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Old HANC Website Homepage:



Infrastructure and Administrative Support

The HANC Public Website

The HANC public website (www.hanc.info) provides information and resources for collaborators, research sites, and the general public. HANC released its newly branded site early in June 2010. Functionality and content added to the website this quarter included:

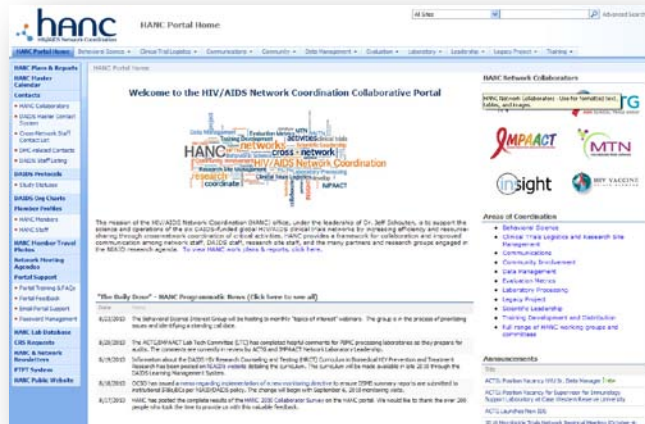
- Improved navigation
- Links to community/trial participant resources
- OCSO SOPs
- Links to HANC’s Facebook and Twitter pages
- Easily updated program spotlight applet on the homepage
- Developed HANC blog
- Pages for the DAIDS-ES Applications Training Information

New HANC Public Website Homepage:



Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC & IT staff	Public site updates and rebranding project.	Improved capacity, ease of navigation flow and access to information.	Ongoing.	Launched new site and HANC is in process of implementing phase II design plans.

The HANC Portal



The HANC Portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. During this quarter we had a net gain of 149 individuals with HANC portal user accounts, for a total of 943 active HANC Portal user accounts. Five additional team sites were developed this quarter, including the new Behavioral Science Interest Group Resource Center, IT Best Practices, IT Infrastructure Working Group, Legacy Women’s Consultation, and the Protocol Costing Project team site for a total of 58 team sites. HANC portal projects for 2010-2011 include:

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Review user statistics and member survey data collected to inform HANC portal improvements.	Improved communication and access to information to support decision-making and completion of cross-network objectives.	Ongoing.	Google Analytics have been installed on the HANC public web site and the portal. HANC staff reviews usage reports on an ongoing basis.
HANC staff	Provision of the DAIDS-ES protocol reports on the HANC portal.	Ready access to all protocol reports including the quick summary data and accrual data from the DAIDS-ES system in real-time for HANC portal users.	Development completed.	Ongoing activities include embedding links to protocol reports in call minutes, linking to protocols referenced in the HANC newsletter, and updating the protocol report details as necessary.
HANC staff	Feasibility of linking to the DAIDS-ES document library of all approved network protocols on the HANC portal.	Ready access to all network approved protocol documents for HANC portal users.	Q2.	HANC received approval to link the DAIDS-ES document library to the protocol reports available through the HANC portal-DAIDS-ES web feed. Connectivity was tested and HANC IT staff is working with DAIDS-ES developers. Expected to be activated in Q2.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC staff	Adding features and resources for HANC members.	Improved resource and information sharing amongst HANC members.	Ongoing.	Expanded the member profile library, and reorganized the portal homepage. Launched new “portal theme” to complement the new HANC website and logo.
HANC staff	Upgrade to SharePoint 2010	Improved functionality and ease of use.	Ongoing.	Consulted with IT staff to determine feasibility and timeline.

Social Networking & Information Sharing

HANC has established 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 bi-monthly to monthly. “HANC Portal 101s” are now offered on a monthly basis and “as requested” basis. HANC members are invited by HANC to participate in a walk-through of portal/website resources and given the opportunity to learn more about SharePoint technology.

Behavioral Science Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Convene plenary sessions at network annual meetings to discuss new developments and their implications for network science.				
Behavioral Science Working Group	Propose behavioral science plenary sessions to network conference planning committees. Curate and organize sessions.	Identify network and behavioral science agendas/priorities and identify gaps, overlaps and provide input from the behavioral science perspective in shaping agenda items.	Ongoing.	The BSWG will continue to propose topics for network meetings. Helped plan a session at the June 2010 ACTG OpART business session meeting and a luncheon at the HTPN June 2010 meeting for the new HPTN Scholars and behavioral scientists. The group discussed the possibility of hosting symposia at the Spring 2011 ACTG and HPTN/IMPAACT conferences.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Create a repository of behavioral science tools and measures.				
Behavioral Science Working Group, NIMH	Create a library on the HANC portal for all BSWG members to access “state of the science” measures, forms, and articles.	Allow investigators to compare efficacy of research tools and share outcomes of behavioral science substudies/practices in network clinical trials.	Ongoing.	The portal library has been created and is updated on a weekly basis. To date, over 159 documents have been loaded to the site. A Behavioral Social Science library with links to PubMed abstracts has been created on the HANC public website.
Objective #3: Collate and analyze behavioral data elements across network studies.				
Behavioral Science Working Group, NIMH	Create a library on the HANC portal for all BSWG members to access “state of the science” measures, forms, and articles. Ongoing updates to the Network “Behavioral and Adherence Measures” table.	Allow investigators to compare efficacy of research tools and share outcomes of behavioral science substudies/practices in network clinical trials.	Ongoing.	The library has been created and is updated as able. The “Behavioral and Adherence Measures” table is updated on an as needed basis. The BSWG will review network CRFs and BSS elements on upcoming calls/webinars.
Objective #4: Collaborate on shared, permanent products such as white papers or manuscripts, conference proceedings and workshops.				
Behavioral Science Working Group, NIMH	Provide opportunity for investigators to share ideas and collaborate on behavioral science materials and recommendations.	Ensure that the best quality behavioral science is integrated into clinical trials.	Ongoing.	The BSWG has finalized the 2010 BSWG F2F Meeting report and recommendations. The group will host one full group meeting and two focus groups in Y5. The Working Group discussed ongoing network behavioral and social science activities.
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 review procedures.				
Behavioral Science Working Group	Identify areas of opportunity and challenges in the development/implementation of cross-network/trans-Institute protocols.	Ensure that the best quality behavioral science is integrated into clinical trials; reduce redundancy.	Ongoing.	Discussed goals on monthly conference calls. Will share objectives at October 2010 SWG presentation.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #6: Improve information exchange among network-affiliated behavioral and social scientists.				
Behavioral Science Working Group, Behavioral Science Interest Group	Compile a list of network-affiliated behavioral and social scientists and create a “Behavioral Science Interest Group” (BSIG) distribution list modeled on the NLOG. The list allows investigators to share updates in the field, innovative research methods, and links to seminal papers.	Improved communication and circulation of ideas.	Ongoing.	Created BSIG listserv and portal-based resource center. HANC circulates a weekly digest of newly published BSS articles, CRFs, funding opportunities, job openings, blog posts, etc.

