Office of HIV/AIDS Network Coordination

2019 Work Plan (Year 13)

December 1, 2018 – November 30, 2019

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Introduction

The Office of HIV/AIDS Network Coordination (HANC) works with the HIV/AIDS Clinical Trials Networks funded by the U.S. National Institutes of Health (NIH) with the intent of creating a more integrated, collaborative, and flexible research structure. The Networks are an affiliated group of national and international medical research institutions and investigators that conduct clinical HIV/AIDS research. They include the AIDS Clinical Trials Group (ACTG), the HIV Prevention Trials Network (HPTN), the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT), and the Microbicide Trials Network (MTN). The NIH HIV/AIDS Clinical Trials Networks have been designed to address NIAID’s five HIV/AIDS scientific priorities:

1. Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, including hepatitis and tuberculosis) (ACTG)
2. HIV/AIDS and HIV-associated infections in children and mothers (IMPAACT)
3. Integrated strategies to prevent HIV infection (HPTN)
4. Vaccines to prevent HIV infection (HVTN)
5. Microbicides to prevent HIV infection (MTN)

HANC is based at the Fred Hutchinson Cancer Research Center in Seattle, Washington and has provided leadership and logistical support for cross-network coordination efforts since 2004. HANC’s mission is to support the science and operations of the networks by increasing efficiency and resource sharing through coordination of critical activities across networks and with other research and advocacy partners. Efforts focus on cross-network coordination, community and behavioral sciences, including: scientific leadership; site management and research logistics; laboratory operations; coordination of data management; development and application of consistent standards of performance evaluation; and facilitating effective community engagement in the research process, including the Legacy Project. HANC is accountable in its activities to the Network Leadership and DAIDS.

This HANC 2019 Work Plan outlines cross-network coordination objectives and activities for the period of December 1, 2018 – November 30, 2019 (Year 13). The objectives, strategies and activities detailed herein have been developed in consultation with each of the relevant work groups. The document is intended to communicate and guide coordination efforts at a high level. Progress in meeting objectives will be monitored, communicated, and revised as needed on a regular basis by HANC staff, as outlined on pages 28-29.
This is the organizational chart for HANC:

Updated September 2018
## Major Cross-Network Projects

<table>
<thead>
<tr>
<th>Area</th>
<th>Group Responsible</th>
<th>Objective</th>
<th>Intended Impact</th>
<th>Timeline and Completion Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Consultative Group</td>
<td>Provide consultation as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral and social science components of their research agenda and studies: including but not limited to, advice on protocol design, protocol implementation and methodology for data collection, and evaluation.</td>
<td>Increase the behavioral/social science components of network studies.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Behavioral Science</td>
<td>Behavioral Science Working Group and HANC staff</td>
<td>Maintain a repository of measures, data forms, and standardized core elements of interventions</td>
<td>Facilitate sharing of information and state-of-the-science practices.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Behavioral Science</td>
<td>HANC staff</td>
<td>Maintain “Behavioral Science Interest Group” alias and resource center for network-affiliated behavioral and social scientists.</td>
<td>Circulate notice of important tools, measures, CRFs, meeting notices, and articles. Host “topics of interest” webinar series.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Behavioral Science</td>
<td>Youth Prevention Research Working Group</td>
<td>Identify, collaborate, and address matters related to international adolescent (ages 12-24) HIV prevention research; conduct training and webinars on related research topics</td>
<td>Increased promotion and sharing of network adolescent research agendas, strategies, and resources.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Communications</td>
<td>Communications WG</td>
<td>Leverage network experience and expertise; collect communications tools and measures; harmonize elements of the networks’ communications plans</td>
<td>Increased coordination and consistent messaging.</td>
<td>Ongoing</td>
</tr>
</tbody>
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### Community Coordination

**Group Responsible:** Community Partners

**Objective:** Facilitate and enhance community representation and input at all levels in HIV/AIDS and related clinical research within the networks. Increase knowledge and awareness of CP, CP tools, and network activities. Support efficiency and effectiveness of local and network community advisory boards and engagement of stakeholders. Address challenges to community engagement in clinical research.

**Intended Impact:** Provide input and recommendations to focus on meeting CP’s Strategic Plan objectives to guide CP’s work over the next three years following the Network restructuring.

**Timeline and Completion Target:** Ongoing

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**Group Responsible:** Research Priorities Working Group

**Objective:** Ongoing discussions to improve and promote transgender inclusion as outlined in the CP Memorandum, including working with DAIDS, the Networks and other groups to encourage adoption and implementation of the recommendations. Review and make recommendations regarding Standard of Care issues for community members. In partnership with CP Ethics WG, review and address understanding of IC among CABs. Continue to review and make recommendations on co-endorsed protocols to ensure community input.

**Intended Impact:** Enable involvement in the development and sharing of research priorities, and harmonization between community and investigator research priorities.

**Timeline and Completion Target:** Ongoing

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**Group Responsible:** Community Training Working Group

**Objective:** Develop a strategy to disseminate and promote new or standardized cross-network Community Partners training materials to Networks, Sites, and other community groups. Assess the value of materials and determine additional priority topics. Work to make CP training modules on the DAIDS LMS available in an open access forum.

**Intended Impact:** Share existing CAB training materials; identify and integrate material and develop new or standardized cross-network CAB training materials when there are unmet training needs or a strong rationale for standardized modules.

**Timeline and Completion Target:** Ongoing
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Community Coordination</td>
<td>Community Ethics Working Group</td>
<td>CP will identify opportunities for improvement and work in collaboration with DAIDS to provide guidance to researchers, communities and stakeholders regarding the ethical considerations and challenges in research with individuals facing stigma, discrimination, legal sanctions and/or interpersonal violence, and social harms.</td>
<td>Review topics across networks; identify areas where there are problems or opportunities for improvement and work in collaboration with the Network Leadership and DAIDS to address those issues.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Working Group</td>
<td>Convene monthly teleconferences to discuss various ongoing data quality assurance projects, identify areas for improvement, provide recommendations, and implement as appropriate.</td>
<td>Provide an open forum for the DMCs to discuss and identify common issues for resolution.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Data Management</td>
<td>DMC Working Group</td>
<td>Biannually review the Information Technology Best Practice Standards (currently under revision as of Q4 2018).</td>
<td>Ensure that sites meet minimum IT infrastructure standards to support clinical trials and infrastructure changes do not negatively impact data management systems used by the DMCs.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Evaluation</td>
<td>Evaluation Committee</td>
<td>Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks with a focus on community engagement.</td>
<td>Identify streamlined and harmonized reporting processes.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Financial Disclosure Database</td>
<td>Financial Disclosure Working Group</td>
<td>Work closely with network staff and DAIDS officers to review the harmonized financial disclosure requirements and maintain the cross-network web-based reporting interface.</td>
<td>Coordinated solicitation minimizes burden on sites, operation center staff, and investigators required to report. Continue to improve and adapt the SOP and secure online system for ease of use and clarity, and to ensure concordance with federal regulations</td>
<td>Ongoing</td>
</tr>
</tbody>
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## HIV/AIDS Network Coordination 2019 Work Plan

