify as needed when providing attribution training in-network.
- The EAE working group will prepare and share complex adverse event case presentations via monthly teleconference. Access to these presentations and discussions will be made available to CTU clinical staff, including nurses and physicians, to assist in their clinical decision making.

B. Training Objective #2: Develop a modular fiscal and administrative training program to help research administrators meet minimum NIH standards.

The Cross-Network Admin-Fiscal Training Working Group was tasked in 2006 with developing an administrative & fiscal training program for CTU staff to meet minimum NIH standards. The working group developed an administrative and fiscal specific training Needs Assessment and CRS contract funding was obtained for distribution and compilation of data into a report. The Admin-Fiscal working group met face-to-face May 2-3, 2006 to review the data, prioritize training needs identified in the report, and plan for curricula development.

Strategies and activities to support this objective:

- Continued development of the following priority modules: Travel, Personnel, Facilities and Administration Costs, Grants and Record Tracking, NIH policy, Budget and Justification, Managing Subcontracts/Consortium Agreements, Close-Out, Applying Cost Principles, Modifications and Restricted Funds.
- Compilation of a manual (to be made available electronically and in print) to include each training module, frequently asked questions, glossary, and tools such as process flow diagrams, samples, templates and checklists.
- Plan and pursue training implementation to ensure that the Admin-Fiscal training program will: utilize multiple strategies that are internationally applicable; use a sustainable model through train-the-trainer approaches and mentoring; provide accessible trainings that will allow multiple

sites to attend the sessions; complement and build upon existing administrative and fiscal training resources; and evaluate the impact of the training.

C. Training Objective #3: Develop a centralized communication process for scheduled domestic and regional trainings and managing training requests.

Strategies and activities to support this objective:

- HANC is assisting DAIDS and the cross-network training committee in developing a cohesive communication plan that will effectively disseminate information about upcoming trainings.
- Development and implementation of a training request mechanism on the HANC portal to capture, evaluate and track resolution of all training requests from networks and CTU's in a timely and transparent fashion.

D. Training Objective #4: Develop and provide access to cross-network standardized training for high priority topics including risk reduction counseling, research methodology, Good Clinical Practice (GCP) and Human Subjects Protection (HSP).

At a December 2006 meeting, the Cross-Network Training Committee identified a number of high priority topic areas for additional coordinated training development.

Strategies and activities to support this objective:

1. Risk Reduction Counseling (RRC) training development:
   - HANC and the Cross-Network Training Committee submitted a CRS request and proposal to fund these efforts.
   - A RRC working group will be formed to focus on the development of the curriculum. Biweekly conference calls and occasional meetings may be scheduled to move these efforts forward in a timely manner.
2. Research Methodology training development:
   - HANC and the Cross-Network Training Committee will submit a CRS request and proposal to fund these efforts.
   - A Research Methodology working group will be formed to focus on the development of the curriculum. Biweekly conference calls and occasional meetings may be scheduled to move these efforts forward in a timely manner.
3. GCP and HSP online training module development and access:
   - HANC is working with Collaborative IRB Training Initiative (CITI) to provide online GCP and HSP training access to all DAIDS-funded networks and their clinical trial sites as an efficient method to meet the requirements of the DAIDS training policy.

E. Training Objective #5: Develop a long-term plan for implementing standardized training across the networks

As standardized training modules in development become available for use, the Cross-Network Training Committee will need to develop a plan for coordinated implementation.

Site Management & Clinical Trials 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 potential high priority for coordination in the second year of the grant period. Although this is an area of coordination with great potential for harmonization, HANC has not yet convened a working group to identify objectives, nor have we initiated any site management & clinical trials logistics activities because DAIDS has been in the process of developing an Office of Clinical Site Oversight (OCSO) and any cross-network activities in this area will need to be undertaken in close collaboration with this nascent unit. Once OCSO is established and functioning, HANC will be working with them to pursue the initial exploratory objectives listed below.

A. Site Management & Clinical Trials Logistics Objective #1: Develop a Cross-Network Committee focused on Site Management and Clinical Trials Logistics Coordination.

Strategies and activities to support this objective:

- Identify staff across the networks and DAIDS to participate in an initial discussion to identify and discuss common challenges related to site management and clinical trials logistics and determine if there is consensus that there would be value in forming a Cross-Network Committee to address some of these issues.
- If there is consensus, identify the membership of and convene the Committee on an ongoing basis. This Committee will likely consist of representatives from networks, research sites, HANC, DAIDS and relevant attendees (e.g. DAIDS contractors). Staff from the newly formed DAIDS Office of Clinical Site Oversight (OCSO) will be important participants in this Committee to ensure communication and avoid duplication of effort.

B. Site Management & Clinical Trials Logistics Objective #2: Identify and prioritize coordination objectives and activities to pursue that will add value for the networks, sites and DAIDS.

- The Site Management and Clinical Trials Logistics Committee will identify and prioritize coordination objectives and implement activities related to site management and oversight, harmonization of clinical trial logistics and operations at the site level across the networks.
- Efforts have already begun to delineate and agree upon individual and shared responsibilities between Site Management (in reference to the networks) and Site Oversight (in reference to DAIDS). As these responsibilities continue to evolve it will be important to identify and refine the respective roles of each to move all efforts forward efficiently and effectively. With the help of network leadership and staff; HANC, OPCRO, and OCSO will be able to facilitate this work.