Communications Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop cross-network strategic message guidelines and recommendations for study results dissemination.				
Communications Working Group	Create a set of Best Practices for study results dissemination.	Harmonize network approach to communicating results and to reinforce the inter-connectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	Discussed CAPRISA 004 results dissemination plan and post-announcement follow-up; consulted NIAID as to the possibility of creating a pass-through disclaimer page allowing NIAID to link out to network websites.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Consider ways to harmonize network communications strategies and external relations policies.				
Communications Working Group	Areas of interest include: review and identify points of commonality across network websites; discuss network policies regarding posting protocol documents on public websites; network website recruitment strategies; links to outside parties including all other networks; evaluate 508 compliance on network websites.	Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	Reviewed network sites and identified possible areas of harmonization, considered how each network maximizes its web presence; ongoing discussion of network policies around posting protocols or synopses; consulted NIAID as to the possibility of creating a pass-through disclaimer page allowing NIAID to link out to network websites; discussed 508 compliance and circulated NIAID guidance; reviewed and circulated network communications policies.
Objective #3: Develop a Communications Resource Center (CRC) on the HANC portal.				
HANC Staff	Create a portal-based library of communications resources including: articles, guides, presentations, contact information, Best Practices, and white papers.	Facilitate communication and share Best Practices across the networks and provide opportunity for clinical trials communications professionals to develop relationships.	CRC created. Updates ongoing.	The CRC is a library of communications resources including: articles, guides, presentations, contact information, best practices, and white papers. Network communications staff and professionals in the field have access to the site and are encouraged to contribute content. Non-network partners include representatives from MMCI, AVAC, and IAVI. HANC is exploring expanding the CRC membership to a broad array of HIV/AIDS advocates and research organizations.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #4: Share IT- and communications-related developments across all areas of coordination.				
HANC Staff	Standing opportunity to share programmatic updates on conference calls across all areas of coordination. Examples include: the IT Best Practices document developed by the DMC Harmonization Working Group; Community Partners and the Site Coordinators Working Group concerns about IT needs at resource-limited sites; implementation and use of DAIDS-ES web services; privacy and IT security issues; Legacy Project activities in the field and use of social media.	Improved communication across networks and HANC activities.	Ongoing.	Cross-cutting issues are addressed on HANC calls and outcomes are shared via email. Programmatic updates are posted on the Daily Dose, Twitter, Facebook, and in the HANC newsletter. Guests are invited to join working group calls on an ad hoc basis. Q1 calls addressed HANC and network website redesign projects. WG members discussed the cross-network trend towards making more documents available on the public websites as well as tips/considerations for networks as they advance through the redesign process. WG members worked with AIDS.gov to reorganize and highlight the series of DAIDS network restructuring blogs .
Objective #5: Review existing methods of evaluating communications efforts and consider which practices could be employed within the networks.				
Communications Working Group, IT Infrastructure Working Group	Areas of interest include: review existing website usage tools; share experiences using social network sites (e.g., Facebook and Twitter) and document web traffic generated from new media sites; discuss focus group guidelines and outcomes; community education strategies.	Leverage individual network successes and share lessons learned. To quantify communications outcomes with a mind to improved efficiency and effectiveness.	Ongoing.	Monthly discussion of network websites, use of social media, and ways to improve communication with network members and the general population. Much attention has been paid to social media tools. Discussed the possibility of employing the AIDS.gov Google map widget on network sites and including clinical sites on the AIDS.gov service locator. Q2 calls will be dedicated to the development of evaluation metrics.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #6: Review and make recommendations about communications best practices and evaluate available resources such as the Microbicide Media and Communications Initiative “Clinical Trial Handbook”.				
Communications Working Group	Review and recommend network communications Best Practices.	Harmonize network communications activities and to reinforce the interconnectedness of all areas of DAIDS-funded clinical trial research.	Ongoing.	Discussed the MMCI Handbook at length and coordinated an additional conversation with the Site Coordinators WG. Established connection with IAVI communications staff and invited the group to present on their social media protocol audit and outcomes.
Objective #7: Invite key stakeholders, opinion-makers, and experts in the field to present on Working Group calls. Areas of expertise could include: journalism, advocacy, blogging, and cultural anthropology.				
Communications Working Group, IT Infrastructure Working Group	Engage communications professionals on monthly conference calls and ad hoc webinars.	Deepen understanding of new tools; learn from other organizations experiences and expertise; share ideas across an array of domains; provide opportunity for clinical trials communications professionals to develop relationships.	Ongoing.	Q1 presenters included: Beth Robinson (FHI/CAPRISA 004 Communications Lead), David Nalos (Social Media Strategist, SFDPH), Evan Urbania (Chatterblast Media Consulting) Michelle Samplin-Salgado (AIDS.gov) Soyon Im (Internet Strategies Manager, HVTN). Upcoming calls will feature IAVI and NHVREI representatives.
Objective #8: Identify, implement, and maintain tools to improve cross-network communication.				
HANC staff	Maintain resources such as the DAIDS staff listing, data management related contact list, cross-network collaborator list, network newsletter library, archive of network meeting agendas, disseminate DAIDS and network updates.	Foster communication and access to contacts within the DAIDS and network structures.	Ongoing.	Updated libraries and resources as able; increased frequency of newsletter; posted updates and notices to the HANC portal’s Daily Dose, Twitter feed and Facebook page. Standing opportunity to share programmatic updates on conference calls across all areas of coordination.