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<thead>
<tr>
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<th>Objective</th>
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<th>Timeline and Completion Target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrastructure and Admin Support</td>
<td>HANC staff</td>
<td>Generate and review website and portal user statistics and member survey data to inform HANC programmatic and portal improvements.</td>
<td>Improved communication and access to information to support decision-making and completion of cross-network objectives. Increase awareness of ongoing HANC coordination activities and potential new opportunities.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>VQAAB, CPQA</td>
<td>Ensure standard quality assurance for all the protocol-specified assays conducted in NIH-sponsored network clinical trials across networks and other partners through the Total Quality Management (TQM) Program.</td>
<td>Maintain data integrity of performed assays by testing for proficiency and tracking quality control standards. Develop proficiency testing programs for non-CLIA assays that can feasibly reflect its performance status in terms of technical skills as well as data measurement.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>LFG, PBMC SOP WG, CCGWG</td>
<td>Identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories at the lab technician level.</td>
<td>Conserve resources for all networks by combining purchasing power, providing subject expertise, and collaborating efforts in projects that benefit the networks as a whole and individually.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Laboratory Coordination</td>
<td>ACTG/IMPAACT Lab Technologist Committee</td>
<td>Identify and harmonize laboratory processes and procedures to reduce redundancy and increase efficiency at the lab technician level. Update SOPs in the ACTG/IMPAACT Laboratory Manual.</td>
<td>Conserve resources and efforts by creating standardized procedures and methodologies that can be utilized by cross-network labs.</td>
<td>Ongoing</td>
</tr>
<tr>
<td>Legacy Project</td>
<td>Legacy Staff</td>
<td>Build the capacity of domestic communities and researchers to equally partner in the research enterprise.</td>
<td>Increased research literacy in domestic communities most impacted by HIV and increased cultural awareness and responsiveness of research staff and sites.</td>
<td>Ongoing</td>
</tr>
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</table>
### Infrastructure and Administrative Support

**HANC Staff Role**

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

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

- A dynamic calendar of scientific conferences, network meetings, community events, training opportunities, and more.
- Some of the Division of AIDS’ Office of Clinical Site Oversight Clinical Research Policies and Standard Operating Procedures that are not listed on the DAIDS website and a link to the official versions of all current DAIDS Clinical Research Policies that are posted on the NIAID/DAIDS website.
- A dynamic announcement section on the home page for posting important notices, such as recent major study results and DAIDS policies.
- An HIV News section with the most recent HIV news and research findings via RSS feeds.
- Information for community members interested in supporting HIV/AIDS research as a community advisory board member.
- Links to clinicaltrials.gov for individuals interested in participating in a clinical research study.
- Free online Good Clinical Practice, Human Subjects Protection and Responsible Conduct of Research Training through the Collaborative IRB Training Initiative (CITI) and DAIDS Learning Portal.
- A dynamic, searchable map showing locations of networks and research sites around the world.
- Information for laboratories, including PNL Contact Assignments, procedures, SOPs, and laboratory training videos.
- A library of centralized laboratory certifications (i.e. CAP and CLIA) for sites.
- Resources and links to direct site and network staff regarding who to contact or where to find the information they are looking for, updated DAIDS organization charts, and OCSO SOPs.
- Library of all the network publications cataloged in one central location for ready access on the HANC public website, including network press releases and responses to study results such as iPrEx.
- Links to Network websites and social media communication resources.
- Resources for communities including, but not limited to: Recommendations for Community Engagement in HIV/AIDS Research, American Indian Alaska Native Two-Spirit HIV Prevention Research Module, Be The Generation HIV Prevention Research Training Module, Basic Scientific Literacy Training Module, NAEHCR Project Guidance and Best Practices Documents, and TB Resources for Communities.
- HANC is exploring an opportunity to redesign the public website in 2019. Discussions with Fred Hutch’s Communication and Marketing Department have begun.

The HANC Collaborator Portal

The HANC portal is an online collaborative environment for cross-network information sharing, document collaboration, and knowledge management. The HANC portal includes document libraries; document development and version control management tools; discussion and collaborative areas (blogs, wikis, and discussion boards); calendaring and announcements; databases; and a cross-network directory linked to the DAIDS-ES Master Contact system. In October of 2018, approximately 1,421 individuals have active HANC portal user accounts and 25 secure team sites are used by specific cross-network working
HIV/AIDS Network Coordination 2019 Work Plan

groups for collective document development, online discussion, and sharing of materials and information. HANC regularly solicits suggestions for the portal and updates the site accordingly.

HANC portal projects for the 2019 Work Plan include:

- Ongoing improvements to the HANC Portal and team site content to better support the objectives of the working groups in 2019.
- Maintaining web services that make the DAIDS-ES Master Contact system accessible to HANC portal users.
- Publicizing the linkage to the DAIDS-ES protocol report data and protocol documents allowing ready access for all HANC portal users to this feature of the DAIDS-ES system.
- HANC program staff provides programmatic updates on the “Daily Dose” announcement box.
- Continued optimization of HANC "Contact Management System" which integrates the portal permissioning, email aliases, and contact lists.
- HANC is in the process of upgrading to a new version of SharePoint for the HANC Portal.

Social Networking & Information Sharing

HANC has Twitter (search for “Hancprograms”), Facebook (search for “Hanc Programs”), and LinkedIn (search for Office of HANC) accounts to share general programmatic updates with a broader audience. The HANC Legacy Project maintains Facebook (@HANCLegacyProject), Twitter (@HANC_Legacy), and Instagram (@HANC_Legacy) accounts to share community engagement resources, training opportunities, and programmatic updates with partners and the general public.

HANC also publishes a monthly newsletter that contains HANC programmatic updates, network updates, webinar events, meetings, and additional resources. In 2018, HANC completed a redesign of the newsletter and will continue to solicit feedback to refine the publication in 2019. HANC will provide individualized trainings for networks and affiliated partners as requested. HANC regularly uses Google Analytics to track the most used resources and pages on both the HANC public and portal websites.

Clinical Research Support Contract

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

Behavioral Science Coordination
HANC supports four behavioral science groups:

Behavioral Science Working Group (BSWG): The Behavioral Science Working Group is a trans-NIH Institute and cross-network committee that was formed as an outcome of the July 2008 HANC and National Institute of Mental Health (NIMH) sponsored Prevention Adherence meeting. The working group is charged with ensuring that the NIH HIV/AIDS Clinical Trials Networks benefit from state-of-the-science methods and procedures that optimize adherence to product and risk reduction counseling and minimize the risk of confounding user- and product failures. Further, the Behavioral Science Working Group endeavors to maximize fiscal and scientific resources, reduce redundancies, improve cross-network communication and collaboration, and ensure that the best quality behavioral science is integrated into clinical trials. The working group, formed in Q4 of Year 3, holds monthly teleconference calls and ad hoc topic-specific calls.

Behavioral Science Interest Group Digest (BSIG): The BSIG was formed as an outcome of the 2010 BSWG face-to-face meeting. The BSIG’s mission is to share state-of-the-science developments and facilitate discussion amongst network investigators, independent behavioral and social science researchers, community members, statisticians, and data managers with the goal of enhancing behavioral research within DAIDS clinical trials. HANC maintains a resource center featuring relevant case report forms, articles of interest, white papers, best practices documents, funding opportunities, and meeting presentations. The over 375 members receive a weekly digest of new library additions and are encouraged to participate in the BSIG Topics of Interest webinar series. HANC also maintains a webpage describing how to propose a network behavioral studies and data analyses.

Behavioral Science Consultative Group (BSCG): The Behavioral Science Consultative Group was formed after the 2013 BSWG face-to-face meeting. The NIMH provides resources through HANC to a group of within-network and external expert behavioral and social scientists to assist the networks in navigating the complex behavioral/biomedical science issues. The BSCG’s overarching objectives are to provide consultation as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral components of their research agenda and studies: including but not limited to, advice on protocol design, protocol implementation and methodology for data collection, and evaluation. The BSCG has provided consultation on a variety of protocols for all the networks since the inception of the group.