SDMC 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 SDMC operations. The SDMC Working Group has been established and will be the basis for harmonization of the SDMCs. This group will focus on the following efforts during the coming year:

A. SDMC Objective #1: Establish Information Technology Best Practice Standards at Division of AIDS Clinical Trials Study Sites and Affiliated Laboratories

DAIDS network sites and laboratories often receive funding from multiple sources; therefore, it is common for sites to share their infrastructure, including data-acquisition devices, for different studies across different networks. In spite of the commonality of multi-network utilization, there are currently no

common strategies for establishing a technological standard at sites, or insuring that changes made to a site's technical infrastructure by one network won't negatively impact the work being done by another.

It is imperative that a mechanism be put in place that: reviews the current IT Infrastructure at each site; identifies the optimal standards achievable for that site, given its location, and financial and personnel resources available; communicates recommended improvements to all networks affiliated with that site; and implements necessary improvements in a way that does not "break" essential systems at any networks involved.

Strategies and activities to support this objective:

- HANC working with the SDMCs will establish a set of baseline technological standards (specifying both the minimum requirements, and ideal standards) for sites and laboratories, both domestic and international, in the following categories: Power Stability/Reliability; Anti-virus/Spyware protection; Data and telecommunications; Local-Area Network; Centralized File and Applications Server; Data Backup/Recovery and Disaster Recovery Plan; Security; and IT Training, Documentation and SOPs/WPGs.
- These standards will be monitored and regulated by an oversight body that consists of representatives from the network SDMCs, CHAVI, DAIDS, and any other relevant partners;
- There will be a coordinated channel of communication among this oversight body for technological issues, to share information that might be relevant across networks and knowledge areas, coordinate travel, training and technological milestones (e.g., switching over to a new internet connection).

B. SDMC Objective #2: Establish a "Data Exchange Standards" book that describes the necessary structure for data interchanges of Assays, Inventories, and Manifests

The establishment of data standards has been shown to improve the quality and lower the costs of data management. To this end, SCHARP and FSTRF propose to identify and document Best Practice data formats used in data pipelines (from creation, transmission receipt, quality assurance, and storage) for the capture of clinical, specimen tracking, and assay data. The University of Minnesota Data Center supporting INSIGHT will also be included in these discussions.

Strategies and activities to support this objective:

- Establish standards for clinical data formats associated with case report forms (CRFs)
- Establish standards for laboratory assay data formats associated with immunological and genomic sequences assays
- Establish specimen tracking data formats associated with the monitoring of specimen repository inventories, and associated with manifests used in specimen shipping.
- Initiate discussions among the Networks surrounding Electronic Data Captures at sites and Data Management Centers.

C. SDMC Objective #3: Laboratory Data Systems Harmonization

Multi-LIMS Manifest Harmonization

The three unique LIMS systems in use in the HVTN network (international site affiliated labs use the Laboratory Data Management System (LDMS) as provided by FSTRF; U.S. site affiliated labs 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 to make additional changes to the manifest format used to send shipments to the Repository, in order to complete Manifest Harmonization efforts.

Strategies and activities to support this objective:

- SCHARP and FSTRF working in coordination will:
  - identify required data elements across the various LIMS systems for specimen shipment and reception;
  - create code mappings across the LIMS systems as needed;
  - and identify common inventory data elements required by the SCHARP Data Management Center to appropriately track and QA the data.
- SCHARP and FSTRF will work with each individual collaborating partners to ensure that these 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.

Build upon Laboratory Harmonization Efforts between FSTRF and SCHARP

Because of its participation across a broad spectrum of networks in the collection of laboratory data, FSTRF has been concerned about the harmonization of such data across these networks. Building on its past experience in providing the LDMS and sequencing data facilities to the ACTG, IMPAACT, and several smaller projects, FSTRF has been working very closely with SCHARP to implement such facilities for the HPTN, HVTN, MTN and CHAVI networks and the upcoming PAVE trial at two levels: the laboratory and the data center. Building upon these efforts, the following work would further improve Lab Data Harmonization:

Strategies and activities to support this objective:

- Streamline training issues surrounding data entry checks and logic across affiliated networks for laboratories participating in multiple networks.

D. SDMC 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 continue to work with the DAIDS MedDRA consultant towards harmonization of MedDRA coding. These efforts will also achieve a higher standard of MedDRA coding.

Strategies and activities to support this objective:

- Each network to designate a lead coder who will have completed formal training in MedDRA. This individual may be shared across networks.
- The lead coders will be organized into a working group, which will be chaired by one of the lead coders; the chair will be rotated annually. The working group will meet face-to-face at least once per year, rotating between network locations, and conduct conference calls at least once per month.
- 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 will also be 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.
- The SDMCs are assuming that DAIDS will provide an individual who had the training and experience to function as an outside reviewer for this working group. The individual should be willing to make a long-term commitment to this group. The lead coders may contact the outside reviewer on individual issues when they believe it is appropriate. DAIDS should be willing to provide medical knowledge support, in the form of a physician, who can serve as a medical advisor not only to the working group but the individual lead coders as well. Also, if necessary, DAIDS should be willing to involve additional expertise to resolve important issues.