Community Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Develop a community research priorities agenda.				
Community Partners Research Priorities Working Group	Draft a clear written outline of the project scope, intent, timeline and criteria to determine project success. Identify CP members to work on this project. Develop the research agenda.	Identify network and community scientific agendas/priorities and identify gaps, overlaps and provide input from the community perspective into the research agenda.	Completed prioritization, will now disseminate results.	The group presented priorities to the full CP and to Carl Dieffenbach during the CP F2F Meeting. The group was instructed to reduce the list of priorities to the top 5-6 in prevention and treatment. The group held numerous conference calls and determined that the best approach was to score and rank the priorities. The group presented the ranked list to full CP and will present the results to DAIDS and Network Leadership at the upcoming SWG Meeting.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Utilize the Community Training Working Group to share existing CAB training materials, identify and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules.				
Community Training Working Group	<ul style="list-style-type: none"> Utilize the Community Training Working Group to share existing CAB training materials; identify and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules. Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Partner with groups to incorporate a human rights perspective into capacity building and research participation. Create simple training materials from existing content describing Community Partners as well as the science and structure of the networks. 	Common CAB member understanding of basic concepts in HIV disease, clinical trials methodology, and CAB role. Improved training quality and consistency.	Ongoing.	In partnership with DAIDS this group worked to implement and facilitate a train the trainer session of the newly developed curriculum at the DAIDS Regional Training Events in Pune, India in May 2010 and Lusaka, Zambia in August 2010 to train the site staff and offer the course at their sites for their community members and new site staff.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Consider evaluation of Community Partners efforts and activities and develop and implement mechanisms to evaluate progress and impact and serve as an advisory group to the EMTF.				
Community Partners Evaluation Working Group	<ul style="list-style-type: none"> Develop a continuous quality improvement process for CP. Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level. Identify objective metrics and mechanisms for evaluating the impact of CP activities. 	<p>Clear measures to demonstrate the value of CP and data to identify opportunities to increase CP effectiveness.</p> <p>Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites</p>	Ongoing.	Collaborated with the EMTF and CP site-level funding WG on evaluating and understanding the CP survey results and requested secondary analyses of survey results.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.				
Community Partners Site-Level Funding Working Group	<ul style="list-style-type: none"> • Research current site/CAB funding structure to understand the system. • Developed and administered Site CAB and Site Staff Surveys to assess community participation at the site level. • Partner with the network leadership to assess how the site funding mechanism has impacted community involvement at the network, CTU and CRS level. • Identify expectations for CAB support and funding that tie into cross-network community evaluation and make actionable recommendations to network leaders and DAIDS. 	Adequate site-level CAB support. Assess CAB activities and knowledge at NIAID's DAIDS funded HIV Clinical Research Sites	Ongoing.	Collaborated with the EMTF and CP evaluation WG on evaluating and understanding the CP survey results and requested secondary analyses of survey results.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #5: Utilize CP to provide broad input and recommendations to DAIDS for upcoming network recompetition and restructuring process.				
Community Partners	Solicit input from networks and other interested groups to provide input and recommendations to DAIDS regarding the Network recompetition and restructuring process.	Identify network and community concerns and provide input in shaping the DAIDS recompetition and restructuring process.	Ongoing.	In follow-up to the CP Meeting in May 2010 formed an Ethics Working Group to address ethical concerns across networks. Collaborated with UNAIDS/AVAC to provide input on revising the Good Participatory Practice (GPP) Guidelines for Biomedical HIV Prevention Trials. Tasked the Executive Committee with gathering and facilitating feedback and input to DAIDS on the upcoming and recompetition and restructuring process. Developed talking points for ARAC, SWG and NIAID Town Hall Meeting.
Objective #6: Review the following topics across networks, identify areas where there are problems or opportunities for improvement and work in collaboration with Network Leadership and DAIDS to address these issues.				
Community Partners Ethics Working Group	Solicit input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding: <ul style="list-style-type: none"> • Informed Consent Process • Management of Pregnancy and Contraception on Study • Trial design relative to guidelines/local standard of care • Placebo arms in prevention trials 	Identify areas where there are problems or opportunities for improvement to address these issues.	Ongoing	Formed a working group and held two conference calls. Invited OPCRO to call to provide a general ethics overview covering the needs for ethical codes and standards.