Youth Prevention Research Working Group (YPRWG): The cross-network/trans-Institute Youth Prevention Working Group (YPRWG) was formed in the Q3 of Year 6. Its creation was a key recommendation emerging from the NIH ”Focused initiatives for Healthier Lifestyles by the Inter Network Advisory Group on Adolescent Prevention” meeting. The group consists of representatives from the NIH HIV/AIDS Clinical Trials Networks, the Adolescent Trials Network (ATN), DAIDS, NIAID, NIMH, NIDA, NICHD, and OAR. The scope is domestic and international and focused on 12-24 year olds. The members conduct bi-monthly calls and convene at network meetings as able. The group addresses the following:
Coordinate sharing of network adolescent research agendas
- Address the challenge of conducting trials across multiple networks
- Consider tangible outcomes such as dropping the mean age of network volunteers
- Compare ongoing and upcoming studies
- Consider adolescent issues early on in design process
- Review relevant informed consent documents
- Host webinars and trainings related to adolescent prevention research

**Behavioral Science Working Group Coordination Objectives for 2019**

**Behavioral Science Working Group Objective 1:** Improve information exchange among network-affiliated behavioral and social scientists. Identify and address opportunities to harmonize behavioral science research and tools across network studies.

**Behavioral Science Working Group Objective 2:** HANC will continue to manage a “Behavioral Science Interest Group” listserv and resource center whereby researchers can receive updates from the field, links to influential articles, network study updates, meeting information, etc. HANC will continue to host a “BSIG Topics of Interest” webinar series. Webinar recordings will be archived on the BSIG Resource Center. Expand the “BSIG Rx Connect” listserv, allowing members to pose research questions and receive comments and recommendations from the BSIG research community.

**Behavioral Science Working Group Objective 3:** Maintain a repository of behavioral and adherence measures, data forms (CFRs), and standardized core elements of interventions accessible to partnering networks. The documents and links are housed on the HANC public website under “Behavioral Science Publications” and/or the HANC portal’s “Behavioral Science Interest Group Resource Center”.

**Behavioral Science Working Group Objective 4:** Members of the BSWG will report back from plenary sessions at network annual meetings to discuss new developments and their implications for network science, take stock of lessons from related domains, provide new and ongoing adherence counselor training, elicit community working group input on adherence measurement and counseling, etc.

**Behavioral Science Consultative Group Coordination Objective for 2019**

**Behavioral Science Consultative Group Objective:** The BSCG’s overarching objectives are to provide consultation as requested to the NIH HIV/AIDS Clinical Trials Networks on the behavioral and social science components of their research agenda and studies: including but not limited to, advice on protocol design, protocol implementation and methodology for data collection, and evaluation. The BSCG will re-engage intermittently with Network Leadership after the release of the FOA.

Ongoing activities that support the above objective:
- The BSCG will continue to provide consultation on behavioral and social science aspects of the following protocols
  - An MTN qualitative sub-study of VOICE evaluating rapid feedback from focus groups and structured interviews. A subgroup of the BSCG completed a poster for presentation in 2017 and the group has drafted a paper that has been submitted to be published in AIDS and Behavior.
  - Adherence counseling and assessments for the PHOENix study
  - Ongoing consultation for the AMP study
  - Ongoing consultation for HPTN 083
  - Other items as Networks reach out to the BSCG for consultation
  - Face-to-face meeting in 2019 (date has yet to be determined).
The BSCG is planning to host a webinar series in 2019 highlighting the work the BSCG has contributed to Network protocols.

**Youth Prevention Research Working Group Objectives for 2019:**

**Youth Prevention Research Working Group Objective #1:** Ensure cross-network/trans-institute communication around research in adolescent populations. Working group members accomplish this goal by liaising with their respective network leadership and protocol team members to share their assessment of ongoing research initiatives as well as identify potential gaps in the adolescent research agenda.

**Youth Prevention Research Working Group Objective #2:** Explore opportunities to provide resources (training materials, webinars, etc.) and expertise to sites conducting research with adolescents. The YPRWG will host webinars, symposiums, and trainings at network meetings and/or conferences as appropriate. Materials from YPRWG hosted webinars, symposiums, and trainings will be stored on the HANC website in the Youth Prevention Research Resource Library to increase visibility of these resources.

**Youth Prevention Research Working Group Objective #3:** Explore the development of co-endorsed protocols or adolescent sub-studies.

**Youth Prevention Research Working Group Objective #4:** Ensure an ongoing dialogue between working group members and relevant stakeholders through regular review of working group projects, priorities, and objectives.

**Communications Working Group**

The Communications Working Group was instituted in June of 2009. Since its formation, the group has considered a wide variety of issues affecting network clinical trials. The group is comprised of network communications professionals and community liaisons. Much attention has been paid to new media and social networking tools, study results messaging, and understanding the networks’ respective communications strategies and policies. The Communications Working Group has bimonthly calls and topic-specific webinars are scheduled as requested.

**Communications Working Group Objectives for 2019**

**Communications Objective #1:** Review network communications efforts and consider best practices that could be employed within the networks.

Strategies and activities to support this objective:

- Share experiences with creative design, advertising, and development of materials to aid with participant recruitment for network studies.
- Share video production tools and experiences.
- Share experiences using new technologies, social media, and network sites such as Facebook, LinkedIn, and Twitter and track web traffic generated from new media sites.
- Share network communications strategies, external relations policies, and strategies related to study launch, DSMB review, and results dissemination.
- Share community engagement strategies.

**Communications Objective #2:** Invite key stakeholders, opinion-makers, and experts in the field to present on working group calls. Areas of expertise could include: journalists, advocates, bloggers, and communications professionals.

**Communications Objective #3:** Share messaging strategies around and leading up to major studies, particularly for high profile studies and multi-network studies.
Strategies and activities to support this objective:
- Share and disseminate network submissions to major conferences for HIV/AIDS research.
- Provide updates on major study milestones that may impact other studies in the field.

**Community Coordination**

Since the late 1990’s, community representatives associated with NIH HIV/AIDS Clinical Trials Networks and studies have been working together to identify common issues and to learn new approaches and solutions from each relating to community involvement. A Cross-CAB Working Group (CCWG) was formed in 2003, and HANC began providing facilitation for their calls shortly afterwards. In 2005, Cross-Network Best Practices for engaging community were developed by a group of community representatives and DAIDS. In June 2007 the CCWG was replaced by Community Partners (CP), an RFA-mandated body with a mission to enhance research by maximizing the effectiveness and benefits of community participation within and across the NIH HIV/AIDS Clinical Trials Networks.

**Community Partners and Working Groups**

HANC supports Community Partners and the topic-specific working groups that it convenes. The HANC Community Partners Project Coordinator serves as a non-voting member of CP and provides group facilitation, project coordination, fiscal oversight, and administrative support.

Community Partners (CP) is a cross-network body charged with promoting effective representation of the many communities within which the NIH HIV/AIDS Clinical Trials Networks conduct research. CP represents cross-Network community research needs and priorities to network leadership and DAIDS and is a venue for sharing resources and experiences across the networks, avoiding duplicative efforts, identifying and addressing challenges to participation in trials. CP is tasked with ensuring effective network representation and articulation of: scientific agenda priorities; ethical conduct of clinical trials; community education; communication and information dissemination; respect for community priorities; and continued community participation. CP members are representative of the global NIH HIV/AIDS Clinical Trials Networks research sites.