E. SDMC Objective #5: Coordination of Resource Allocation for DMC Activities with DAIDS Study Sites

There continues to be questions surrounding who is responsible for covering costs associated with DMC activities with DAIDS study sites. The purpose of this objective will be to establish a standardized plan for allocating resources for DMC activities in order to clarify the party responsible for costs, and help sites plan for what items should be included in their budget request to DAIDS.

Strategies to support these efforts include:

- Document the current year's resource allocation for DMC activities with DAIDS study sites for all DAIDS-funded DMCs;
- Decide on the preferred resource allocation for DMC activities with DAIDS study sites for all DAIDS-funded DMCs;
- Identify current gaps in resource allocation and come to consensus on who is responsible for costs;
- Develop a plan for standardization of Resource Allocation for DMC activities with DAIDS study sites.

Evaluation Coordination Objectives and Activities

The need for enhanced and harmonized network evaluation has been recognized among all the groups coordinating the management, operations, and scientific agendas of the networks. A Cross-Network Evaluation workgroup was established in December 2004 to address cross-network evaluation issues. The evaluation group shared their evaluation handbooks, which include performance measures and standards.

A. Evaluation Objective #1: Work with CSI and DAIDS to review the data generated by CSI project activities and participate in developing an evaluation framework, metrics and processes.

DAIDS has contracted with an external consultant group, Concept Systems Incorporated (CSI), to develop an Evaluation System for DAIDS and its funded research programs. HANC has worked with DAIDS and CSI to collect and synthesize network input for the DAIDS Network Evaluation Project, and involve the networks and the cross-network committees and working groups in the project. Individuals across the networks and DAIDS participate in sorting information in October and November 2006 in an online environment provided by CSI. CSI will use these results to compare the value of different success factors, assess consensus across groups, and create value maps for specific groups of stakeholders. The resulting map and associated

graphics and data summaries will be shared with DAIDS, HANC and the Cross-Network Evaluation Committee in summer 2007.

Strategies and activities to support this objective:

- The Cross-Network Evaluation Committee will reconvene in summer 2007 to review the concept mapping CSI activities will generate.
- In the autumn the Cross-Network Evaluation Committee will actively participate in a broadly representative Evaluation Measurement Task Force CSI will convene to assist in interpreting the framework and using it as the foundation for deciding what should be evaluated and how those priority elements should be evaluated.

V. Activity Updates and Evaluating Coordination Progress

The HANC office has identified coordination objectives across the topic areas listed in Table 1 of the Introduction. To meet these objectives a certain level of transparency will be required among the stakeholders. Clear progress updates by the HANC office will inform the various partners of progress, challenges, and the value added by meeting these objectives. Cross-network coordination activity status and progress reports will be shared with stakeholders via the following:

- Presentations from cross-network committees and working groups on NLOG teleconferences highlighting progress, challenges, and new issues for consideration;
- Quarterly progress reports posted on the portal and sent to each Network Executive Committee; and
- An annual Progress report provided to DAIDS.

As mentioned in the Executive Summary, this Scope of Work document outlines cross-network coordination objectives and activities proposed by the current cross-network committees and working groups at a high level. The details of these strategies and activities that must be implemented in order for the objectives outlined in this document to be achieved will be determined by HANC staff in coordination with the cross-network committees and working groups. The details of process, schedule and outcomes will be handled at a committee or working group level, and progress in meeting these objectives will be monitored and communicated on a regular basis by HANC staff, as outlined above. Table 1 in the Executive Summary contains an overview of the current objectives proposed for each area of cross-network coordination

Performance evaluation of the HANC office will also be an important tool to identify any areas of improvement, and thereby guide future directions for coordination and increasing efficiency. Believing that well-structured metrics will drive change and encourage more effective coordination processes, HANC staff have begun the process of identifying quantitative and qualitative metrics to assess how well both cross-network coordination activities and HANC staff efforts to support them are working. Metrics for assessing the success and value of cross-network coordination activities and the success of HANC efforts to support these activities are related but not the same.

Cross-network coordination metrics will be an important tool to:

- Ensure that success factors for collaboration are in place
- Uncover underlying issues that will impede success
- Capture lessons learned and improve processes
- Document and illustrate the value of coordination efforts and increased collaboration
- Identify and prioritize areas of action and areas that need improvement
- Assess the effectiveness of HANC staff and tools provided to support coordination activities

Evaluation measurements to assess the progress of the HANC office and cross-network coordination will be linked to the coordination objectives in each topic area, and will be incorporated into the activity reports and progress reports highlighted above. HANC also realizes that the success of collaborative efforts depends on the motivation and active participation of all partners, which HANC can encourage but cannot control. Evaluation and performance standards for HANC support will be established in such a way that when objectives are not met due to external factors this is clearly identified and HANC staff are not unreasonably held accountable for challenges outside of their control.