Data Management Center Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Implement Information Technology Best Practice Standards developed in Year 3 at DAIDS clinical trials study sites/affiliated laboratories and monitor infrastructure changes.				
DMC Harmonization Working Group	Implement Information Technology Best Practice Standards developed in Year 2 at DAIDS Clinical Trials study sites and affiliated laboratories. Monitor infrastructure changes.	Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems.	Review and updating ongoing.	Standing opportunity to discuss proposed infrastructure changes on monthly DMC calls. Created IT Best Practices Document Taskforce to review the documents, make recommendations, and consider possible application of IT Best Practices at DAIDS-funded sites. The Taskforce includes representatives from the DMCs, OCICB, and DAIDS.
Objective #2: Complete Laboratory Data Management Systems / Multi-LIMS Manifest harmonization.				
DMC Harmonization Working Group	Maintain code mappings across LIMS systems and modify specimen inventory data elements as requested by SCHARP to track and QA data. Work with individual collaborating partners to ensure that previously identified common data elements are included and supported in electronic manifest files readable across multiple systems and reported back to SCHARP in an inventory data feed.	Electronic manifest files readable across multiple systems and reported back to SCHARP as part of an inventory data feed.	Ongoing.	Discussions with DAIDS are ongoing.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.				
DMC Harmonization Working Group, Training Committee	Collaborate with the cross-network Training Committee to identify and address data management training needs.	Inform training plans and ensure that sites receive the data management training necessary to participate in clinical trials.	Ongoing.	Standing opportunity for DAIDS staff to address DMC training-related concerns. Ongoing discussion of DAIDS Learning Management System (DAIDS LMS) training at DRTEs. Invited DAIDS staff to join calls and discuss training needs resulting from the EAE Manual revisions.
Objective #4: Harmonize MedDRA coding.				
AIDS Defining Events Working Group	Reconcile CDC and WHO diagnostic classifications with MedDRA codes	Realize DAIDS' mandate to use MedDRA codes in DAIDS-funded clinical trials	Ongoing. Expect resolution in Q2.	Mappings have been completed and up-versioned to the current MedDRA standard. SDAC coders are running beta tests with mappings and HANC staff has coordinated a review with DAIDS-affiliated clinicians.
Objective #5: Harmonize data definitions and standards for compatible all-network use.				
DMC Harmonization Working Group	Identify data elements to be harmonized across network studies.	Improve efficiency and harmonization. Allow for cross-network studies/analyses.	On hold.	On hold pending DAIDS' recommendations.
Objective #6: Implement clinicaltrials.gov results reporting requirements.				
DMC Harmonization Working Group	Network Leaders asked that HANC work with DMCs to address cross-network issues and points of ambiguity.	Improved communication.	Ongoing.	Opportunity to share updates on monthly calls. HANC reports on Site Coordinators WG and Network Leader comments as appropriate.
Objective #7: Harmonize Clinical Event Collection policies and procedures to make recommendations on Adverse Events Reporting.				
DMC Harmonization Working Group	Coordinate and harmonize ongoing activities at DAIDS and the networks around clinical event data collection and adverse event reporting.	Create consistent policies and procedures for clinical event data collection and adverse event reporting.	Ongoing.	This objective is addressed in ongoing calls with OPCRO and the DMC Harmonization Working Group. The WG discussed the changes to the DAIDS EAE Manual on monthly calls. HANC disseminated DAIDS-issued memos.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #8: Monitor implementation of the DAIDS Expedited Adverse Events Reporting System (DAERS).				
DMC Harmonization Working Group	Provide DMC perspective and feedback to DAERS program staff and DAIDS leadership.	Ensure DMC systems are considered in the development and implementation of policies relating to DAERS.	Ongoing.	Opportunity to discuss experiences using DAERS on monthly and ad hoc conference calls. HANC will organize a call with the DAERS product champion in Q2.
Objective #9: Coordinate a one day DMC face-to-face meeting.				
DMC Harmonization Working Group	DMC representatives will use the time to present ongoing intra-DMC projects and consider additional areas of coordination.	Improve efficiency and harmonization.	On hold.	On hold pending further discussion of EAE Manual v2.0 implementation needs and DAIDS' recommendations on data element harmonization.
Objective #10: Create an email alias for DMCs and network operation center staff. The list serve will be a vehicle to share important DAIDS updates and HANC working group activities.				
HANC Staff	Create a DMC/network operations center staff alias.	Improved communication across DMC and network operation staff.	Q1.	Completed. The alias is used for relevant DAIDS' memos and policies and cross-cutting updates.

Evaluation Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.				
Evaluation Measurement Task Force	Hold calls as needed with each working group and CSI to advance the development of an evaluation system.	Develop evaluation metrics and processes to evaluate DAIDS and network success and identify opportunities for improvement.	Ongoing.	<p>Calls with the EMTF planning group are ongoing every other week and will switch to monthly calls starting in October. HANC and CSI met F2F in Seattle, 26th of August to review and discuss the Phase III scope of work for the next fiscal year.</p> <p>The first cross-network CAB survey, developed by the Community Partners and their relevant WGs was disseminated to CABs and sites. The survey assesses community participation at the site level. Survey results from over 100 CABS and sites are currently undergoing a secondary analysis. The protocol implementation timeline review is ongoing as is collection of accrual data for pluripotent sites compared to single-network affiliated sites in the Operations, Policy and Resources Advisory Group. Manuscripts are being drafted on the bibliometric analysis and protocol timeline implementation analysis.</p>

Laboratory Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Utilize and expand tools and venues for consistent communication and access to critical information across the network laboratory programs.				
ACTG/IMPAACT LTC and HANC Support Staff	Maintain a Lab Tech (LT) Committee Workload Tracking System; generate reports as requested.	Track information about LT work assignments to ensure equitable sharing of responsibilities and accurate awarding of credit.	Maintain and update data throughout the year; Q2 further develop reporting system	LT Workload Tracking System updated with current protocol and lab tech information in an ongoing manner.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Lab PI/Manager Committee	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and updates from the laboratory working groups.	Ongoing throughout the year.	On hold during Q1
LFG-DCLOT Collaborative Working Group	Determine process for vetting new labs.	Minimize unnecessary additions of new labs to DAIDS system, thereby minimizing resources necessary for lab start-up and monitoring.	Q2 Collect information; Q3 determine process.	Held one call during which the group clarified six DCLOT decisions regarding laboratory requirements and SMILE training and DAIDS Regional Training Events.
Lab Focus Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for cross-network discussion and resolution of issues that affect multiple networks.	Ongoing	Held 4 calls during which the group: <ul style="list-style-type: none"> • Discussed the DCLOT decisions regarding laboratory requirements • Reviewed draft guidelines for the validation of non-FDA-cleared tests • Weighed the pros and cons of moving testing from a particular lab to a new lab • Finalized revisions to “Cross-Network Guidelines for Diagnosis of HIV-1 Infection in DAIDS-Sponsored Clinical Trial Protocols” • Agreed on mandates for PBMC processing labs to use LDMS fields for the monitoring of PBMC processing and storage; distributed memo about mandates to affected labs • Finalized a cross-network CRS request for additional LDMS training resources • Revised a list of laboratory costs to be included in CTU budgets • Determined that the new CITI Biosafety Training Module would not be necessary for the networks