**Map of Community Partner members’ locations:**
The Community Partners Executive Committee is drawn from the general membership of Community Partners and is empowered to make decisions on behalf of and in the best interests of CP and its general membership in accordance with CP Organizational Guidelines.

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

The Community Research Priorities Working Group considers areas of community research priorities across networks and makes recommendations to DAIDS and Network Leadership.

The Community Partners Ethics Working Group solicits input from networks and other groups to provide input and recommendations to DAIDS and Network Leadership regarding the informed consent process, management of pregnancy and contraception in clinical trials, trial designs relative to guidelines and local standards of care, and placebo arms in prevention trials.

Community Coordination Objectives for 2019

Community Partners Objective #1: Enable involvement in the development and sharing of CP research priorities, and harmonization between community and investigator research priorities. CP Research Priorities Working Group

Strategies and activities to support this objective:

▪ Work directly with DAIDS Cross-Network Transgender working group to promote the Transgender Training Curriculum for HIV Research with the Networks and other groups to encourage global adoption and implementation of the recommendations.
▪ Continue to review and make recommendations on co-endorsed protocols to ensure community input.
▪ Work with the CP Training WG on updating the Recommendations Document
▪ Work with CP Training WG on developing FAQ sheet on Long-acting injectables and Broadly neutralizing antibodies (bNAb)
Review network efforts on the CP priorities and identify priority gaps in research prior to and after the Leadership RFA and focus on the following:

- Continue to support TB/HIV co-infection education efforts
- Pediatric and Adolescent issues across networks

Community Partners Objective #2: Utilize the Community Training Working Group to identify unmet training needs that are common across the networks and determine how they can best be addressed.

Strategies and activities to support this objective:

- Examine the Recommendations Document to determine if and how it needs to be updated
- Develop or promote materials around how to review a protocol
- Promote CP Training Materials
  - Network meetings and conferences
  - Develop FAQ sheets on how to access resources and training materials including the DAIDS Learning Management System
- Develop a multi-network CAB lessons learned/best practices document (protocol review, CAB orientations, CAB meetings, etc.)
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices
- Host webinar around use of new research language (open label, superiority/inferiority) to educate communities
- Partner with other groups to develop or disseminate materials addressing HIV in the context of sexual violence against girls and women

Community Partners Objective #3: CP will collaborate on the analysis and manuscript of the network-level community input survey conducted in 2013.

Strategies and activities to support this objective:

- Analyze survey data evaluating the impact of network-level community input
- Collaborate with colleagues from Concept Systems Inc. in this effort
- Submit a manuscript for publication with the network-level community impact survey data

Community Partners Objective #4: Utilize CP to provide input and recommendations to focus on meeting the mission of Community Partners to facilitate and enhance community representation and input at all levels in HIV/AIDS and related clinical research within the networks. Community Partners Executive Committee

Strategies and activities to support this objective:

- Develop specific strategies and tools to address stigma, including working with the TBTC CRAG community representatives
- Develop strategies to assist communities to prioritize research activities globally and locally by means of engagement as needs arise
- Facilitate and enhance more effective collaboration with the Legacy Project and the WHRC with inclusion of CP membership to these groups
- Lead or collaborate on letters of support for international or domestic advocacy
- Continue to monitor and provide support to CABs and communities impacted by site closures or changes in research or protocols (e.g. Site Closure Slide Deck)
- Identify opportunities for improvement and work in collaboration with DAIDS and Network Leadership to ensure dissemination of research results (NIAID to share press releases with HANC to share with CP, communities and sites)
- Host or co-host community-focused workshops/presentations on ongoing network research and community engagement activities
- Host workshops/presentations at USCA 2019, Union Conference Community Space in Amsterdam in 2019 and other meetings/events to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG
- Develop a White Paper to highlight the collaboration of CRAG and CP in addressing issues around TB/HIV co-infection from a community perspective
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- Develop strategies and define scopes to measure community engagement globally and locally from a community perspective
- Using information from the HANC monthly newsletter, post CP information in CAB and network newsletters and network public websites (follow-up on a quarterly basis)
- Link to CRAG Site and Resources on CP Site

Community Partners Objective #5: Review topics across networks; identify areas where there are problems or opportunities for improvement and work in collaboration with the Network Leadership and DAIDS to address those issues.

Community Partners & Community Ethics Working Group

Strategies and activities to support this objective:
- Identify opportunities for improvement and work in collaboration with DAIDS to provide guidance to researchers, communities and stakeholders regarding the ethical considerations and challenges in research with individuals facing stigma, discrimination, legal sanctions and/or interpersonal violence, and social harms
- Support CABs and community members who review protocols for stigmatizing language and make language change recommendations

Community Partners Objective #6: Utilize CP members to provide information exchange to enhance collaboration and identify further engagement topics/issues. Community Partners

Strategies and activities to support this objective:
- Formalize engagement with ATN Youth CAB
- Promote CP training materials at full network group meetings and other trainings as requested for the benefit of community members and site staff
- Gather and organize existing network CAB newsletters to post on the HANC Website

Data Management Center Coordination

The network Statistical and Data Management Centers (SDMCs) have identified key areas in which the sharing of expertise, resources, and procedures will strengthen the capacity and increase the efficiency of data management operations.

The DMC Working Group includes representatives from FSTRF, SDAC, and SCHARP, and meets on monthly teleconferences to carry out activities to address cross-network data management coordination objectives.

DMC Working Group Objectives for 2019

DMC Coordination Objective #1: Convene monthly teleconferences to discuss various ongoing data quality assurance projects, identify areas for improvement, provide recommendations, and implement new processes and procedures as appropriate.

Strategies and activities to support this objective:
- Solicit agenda items from the DMCWG for the monthly DAIDS-ES All Collaborators call.
- Monitor cross-DMC standardization support needs for AE/EAE reconciliation. Strategies to support this include: working with DAIDS to identify data elements that are required to be reconciled, maintain ongoing dialogue with DAIDS staff regarding challenges encountered with reconciliation.
- Liaise with NIAID CRMS team to identify areas for collaboration and enhanced data sharing across NIAID CRMS and the SDMCs.
- Share CDISC implementation activities across DMCs; e.g., regularly check in with CDISC consultant, assist in coordination, and discuss developments across the networks.
DMC Coordination Objective #2: Work with appropriate regulatory groups to assist in the development of procedures and processes related to electronic data capture (EDC), electronic signatures, protocol deviation reporting, etc. Share developments in these procedures and processes across networks and data management centers.

Strategies and activities to support this objective:
- Disperse information on EDC to networks and sites for new and transitioning studies.
- Liaise with network performance/evaluation committees and OCSO to adapt new policies and procedures as appropriate for the transition to EDC as it impacts site performance evaluation metrics and site monitoring procedures.
- Liaise with relevant cross-network working groups to solicit site-level and other appropriate feedback on processes and policies involving the data management centers.
- Liaise with OPCRO and OSCO to provide feedback on proposed policies and procedures.

DMC Coordination Objective #3: Work with HANC to provide broad access to DMC-related online training resources on topics such as the DAIDS Toxicity Table and Electronic Data Capture (EDC) systems.

Strategies and activities to support this objective:
- Select appropriate training resources for consolidation in the HANC training library, working with other groups to ensure relevant and broad selection of appropriate training materials.
- Publicize training opportunities by reaching out to network DMCs and other network members through HANC and other means as appropriate.
- Respond to requests for training materials, update training topics when appropriate, and monitor resource usage via HANC staff.

Evaluation Coordination

Evaluation Committee

The Evaluation Committee discusses and provides a forum to share network approaches to evaluation, including the site evaluation processes. The Committee consists of representatives from each Network Evaluation Committee and additional Network Evaluation Committee members as determined by the network.

Evaluation Working Group Objectives for 2019

Evaluation Objective #1: Discuss opportunities to harmonize timelines and formats of evaluation reports across the networks. Strategies and activities to support this objective:
- Monthly-bimonthly cross-network evaluation teleconferences will provide a forum to discuss and address opportunities.
- Ongoing discussions on the revisions to the network evaluations processes and setting site performance criteria and expectations.
- Share experiences around software programs for real-time reporting of evaluation metrics.

Evaluation Objective #2: Discuss opportunities to harmonize the definition, calculation, and implementation of site evaluation metrics related to data management. Strategies and activities to support this objective:
- Continue collaboration with DMC staff to harmonize how metrics related to data management are calculated using data from Medidata Rave.
- Ongoing discussions with evaluation staff on the implementation of these metrics as part of the site evaluation process.
Evaluation Objective #3: Share approaches to reporting protocol deviations as part of site evaluation reports.
Strategies and activities to support this objective:
• Track developments in DAIDS policies related to protocol deviation reporting.
• Ongoing discussion on network approaches to and utility of reporting protocol deviations as part of the site evaluation process.

Evaluation Objective #4: Harmonize the community indicator survey for evaluation of community engagement.
Strategies and activities to support this objective:
• Review and update the community indicator survey library.
• Collaborate with evaluation staff to identify areas of overlap in survey content and opportunities to streamline delivery of the community indicator survey.

Financial Disclosure Database

Financial Disclosure Database Objective: Work closely with network staff and DAIDS to periodically review the harmonized network financial disclosure requirements and maintain the cross-network web-based reporting interface developed in 2011.
Strategies and activities to support this objective:
• Continue to review U.S. Health and Human Services financial disclosure regulations and audit requirements.
• Continue to clarify with DAIDS, sites, and product sponsors’ FDA-specific financial disclosure requirements and SOPs.
• Consult network grantee institutions on matters of financial disclosure requirements, processes, and reporting.
• Update and improve online reporting system functionality.
• Coordinate investigator lists across the NIH HIV/AIDS Clinical Trial Networks and PHACS.

Laboratory Coordination

Laboratory Committees and Working Groups

The Lab Focus Group:
The Lab Focus Group (LFG) is comprised of Network Laboratory Leadership and management staff. It holds teleconferences monthly to oversee all cross-network laboratory activities, including policy and process development and follow-up work to complete cross-network projects and tasks that address laboratory training, operations, and support issues. The teleconferences provide a forum for identifying, discussing and resolving issues, sharing information, and identifying new projects and tasks to be included in cross-network laboratory coordination efforts.

LFG Objectives:
1. Continue to identify laboratory issues that require input from all the networks, in collaboration with DAIDS Clinical Laboratory Oversight Team (DCLOT), to assure that network labs are implementing quality and efficient lab processes.
2. Continue to identify where economies of scale can be achieved by sharing resources, shared pricing agreements, technician training opportunities, laboratories, etc. and address these opportunities in existing or new working groups as necessary.
   a. Continue to monitor reagents or materials for possible issues that may affect multi-networks.
3. Continue to identify and address opportunities to harmonize laboratory processes and procedures to reduce redundancy, increase efficiency and clarify expectations, especially at shared site laboratories.
   a. Review the Cross-Network Guidelines for Diagnosis of HIV infection in general terms and revise as needed to reflect any changes per network.
4. Continue to identify areas in lab operations and processes to incorporate principles of GCLP and ensure that data generated are of the highest quality, including but not limited to timeliness, accuracy, and clinical appropriateness. GCLP guidelines will be reviewed on an annual basis.

**PBMC SOP Working Group:**

The PBMC SOP Working Group is charged with developing, publishing and reviewing the Cross-Network PBMC Processing SOP for all network-affiliated labs that process PBMC. The SOP is reviewed and updated by the PBMC Working Group on a biannual basis.

**The Cross Network Cold Chain Guidelines Working Group:**

The Cross Network Cold Chain Guidelines (CCGWG) group is charged with maintaining guidelines for utilizing and maintaining optimal cold chain temperature of specimens during the retrieval process within the laboratory or upon shipment to an external laboratory/repository. The SOP is reviewed and updated by the CCGWG at the direction of the LFG.

**The ACTG/IMPAACT Laboratory Technologist Committee:**

The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is a joint ACTG/IMPAACT committee. Voting and nonvoting protocol support members serve on protocol teams and provide technical expertise in the development of the laboratory components of protocols as well as standardizing the handling, processing, labeling, storage and shipping of clinical specimens across all ACTG/IMPAACT clinical sites and laboratories. HANC support staff coordinates specific projects and give technical support to the committee and maintains the committee’s site on the HANC portal. HANC support staff also helps to track LTC member workloads, helps to maintain existing documents and develop new documents stored in the resource document libraries, and maintains a discussion board to facilitate communication across the members of the committee. Several other resources, including the ACTG/IMPAACT Laboratory Manual, are posted on the HANC public website, and HANC support staff helps to facilitate the review of new and updated SOPs and provide standardization of templates and formatting. HANC also maintains regularly updated vendor pricing, ordering details, and product information for Fetal Bovine Serum for ACTG and IMPAACT laboratories on the HANC webpage. The LTC holds teleconferences twice per month, and HANC support staff attends the calls, records them, and posts committee-approved minutes on the HANC website.

**LTC Objectives:**

1. Promoting uniform handling, processing, labeling, storage, and tracking of specimens (according to consensus procedures) across all clinical sites and laboratories; maintaining a regularly updated laboratory manual of consensus procedures readily available for access by all ACTG/IMPAACT laboratories.
   - HANC provides a forum to share technical expertise and resolve laboratory issues including but not limited to assay/processing procedures, LDMS use, and laboratory operations. Topics may also include discussions on protocol complexity as well as upcoming novel/esoteric assays.
   - HANC support staff helps to facilitate the regular review and update of laboratory standard operating procedures (SOP) and maintains the document control processes.
   - HANC support staff helps to facilitate the regular update and maintenance of Standardized Wording documents for use in developing LPCs, and maintains other documents, such as the LPC templates and the budget cost list used by the LTC for creating processing budgets for ACTG clinical trials.

2. Serving as a resource to the NIAID/Division of AIDS, Statistical and Data Analysis Center, Data Management Center, Operations Center, and Clinical Site Monitoring Group; acting as a liaison between site personnel, laboratories, clinics and the leadership of the ACTG/IMPAACT and its contractors as well as facilitating communication and networking among the laboratories, clinics and Data Management Center.
a. HANC serves as a resource for facilitating communication between the LTC and other the NIAID/ Division of AIDS, Statistical and Data Analysis Center, Data Management Center, Operations Center, and Clinical Site members.

3. Providing information and education for laboratory personnel in the areas of protocol implementation, collection and regular export of quality data, regulatory requirements, new procedures and policies;
   a. HANC support staff helps the LTC members train new members by facilitating the creation of training packets, offering training webinars, and maintaining support documents on the HANC website.