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
HANC Support Staff	Redesign Laboratory Coordination and Laboratory Resources portions of the HANC public website.	Provide clear information to the general public and laboratories about the working groups and their roles and make various resources available to labs.	Q1 Complete redesign	<ul style="list-style-type: none"> Completed redesign of Laboratory Coordination and Laboratory Resources portions of the HANC public website. Regularly updated page about ordering fetal bovine serum Updated Laboratory Working Groups and Committees page to include new Malaria Laboratory WG Updated Objective and Activities page to reflect those in Year 5 Work Plan Regularly updated VQAAB reports and minutes Updated VQAAB roster Added to Useful Links
HANC Support Staff	Develop and maintain a HANC Laboratory Database for network-affiliated international labs.	Provide a common resource for the storage and maintenance of laboratory information; develop consensus laboratory names to ease communications among network laboratory staff and contractor staff.	Ongoing.	On hold during Q1
Objective #2: Ensure standard quality assurance for all of the protocol-specified assays conducted in DAIDS-sponsored network clinical trials across networks and other partners through the development and implementation of a Total Quality Management (TQM) Program.				
Lab Focus Group/LFG-DCLOT Coll. WG/IQA CD4 WG/VQAAB	Develop guidelines for back-up plans for safety testing, CD4 testing and virology testing labs.	Consistent quality control of safety, CD4 and virology testing at network-affiliated laboratories and back-up labs.	Q2 Finalize and post	On hold during Q1

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
IQA CD4 Working Group	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA CD4 labs.	Consistent quality control of IQA CD4 testing at Network-affiliated laboratories.	Ongoing.	Held two calls during which: <ul style="list-style-type: none"> • Testing issues at labs were discussed and resolved. • Reviewed results of a FACSCount-FACSCalibur comparison study • Revised a draft flow cytometry instrument evaluation plan • Reviewed results of an IQA survey of laboratories' instruments
IQA Cryopreservation Proficiency Testing Advisory Group (ICAG)	Develop IQA intervention, corrective action, remediation and training approach;	Consistent quality control of PBMC Cryopreservation at Network-affiliated laboratories.	Completion target Q4 (May 11).	<ul style="list-style-type: none"> • Discussed the use of internal comparison testing between tech at PBMC processing labs • Determined an alternative proficiency testing scheme for a laboratory with a special shipping situation • Reviewed status of back-up lab query and determined next steps
ICAG	Maintain a structure, processes and a forum for consistent communication about and performance review of IQA PBMC labs.	Consistent quality control of IQA PBMC cryopreservation testing at Network-affiliated laboratories.	Ongoing throughout the year.	Proficiency testing summary was reviewed and specific laboratory issues were resolved.
ICAG	Develop and implement a plan for quality control of cryopreserved PBMC at the BRI repository.	Reliable results in functional and phenotypic assays.	Q1 Review results of pilot study; Q2-4 Collect and analyze additional samples; Q4 Evaluate results	Reviewed the results of a pilot study of PBMC samples stored at the Biomedical Research Institute and discussed next steps

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
ICAG	Formulate communication scheme and document (ICAG Working Group Guidelines for Communication and Data Flow) as part of the TQM document.	Clarify and outline responsibilities, monitoring, data and communication flow within the IQA PBMC Cryo PT program as part of the TQM document.	Q2 Review and revise; Q3 Finalize and post	Guidelines were drafted and then put on hold in favor of more urgent issues.
CPQA working groups (Advisory Board, Steering Committee and Lab Group)	Maintain a structure, processes and a forum for consistent communication about the CPQA PT program and labs.	Consistent quality control of pharmacology testing at Network-affiliated laboratories.	Ongoing throughout the year.	Held 5 calls during which the CPQA working groups communicated program details to relevant parties and reviewed: <ul style="list-style-type: none"> • Recommendations for HIV RNA processing time • AVR/SOP submissions • Validation of methods in rare matrices • Training options and plans • CPQA Program By-Laws • Advisory Board membership • Assay validation • Use of dried blood spots • Changes to the CPQA website and LDMS.
Virology Quality Assurance Advisory Board (VQAAB)	<ul style="list-style-type: none"> • Maintain a structure, processes and a forum for consistent communication about and performance review of VQA labs. • Review data and revise policies of the VQA proficiency testing program as necessary 	Consistent quality control of virology testing at network-affiliated laboratories.	Ongoing throughout the year.	Held 3 monthly calls during which VQAAB: <ul style="list-style-type: none"> • Reviewed proficiency testing reports and cumulative performance summaries • Approved memos to labs regarding a VQA specimen dilution plan and manual Abbott m2000 validation plan • Reviewed proposed changes for HIV RNA PT scoring • Determined that mid-protocol switch-over plans for the Abbott m2000 would need to be determined by the protocol team

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
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.				
ACTG IMPAACT/LTC and HANC Support Staff	Update Lab Processing Chart (LPC) standard wording and format.	Improve design of LPC for efficiency and user-friendliness and update standard wording to reflect current practice.	Q2 Complete updates to standard wording and conduct reviews and initiate reformatting; Q3 Finalize	Continued revisions to standard wording.
ACTG IMPAACT/LTC and HANC Support Staff	Add comments and example reference documents to PBMC Lab Audit Shell.	Provide laboratories with guidelines for audit readiness.	Q1 Finalize	Completed
Lab Focus Group	Recommend and implement new real-time viral load assay for use in network protocols with viral load primary endpoints.	Ensure reliable and consistent data collection.	Q2 Complete installation, validation and training.	Held 2 calls with Abbott to review status of implementation and provide information and guidance; status of installation pending.
Lab Focus Group	Develop common policies and tools for tracking PBMC processing time.	Reduce confusion and increase efficiency at labs; increase overall quality of PBMC specimens.	Q1 Finalize decisions and distribute memo to labs	Completed
Objective #4: Continue collaborating amongst the Networks, HANC, DAIDS and SMILE to improve TB diagnostics, TB proficiency testing and participation of labs with TB diagnostic capacity in Network protocols where TB is a component.				
TB Diagnostics Working Group	Maintain a structure and processes for consistent communication and access to critical information.	Provide a forum for communication among the networks, SMILE and DAIDS regarding TB laboratories and diagnostics.	Ongoing.	Held two calls to discuss: <ul style="list-style-type: none"> • Group name and role • Laboratory status • Microbank tube validation
TB Diagnostics Working Group	Plan site visits to TB diagnostics labs.	Evaluate TB diagnostics labs for capacity to participate in network protocols and serve as regional training centers.	Ongoing.	Completed site visits; no further visits are planned at this time.
TB Diagnostics Working Group	Develop draft language for network protocols that use TB diagnostics.	Provide standard language for networks to use in protocols that use TB diagnostics.	Placed on hold in Year 4.	This project is on hold.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #5: Collaborate among the networks, HANC, DAIDS and SMILE to establish a Malaria Laboratory Working Group.				
Malaria Laboratory Working Group	Determine working group membership, purpose and goals	Establish a forum for cross-network communication regarding malaria laboratories and diagnostics.	Q1 Establish membership and initiate discussions of working group purpose and goals; Q2 Share critical information across group members in order to finalize working group purpose and goals	Held two calls to establish working group membership and initiate working group purpose and goals.