**EQA Provider Working Groups:**

The EQA Provider Working Groups ensure standard quality assurance for all the protocol-specified assays conducted in DAIDS-sponsored network clinical trials across networks and other partners through the Total Quality Management (TQM) Program. The TQM Program improves the transparency and responsiveness of decision-making regarding results of proficiency testing at DAIDS- funded site laboratories by improving communication and timely access to relevant information.

1. The cross-network QA working groups including the CPQA groups and VQAAB will continue to provide a forum for the review and discussion of program-specific proficiency testing results and other questions that affect external quality assurance on regular teleconference calls.

2. Cross-network QA working groups and the LFG (for patient safety QA) will develop, review, and/or modify as needed standard operating procedures for the monitoring of external quality assurance and investigation and reporting of root cause and corrective action.

3. HANC staff provides the following in support of the CPQA:
   a. Participate in Steering Committee to assure synchronous activities among stakeholders
   b. Provides virtual communication platform for CPQA groups, including ad hoc calls for leadership and/or collaborators
      i. Polls for calls as needed
      ii. Sends out call announcements with agenda and materials
      iii. Sends call reminders and reports back to CPQA on “regrets” responses
      iv. Provides draft minutes to CPQA groups for edits and approval
      v. Sends out final call minutes to respective CPQA groups
   c. Provides software and document development support; provides a website area for maintaining CPQA group documents, agendas and minutes.
   d. Posts any webinar presentations with permission from speaker(s)

**The Clinical Pharmacology Quality Assurance (CPQA) Advisory Board:**

The Leadership of the CPQA Advisory Board (AB) is composed of a balance of leadership members from DAIDS funded research and laboratory networks, the community of established HIV investigators, the contract sponsor, and CPQA. To implement the functions of the CPQA, the AB may form such committees, subcommittees, working groups, and external advisory boards as are necessary to carry out the mission of the CPQA. The Advisory Board provides the following:

1. Communication regarding scientific and regulatory changes and developments that are likely to influence the operation of the CPQA.
2. Feedback from NIAID/DAIDS and the HIV Research Networks that includes items discussed at NIAID/DAIDS leadership meetings, HIV Network leadership meetings and Laboratory Center Network meetings.

3. Expertise and guidance in areas that are on the horizon for network research priorities such as new biomatrices, point of care diagnostics and strategies for therapeutic approaches.

4. Review of controversial areas that arise within the ongoing CPQA activities with regard to proficiency testing, CPL site performance, guidance for current and future CPLs, and longitudinal analysis of the CPQA program and its performance.

5. Recommendations for program additions, revisions and quality improvements.

**CPQA Working Group - HIV Monoclonal Antibodies and Small Molecule Tissue Pharmacology:** This is an active Working Group that focuses on HIV Monoclonal Antibodies and Small Molecule Tissue Pharmacology. The working group is chaired by Peter Anton and includes others from the Mucosal Immunology Group. The group meets monthly via conference call coordinated by HANC. The goals will be:

1. Draft a best practice document for DAIDS that summarizes the state of the art for collection, processing and bioanalysis of HIV broadly neutralizing antibodies and small molecule ARVs in tissue pharmacology protocols.

2. Identify gaps in our knowledge that would form the agenda for an NIH conference in late 2018.

**The CPQA Cross-Network Clinical Pharmacology Laboratory Forum (CNCPFLForum):** The Cross-Network Clinical Pharmacology Laboratory Forum is an open forum comprised of technical and scientific representatives from each Network Clinical Pharmacology Laboratory (as well as other DAIDS funded clinical pharmacology laboratories), DAIDS, and CPQA. The CNCPFLForum provides a forum to present new pharmacology research areas and the associated technical laboratory technologies and details. The CNCPFLForum facilitates communications between the CPQA program and DAIDS Clinical Pharmacology Laboratories. Members of administrative laboratory support systems for the Networks are also welcome to join the calls.

- **Bioanalytical Method Validation Group (BRAG)** is tasked with revising the CPQA AVR Assay Method Guidelines to incorporate the changes made by the FDA, published in the draft version of the 2013 Revised Bioanalytical Method Validation (and Application) Guidance and consensus paper from the corresponding Crystal City V meeting (December 2013). The revised CPQA guidance was implemented in April 2017. The BRAG took a break at that time and will start up once again shortly after the FDA publishes its final. The FDA published the Revised Bioanalytical Method Validation Method (and Application) Guidelines on May 21, 2018. CPQA has been reviewing drafting proposed changes to CPQA Guidance. The BRAG will become active at the end of 2018 and continue through 2019 until a final version 2 is completed. At that time (TBD) the CPQA guidance addendum for method validation and implementation for ligand binding assays will be available to discuss and finalize.

- **Tenofovir-diphosphate (TFV-DP) Assays Working Group (TAWG)** has been formed and will begin meeting in the Fall of 2018 to focus on determining if a strategy for inter-laboratory comparisons of TFV-DP measures can be developed and implemented. Laboratories that participated in Pilot Rounds 1-3 of TFV-DP and FTC-TP in PBMCs will be meeting to discuss the final report and conclusions. The first pilot round for TFV-DP in dried blood spots has been distributed with Round 42 proficiency panels and those laboratories reporting results will meet to discuss these results in 2019 after they are compiled with figures and tables by CPQA.

**The Virology Quality Assurance Advisory Board:**

The Virology Quality Assurance Advisory Board (VQAAB) serves as an external group that reviews data generated for the Virology Quality Assurance (VQA) proficiency testing programs, provides input and guidance on new issues/ideas/programs, and provides an open forum for discussing new topics raised by other VQAAB members during monthly teleconferences. The VQAAB is comprised of non-voting representatives from the VQA Laboratory, the VQA Data Management Group (DMG) at Frontier Science and Technology Research Foundation, Inc., the VQA Statistical Analysis Group (SAG) at the Research Triangle Institute (RTI) International, DAIDS, the Statistical & Data Analysis Center (SDAC), and a voting representative from each of the respective NIH-funded HIV Research networks.
The VQAAB holds monthly and ad hoc calls to:

1. Review and approve proposed scoring from VQA proficiency testing (PT) analyses which include programs for Quantitative HIV-1 RNA testing, Qualitative HIV-1 RNA testing, Qualitative HIV-1 total nucleic acid or HIV-1 DNA testing (whole blood and DBS), and genotypic HIV-1 drug resistance testing for reverse transcriptase (RT), protease (PR) and integrase (INT) gene regions.

2. Establish monitoring standards that differentiate between technical problems and non-technical problems (e.g. late data, query unresponsiveness, or data containing patient identifiable information [PII] or protected health information [PHI]).

3. Request, review and approve proposed method evaluation/validation studies.

4. Review and approve proposed changes in policies or procedures to promote quality assurance in virology assay testing.

5. Review and approve proposed implementation of external quality control standards for use in virology assay testing.

6. Review and approve changes in VQAAB approval status for protocol testing laboratories.

7. Review proposals for new proficiency testing programs for other virology assays such as: Quantitative HCV RNA, Quantitative HBV DNA, Qualitative HPV DNA.

HANC staff provide the following in support of the VQA and VQAAB:

1. Provide a forum and communication channels for discussion of proficiency testing results via teleconferences or emails.

2. Help organize conference calls and distribute documents prior to the call.

3. Facilitate the sending and tallying of VQA report reviews which occur outside the regularly scheduled conference calls, and report those results to the VQA SAG.

4. Maintain the VQA web page for posting of VQA documentation on the public domain and maintain the VQA reagent order form on the HANC password-protected portal site.

5. Post updates from the VQA that document laboratory status for virology testing based on proficiency testing scores.

6. Post and maintain minutes generated by the VQA for monthly teleconferences.

**Legacy Project**

The Legacy Project builds trust and collaboration between HIV research institutions and marginalized communities most impacted by the US HIV epidemic. The Legacy Project works to support NIAID’s five HIV/AIDS scientific priorities, including:

1. Therapeutics for HIV/AIDS and HIV-associated infections in adults (including HIV cure, as well as co-occurring noninfectious and infectious diseases, including hepatitis and tuberculosis) (ACTG)

2. HIV/AIDS and HIV-associated infections in children and mothers (IMPAACT)

3. Integrated strategies to prevent HIV infection (HPTN)

4. Vaccines to prevent HIV infection (HVTN)

5. Microbicides to prevent HIV infection (MTN)
The Legacy Project 2019 Work Plan is in line with the National HIV/AIDS Strategy, cutting across areas of basic research, health disparities, and training, including research to reduce health disparities in HIV incidence, research in treatment outcomes for those living with HIV/AIDS, research training of the workforce required to conduct high priority HIV/AIDS-related research, and addressing health and social issues that are linked with HIV such as racism, transgender antagonism, homonegativity, misogyny, poverty, stigma, and discrimination.

**Legacy Project 2019 Objectives:**

1. Build capacity among community members, researchers, and sponsors to address disparities that impact HIV acquisition and treatment outcomes by providing culturally appropriate guidance and leadership in the development, implementation, and dissemination of information about HIV research focused on and responsive to the needs of disparately impacted populations.

   **Strategies and activities to support this objective:**
   - Consult/collaborate with populations especially vulnerable to HIV, as well as those underrepresented in HIV clinical research (Black and Latinx MSM, women, transgender persons, house/ballroom communities, indigenous and two-spirit peoples, etc.) to identify community-level priorities and raise awareness of these priorities among all the NIH HIV/AIDS clinical trials networks and sites.
     - Monitor and promote improved representation of underrepresented populations’ participation in clinical trials through collaboration with partners such as network communications and community engagement staff, Community Partners, the WHRC, the DAIDS Cross-Network Transgender Working Group, the HPTN Black Caucus, the HANC-facilitated Communications Working Group, the ACTG Underrepresented Populations Committee, and others.
     - Develop and broadcast a podcast on HIV research and community engagement in collaboration with research and community stakeholders in the HIV response.
   - Conduct capacity building and HIV scientific literacy training with Legacy Project collaborators and populations underrepresented in HIV clinical research to increase awareness and knowledge of HIV clinical research and community readiness to engage in trial participation activities through presentations, abstracts, meetings, conferences, podcasts, and webinars.
     - Engage the Conference Engagement Working Group to discuss and plan for network meetings and other national conferences and events.
     - Host community-focused webinars on HIV prevention, treatment, and cure clinical research advances in collaboration with the NIH HIV/AIDS clinical trials networks.
     - Develop and broadcast a podcast on HIV research and community engagement in collaboration with research and community stakeholders in the HIV response.
     - Host or co-host community-focused workshops/presentations on ongoing network research including cure, PrEP, TasP, microbicides, and vaccines at meetings/events focused on key populations impacted by the domestic HIV epidemic.
     - Host a community-focused webinar on Molecular HIV Surveillance and HIV phylogenetics research in collaboration with CDC representatives and HIV researchers.
     - Maintain the Legacy Project’s presence on social media to disseminate information related to HIV research and community engagement.
     - Invite Martin Delaney Collaboratory to Legacy call or webinar to present on HIV cure research.
     - In partnership with Community Partners, host webinars focused on issues and research related to HIV & Aging.
     - Invite Latinx researchers and the Latino Commission on AIDS to collaborate with Legacy on national presentations and future webinars and calls.
• Disseminate training materials designed to increase scientific literacy among historically underrepresented communities most impacted by the domestic HIV epidemic.
  o Oversee publication of the quarterly Be The Generation e-newsletter, *BTG News*, in collaboration with the HPTN, HVTN, and MTN.
  o Update and promote the BTG HIV Prevention Research and Basic Scientific Literacy Modules.
  o Regularly maintain and promote the BTG website.
  o Collaborate with DAIDS, WHRC, Community Partners and the NIH HIV/AIDS clinical trials networks and other stakeholders with the development and implementation of the *Transgender Training Curriculum for HIV Research*.

• Collaborate with HBCUs to build on the findings and recommendations of the HBCU Project to increase awareness and support for HIV/AIDS clinical research among HBCU faculty and students.
  • Enhance partnerships with researchers and key HBCU stakeholders to implement the Be the Generation HIV Prevention Research Training Module as part of ongoing research initiatives examining facilitators and barriers to implementing Pre-Exposure Prophylaxis (PrEP) services and enhancing awareness of PrEP on select HBCU campuses.
  • Establish and/or enhance linkages/partnerships with National Native American groups focused on addressing disparities, health, and social issues in the context of HIV among Native Americans
    o Host a community-focused webinar on Native American engagement in HIV/AIDS clinical trials.
    o Review and update the guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project.

2. Seek funding to convene a Legacy Project/WHRC face-to-face meeting in 2019 to discuss and develop engagement strategies for the upcoming HIV research networks 2020-2027 funding cycle.

   Strategies and activities to support this objective:
   • Solicit funding for a face-to-face meeting
   • Meeting Logistics Planning
     o Identify meeting date and location
     o Invite attendees/presenters
     o Develop agenda
     o Arrange Travel

**Network Leadership**

**SWG**

The Strategic Working Group (SWG) is an advisory group convened by NIAID that is intended to provide strategic review and planning for the coordinated research efforts of the NIH HIV/AIDS Clinical Trials Networks. The SWG provides input on strategic issues that cut across the HIV/AIDS clinical trials networks, including overall priority setting for research plans, assessment of research opportunities and coordinated strategic planning across the networks. The working group is convened 1-2 times a year by NIAID to review and discuss scientific plans, progress and opportunities, specific protocols and cross-network issues. The HANC director participates in the SWG, but the group is organized and facilitated by NIAID. The next SWG meeting is tentatively scheduled for January 29-30, 2019.
Network Leaders and DAIDS

HANC organizes focused monthly and ad hoc conference calls with the network Principal and Co-Principal Investigators to address cross-cutting network leadership issues. HANC and DAIDS leadership also hold bimonthly conference calls to collaboratively identify and address issues and share updates on activities. HANC also holds a bimonthly call with the leadership of OCSO and OPCRO.

Site Management Coordination

Clinical trial logistics and operations, site management, and site oversight have been identified as areas of high priority for coordination and harmonization across the networks.

Site Management Working Groups

Site management and clinical trials logistics issues are diverse, and addressing these issues is likely to require different individuals with specific expertise. Network Leadership, DAIDS Leadership, and HANC work closely with the Office of Clinical Site Oversight (OCSO) and Office of Policy in Clinical Research Operations (OPCRO) at DAIDS to identify site concerns and identify appropriate individuals to engage in order to address issues raised.

HANC facilitates a cross-network Site Coordinators Working Group (SCWG) to address topics of common concern as well as to harmonize policies and procedures related to site-level operations.

Site Management Coordination Objectives for 2019

Site Management Coordination Objective #1: Work closely with network staff, OCSO, OPCRO, and other DAIDS offices to identify and address priority site management issues.