Legacy Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Continue the development of the HANC cross-network Legacy Project.				
Legacy Project Leadership Team	Develop a HANC cross-network Legacy Project including detailing the project scope, intent, timeline and criteria to determine project success.	Enhanced cultural competency within the networks and build relationships of trust with African-American and Latino communities within the U.S. to enhance participation of African-Americans, Latinos, and Latinas in network trials.	Ongoing.	Continued search for Legacy Project Scientific Director and began recruitment for a new Legacy Project Manager. Staffing changes resulted in delay of strategic planning which will begin in Q2. Continued coordination with the HVTN Legacy activities.
Objective #2: Continue implementation of the Legacy Project transition strategy across the DAIDS-funded networks to ensure activities build upon and include HVTN-focused Legacy Project activities and the cross-network expanded activities.				
Legacy Project Leadership Team	Continue with transition planning.	Ensure collaboration with the HVTN Legacy Project and the HANC cross-network Legacy Project.	Ongoing.	Regular meetings were held with HVTN Community Relations and Education Unit and Legacy Project. HVTN formed two new groups, Site Expansion Team and Community Assessment & Site Assistance (CASA). Legacy Project staff were appointed to both bodies for support of HVTN and to ensure opportunities for cross network expansion were included in planning processes.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Continue to establish and implement clear definitions of synergy and cohesion between Legacy Project activities within the HVTN and HANC to ensure coordinated fiscal operations and maintain programmatic distinction while also ensuring singleness among external partners and collaborators.				
Legacy Project Leadership Team	Develop definitions and expectations.	Clear distinction but also coordination of programmatic activities to assure efficient implementation of both HVTN and the expanded network activities.	Ongoing.	Regular meetings were held with HVTN Community Relations and Education Unit and Legacy Project to coordinate the cross-network expansion. Those meetings included planning HVTN 505 Core support to boost site enrollment at Pride/Black Gay Pride events. Participation in those events provided opportunities for maintenance of connections established at ACTG CHPP training (Chicago, April 2010). For example, in Chicago, June 2010, Legacy Project Community Engagement Officers were able to support research recruitment efforts for HVTN 505, HPTN 061, and a local ACTG behavioral assessment simultaneously.
Objective #4: Expand the current Legacy Project Working Group (LPWG) to include membership and participation of all DAIDS-funded networks and establish regular communications with the working group.				
Legacy Project Working Group	Invite at least 2 representatives from each of the 6 DAIDS-funded clinical trials networks to join the current LPWG.	Ensure inclusion of each network's priorities and establish an efficient linkage between the Legacy Project and each of the Networks.	Ongoing.	Monthly call of the LPWG were held and focused on mission, structure, function and membership of the group. Work is ongoing in Q2. Expanded network representation on the LPWG includes: ACTG, HPTN, MTN, and INSIGHT. Representation from the HVTN remained the same.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #5: Establish effective and efficient operating systems for the LPWG via Subcommittees.				
Legacy Project Working Group	Establish and maintain LPWG Subcommittees; Vaccine Working Group, Communications Working Group, and the Behavioral Social Science Core. The Long Range Planning Task Force, which focuses on cohesive long range planning, which was previously established, continues its work.	Provide effective operations support for Legacy Project activities with maximum support for and from LPWG representatives.	Ongoing.	The LPWG held monthly calls which focused on issues including structure of the group and subgroups. Discussion continue in Q2 revisiting the structure of the LPWG.
Objective #6: Establish a cross-network advisory group, the Legacy Project Women’s Caucus, composed of women leaders from around the country who represent low-income women, high risk women, women who are living in high risk populations, or women experienced working with these populations.				
Legacy Project Women’s Caucus	Establish the Legacy Project Women’s Caucus. The Legacy Women’s Caucus operates as an integral part of US domestic HIV prevention and therapeutic research effort, focusing on women, especially those living in low-income, high risk areas, and other at risk women.	The Legacy Women’s Caucus will operate as an advisory and collaborative entity to the Legacy Project providing important direction and guidance from the perspective of at-risk women and their representatives to the DAIDS HIV clinical research effort.	Ongoing.	Legacy Project staff engaged the concept of a National Women’s Consultation. Borris Powell enlisted the support of Dázon Dixon Diallo (Sisterlove Inc.) and Dr. Stacey Little (AED), and Georgette King (FHI). This group serves as the Women’s Consultation working group. The meeting occurred June 11-12, 2010. Representatives from each DAIDS network provided overviews of ongoing and upcoming research related to and focused on women. Network representatives, Community Advisory Board (CAB) members, and women from various communities convened and dialogued on the future of research and women. A summary of those conversations has been communicated through a Women’s Urgency Document. Development of this group is ongoing on monthly calls.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #7: Coordinate HANC Legacy Project activities with other HANC cross-network working group and projects.				
Legacy Project Staff	Facilitate collaboration and harmonization among the various HANC working groups and projects.	Integration of the Legacy Project's focus on the populations most impacted by the HIV epidemic in the US into relevant HANC Working Groups for increased collaboration, harmonization and efficiency.	Ongoing.	Legacy Project staff established membership and participation on the HANC Behavioral Science Working Group, Site Coordinator Working Group, Community Partners and the Communications Working Group. The Legacy Project now has active participation on the Behavioral Science and Paris Mullen represents Legacy on the HANC Communication Working Group Call. The new Legacy Project Manager will participate on the Site Coordinator Working Group Call. Borris Powell and a Co-Chair of Legacy Women have active participation with HANC Community Partners, Legacy Women and HANC Community Partners are in communication about addressing ethical issues of women and pregnancy in research.
Objective #8: Provide protocol support, especially where Legacy Project target populations are a major and or priority population for study enrollment.				
Legacy Project Staff	Participate on protocol teams, where applicable, and/or in advisory, leadership or other roles.	Provide insight, advice and leadership from the Legacy Project perspective and representing the Legacy target populations.	Ongoing.	Borris Powell has assumed active participation on HPTN 061 Black Caucus. Borris Powell provides advisory and leadership support to HPTN 065 community engagement and relations activities and is the Legacy Project representative on the HPTN 065 Community Advisory Group. This group recently completed FAQ document for HPTN 065.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #9: Collaboration between the HANC Legacy Project and historically African-American Organizations				
Legacy Project Staff	<p>Strategies and activities to support this objective:</p> <ul style="list-style-type: none"> The Legacy Project will work with the leadership from these organizations. 	<p>The purpose would to develop a national campaign or strategy unique to each specific organization that would raise awareness and educate the African- American community about HIV prevention and treatment research, and engage in discussions about ongoing and planned HIV clinical</p>	On hold.	<p>In light of the organizational transition that has taken place with the absence of a Legacy Project Manager this initiative is on hold.</p>
Objective #10: Collaboration with the Black AIDS Institute (BAI) sponsored Black Gay Men’s Network (BGMN)				
Legacy Project Staff	<p>Provide leadership and workshops regarding the importance of clinical trials in the local community. Facilitate cross network collaboration at BGMN events. Provide cross network information at BGMN events. Educate the network about the science of HIV/AIDS treatment and prevention as well as prevention and treatment technologies (provide leadership).</p>	<p>Establish a relationship with the Black Gay Men’s Network that will allow for an increase of the participation and engagement of African American men into DAIDS-funded clinical trials; as well as to educate this demographic of almost 800 African American men about the science and research involved in HIV/AIDS treatment and prevention. Provide DAIDS-funded cross network exposure to the membership of the BGMN.</p>	Ongoing	<p>Hosted regional events where we have had cross network materials available to BGMN members. As well we have coordinated site representation for recruitment and education about current clinical trials at BGMN events. Currently organizing BGMN international retreat. There we will conduct workshops on clinical trials, HIV/ AIDS treatment and prevention. Legacy Project team attended the re-launch of the BAI Black Treatment Advocacy Network (BTAN). BAI Leadership was engaged in the possibility of establishing a chapter comprised of on –going relationships between network representatives and Legacy staff.</p>
Objective #11: Legacy, NASTAD and health department Initiative				

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Legacy Project Staff	Conduct a needs assessment of the current relationship between health departments, community based organizations and DAIDS-funded clinical trial sites. Develop a proposal to address that need and establish a formal relationship between these organizations.	Establish cohesive and formal relationship with health departments their contracted community based organizations and local DAIDS-funded clinical trial sites to foster referrals to research opportunities for people who both test HIV- negative and positive at local VCT sites.	On going	Conducted preliminary meetings with health department officials, Dave Kern, Prevention Director for Washington State Health Department National Alliance of State and Territorial AIDS (NASTAD), National Association for County and City Health Official NAACHO,
Objective #12: Legacy and Creating Change collaboration.				
Legacy Project Staff	Conduct an all day health summit that will address disparities within the US healthcare system for LGBT communities. Provide opportunities and information that will equip individuals to impact US healthcare reform from a grass roots and legislative level. Provide education and discussion around LGBT health, Healthy People 2020, National HIV/AIDS Strategy and relevance of the 6 DAIDS-funded clinical trial networks and their trials.	Engaging and educate communities about DAIDS funded networks. Provide opportunity for cross network collaboration. Provide scientific training around the new HIV technology and treatment and prevention modalities, Provide opportunities for community members to engage with and impact legislation in their local communities as it pertains to healthcare. Educate and facilitate conversations about LGBT health disparities and standards of care.	February 2011	Paris Mullen is Chair of CC2011 Health Institute. Responsible for organizing health institute planning committee, creating mission and objective of health institute.

Network Leadership

The AIDS Clinical Trials Network Leadership Operations Group (NLOG) held one call this quarter, in July, during which the results of CAPRISA 004 were presented by Quarraisha Abdool-Karim and disused. The draft report from the Behavioral Sciences Working Miami meeting was also reviewed. The SWG agenda for October’s SWG meeting was prepared and HANC will be allocated time to present an update on its activities. HANC organized 3 focused monthly conference calls with the six Network Principal Investigators and Co-PIs to address cross-cutting network leadership issues. HANC and DAIDS leadership also held monthly conference calls to collaboratively identify and address issues and share updates on activities. HANC had one call with OCSO leadership and was in frequent contact with OCSO to discuss the Protocol Costing Project and distribute policies in development to the Network Leadership Group. HANC held one call with OPCRO leadership during which OPCRO presented updates on the DAIDS EAE Reporting Manual Version 2.0 and implementation plans and timeline; ClinicalTrials.gov reporting; and OPCRO reorganization. HANC continued to work with OPCRO on the implementation of the “Manual for Expedited Reporting of Adverse Events (EAEs) to DAIDS”, version 2.0. HANC also continued to work with OPCRO and the networks and disseminated information about the new ClinicalTrials.gov results reporting requirements, and the resultant shift in responsibility to the networks for studies for which DAIDS is not the IND holder.

Site Management & Logistics Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Work closely with network staff and DAIDS representatives to review the harmonized network Financial Disclosure/Conflict of Interest requirements, synchronize network financial disclosure reporting schedules, and evaluate the feasibility of developing a cross-network web-based reporting interface.				
Network staff, OPCRO and OCSO	Develop a cross-network SOP addressing Financial Disclosure reporting requirements.	Harmonize the collection of financial disclosure data across the networks for their benefit and that of site investigators. Realize the cost-saving opportunity possible with a cross-network reporting system.	Completed SOP in Y4. Scope discussions are ongoing and will be completed by Q3.	The SOP was approved by Network Leaders in Q4 of Y4. The WG is now considering harmonizing the definition of members required to report as well as the implementation of a cross-network online reporting system.
Objective #2: Work closely with network staff, OPCRO, OCSO and other DAIDS representatives to identify and address priority site management issues.				
Network Leaders, OCSO, OPCRO	Identify an evolving list of site management issues and opportunities. Work closely with network staff, OPCRO, OCSO and other DAIDS offices to address priority site management issues.	Improve communication and site operations.	Ongoing.	HANC conducted one call with OPCRO and one call with OCSO. HANC had frequent communication with OCSO to share policies in development and information with the Network Leadership Group and the Data Management Harmonization WG.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #3: Discuss and address issues relevant to harmonization of policies, procedures and training at the site level across the networks.				
Cross-Network Site Coordinator working group	Provide a discussion forum dedicated to addressing significant issues common across the networks that need to be addressed.	To address issues of common concern and harmonize policies and procedures regarding site-level operations.	Ongoing.	This Working Group has been discussing the implementation and training plans for v 2.0 of the DAIDS EAE Reporting Manual, the DAIDS Protocol Registration System, and site monitoring visits. Issues that have emerged from the monthly calls have been communicated and resolved with OCSO.

Training Coordination Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Identify and provide access to cross-network standardized training for high priority topic areas.				
Training Committee	Identify and discuss training needs and ways to provide access to trainings. Use HANC portal team site for information sharing, training announcements, training requests, and document development.	To address training needs.	Ongoing.	HANC worked with the CITI training program to make the GCP curriculum available in the following languages: Spanish, Portuguese, Chinese, Thai, Korean, and French. The HSP curriculum is also available in Spanish and Portuguese. Information on trainings DAIDS will be offering on the DPRS, Policy and Manual, EAE Manual v2.0, DAERS and CQMP were discussed. Feedback was asked for by DAIDS and collected from the networks on preferences for the next timing and location of the DAIDS Regional Training Event. The HRCT planning team has been keeping the Committee regularly updated and involved with the deployment plan of the curriculum. See Training Objective #2 for details.
HANC Support Staff	Redesign Training Coordination and Training Resources portions of the HANC public website.	Provide clear information to the general public and Clinical Research Site Staff about the working groups and their roles and make various training resources available to site staff.	Q1 Complete redesign	Created a training courses library which provides detailed information on various trainings offered by DAIDS, CITI, FHI and other various institutions. Created a quick link area of the webpage to access information on DAIDS, RSC, DLMS, CITI, HANC training calendar etc. Maintained web pages on current working groups and ongoing activities.

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #2: Finalize, revise and deploy the HIV Research Counseling and Testing eLearning curriculum addressing risk reduction and adherence counseling in biomedical prevention and treatment trials.				
Risk Reduction Counseling Training Working Group	Meet on regular calls to develop and review the training curriculum and ensure the project stays on track and within budget.	Improve the quality of risk reduction counseling in biomedical prevention and treatment trials.	August 2007-TBD.	NIAID OD is established a webpage on their website under the section of Resources for Researches: http://www.niaid.nih.gov/labsandresources/resources/Pages/default.aspx which will link to the DAIDS Learning Management System (DLMS). This will allow DAIDS funded sites to access the curriculum online. The HRCT development team is still working towards making it available to external users outside of DAIDS and continues to review and revise the original 8 modules, complete modules 9 and 10, edit the Training Resource Manual and Study Guide and the contractors who produced the curriculum are making all technical changes necessary to the curriculum as required by the NIAID OD, i.e. 508 compliant, logos, colors etc. The curriculum will then migrate to the DLMS. The team is working with the networks on how to best roll-out the curriculum to CRS staff. Some potential venues include time set aside at upcoming network meetings (both HVTN and ACTG have sessions at their upcoming meetings in November), plan a series of Webinars that CRS staff can attend to learn about the curriculum and have training representatives discuss and share within their internal training education committees. On-going biweekly check-in calls with all contractors and the HRCT development team continue as planned. Monthly HRCT Executive Committee calls continue as planned.

Protocol Costing Project Objectives and Activities

Group	Deliverables / Activities	Intended Impact	Timeline	Progress in Q1
Objective #1: Recommend to DAIDS method(s) for costing clinical trial protocols that could be applied to all Clinical Trial Units/Clinical Research Sites for all trials sponsored by DAIDS through any of its Clinical Trial Networks.				
HANC, working with an ad hoc working group on protocol costing	Identify and recommend a uniform method(s) for estimating the costs for the participation of DAIDS CTU/CRSs in trials sponsored by any of the DAIDS clinical trial networks. Recommendations must take into account relevant issues impacting the CTU/CRSs and the Network Operation Centers, and build upon what is currently working well in the Networks.	To define methods for incorporation into the next round of Cooperative Agreements.	June 1, 2010-February 28, 2011.	Richard Shikiar, former COO of the HVTN, was hired to lead this project. Relevant literature was reviewed. A list of issues impacting methods for costing protocols was developed and reviewed with staff from DAIDS/OCSO. Templates, SOPs, and MOPs from the Networks for fiscal operations and specifically for developing protocol budgets were reviewed. A meeting was held in Bethesda with OCSO staff to review the pertinent issues identified in this project. The first meeting of the Ad Hoc Working Group on Protocol Costing was scheduled for September 13 in Seattle; an agenda and preparatory instructions for that meeting were developed and circulated.