Strategies and activities to support this objective:

- Network Leaders, OCSO, OPCRO, and other stakeholders will identify an evolving list of site management issues and opportunities to better coordinate their respective efforts. This list may include: SDMC issues, reducing confusion around site monitoring by clarifying site new performance monitoring policies, clarifying DAIDS and networks respective responsibilities, harmonizing site establishment and protocol activation processes, identifying fiscal management best practices, and ensuring site preparedness for regulatory audits.

- HANC will disseminate OPCRO and OCSO policies, memos, SOPs for comment and/or general distribution to network operation centers as requested.

- HANC will hold regular calls with OCSO and OPCRO leadership to facilitate communication and coordination of site-level activities.

- HANC will convene topic-specific working groups on an ad-hoc basis to address site-level issues.

Site Management Coordination Objective #2: Discuss and address issues relevant to harmonization of policies, procedures, and training at the site level across the networks core operations centers.

Strategies and activities to support this objective:

- The SCWG will hold monthly site coordinator teleconferences dedicated to addressing significant site issues common across the networks.

- The SCWG will discuss issues that emerge with network leadership, core/operations centers, OCSO, OPCRO, and/or the Office of the DAIDS Director as appropriate.

- The SCWG will provide site-level perspective to DAIDS, SDMCs, and or core/operations centers on new or revised policies and procedures.
The SCWG will identify opportunities to harmonize the protocol site activation process and procedures across the core/op centers and SDMCs.

**Training Resources**

**Training Resources Objective for 2019**

**Training Objective #1**: Maintain the training resources public webpages. The HANC public website provides CTU/CRS staff with information on upcoming training events and training resources available in various formats.

**Women’s HIV Research Collaborative (WHRC)**

**WHRC Objective 1**: Increase awareness of HIV prevention modalities for transgender and cisgender women.

Strategies and activities to support this objective:
- Highlight HIV prevention modalities available or under research for use by women (oral PrEP, vaginal and rectal microbicides, injectables, infusions, vaccines, etc.) through webinars or local events and/or regional and national conferences.
- Draw attention to the development of multi-use products with HIV prevention and contraceptive properties.
- Synthesize and contextualize research findings relevant to HIV prevention for women to educate and inform the community.
- Develop a slide deck on HIV prevention for trans and cis women.

**WHRC Objective 2**: Explore issues related to the participation of pregnant and lactating women in HIV clinical trials.

Strategies and activities to support this objective:
- Assess protocols underway or in development across networks that include or are specific to pregnant and breastfeeding women.
- Synthesize and contextualize research findings relevant to pregnancy and lactation to educate and inform the community.
- Partner and strategize with organizations interested in addressing and promoting the participation of pregnant and postpartum women in HIV treatment and prevention trials;
  - Submit abstracts to conferences/meetings
  - Develop a webinar or twitter chat.

**WHRC Objective 3**: Increase awareness of the intersection of mental health, HIV, and gender.

Strategies and activities to support this objective:
- Host a collaborative webinar exploring the links between mental health, trauma, gender, and HIV acquisition.
- Highlight HIV stigma as a mental health hazard for women and girls with HIV.
- Partner with women-centered organizations that focus on healing and post-traumatic growth.
- Advocate for inclusion of psycho-social endpoints as part of HIV biomedical studies, particularly those involving high risks (e.g. HIV cure-oriented studies).
- Revise or advocate for the revision of antiquated stigma scales and quality of life scales used in HIV research.

**WHRC Objective 4**: Advocate for the meaningful involvement of women in HIV cure research.

Strategies and activities to support this objective:
- Develop a slide deck on women’s involvement in HIV cure research.
- Cultivate partnerships with the Martin Delaney Collaboratories, the ACTG, and other organizations working on HIV cure research.
- Advocate for the meaningful inclusion of women in studies involving female-relevant modalities.
- Critically analyze the use of treatment interruptions in HIV cure research and what this strategy may mean for women in the era of U=U and long-acting ARVs.
WHRC Objective 5: Engage in efforts to curb the effects of gendered violence on HIV acquisition with a focus on transgender and cisgender women.

Strategies and activities to support this objective:
- Develop a webinar, workshop, or panel discussion on assessing for intimate partner violence in the HIV clinical research setting and using a trauma-informed approach as a way to enhance cultural responsiveness, outreach, recruitment, and retention of women in clinical trials.
- Have a guest blogger write a post-webinar reflection for a public blog website such as Medium.

WHRC Objective 6: Promote increased representation of women of color in the field of research.

Strategies and activities to support this objective:
- Join the Legacy project’s efforts to harmonize activities across the minority investigator programs of the ACTG, HPTN, and HVN, and IMPAACT.
- Mentor junior female investigators interested in making an impact in HIV prevention, treatment and cure-related research particularly as it relates to issues relevant to women.

WHRC Objective 7: Recruit new WHRC members with a focus on racial, ethnic, and gender diversity.

Strategies and activities to support this objective:
- Identify potential new members in and outside the NIH-funded HIV/AIDS clinical trials networks.
- Invite new members to participate in regular calls and WHRC events/activities.
- Cultivate leadership within the WHRC membership with a focus on historically underrepresented voices.

WHRC Objective 8: Build relationships, partnerships, and coalitions with other women-centered organizations to collaborate on projects.

Strategies and activities to support this objective:
- Convene some of the female study chairs to discuss differences across networks in conducting women-specific studies.
- Partner with local and national organizations to promote scientific developments in HIV prevention and treatment.
- Partner with women-centered organizations focused on healing and post-traumatic growth.
- Cultivate partnerships with the Martin Delaney Collaboratories, the ACTG, and other organizations working on HIV cure research.
- Conduct a “state of the field” activity on HIV research and women
  - A webinar
  - A one-sheet commemorating National Women and Girls HIV/AIDS Awareness Day

HANC Activity Updates

Clear progress updates from the HANC office inform our partners of cross-network activities undertaken, progress made and challenges encountered. HANC progress reports are shared with stakeholders via:
- An annual HANC research performance progress report provided to NIAID Grants Management.
- Lists of HANC collaborators are provided to the Networks and SDMCs annually for inclusion in their research performance progress reports.
- HANC produces monthly newsletters distributed to all portal users and posted on the home page of the HANC portal.
- Maintain and add functionality to a dynamic web-based map of all NIH HIV/AIDS Clinical Trials Network Sites.
- Maintain the “Network Study Results & Publications” page and library on the HANC public website.
- Topic-specific webpages (e.g., network presentations at prominent scientific conferences: “Network Conference Presentations” (including CROI, IAS, HIVR4P, and USCA) on the HANC public website.
- HANC plans to create two different website tour/tutorial videos. One video will highlight the resources on the public website and the second video will highlight the resources on the HANC portal.

- HANC maintains the following portal resources:
  - DAIDS staff listing.
  - DAIDS topic-specific contact list.
  - Cross-network collaborator list.
  - Network newsletter library.
  - Network press releases and study results.
  - DAIDS Protocol Management feature which provides access to all approved protocols.
  - DAIDS Master Contact System linkage.
Appendix I: Tangible Deliverables by Area of Coordination:

**Behavioral Science Coordination**

- The Behavioral Science Working Group (BSWG) will host a webinar on behavioral economics/economic incentives presented by Dr. Omar Galarraga. The webinar should be scheduled to occur in Q1 2019. We are waiting on a paper to be published before the information can be shared.
- The BSWG will likely host other webinars in 2019 once topics have been discussed on future BSWG calls.
- The Behavioral Science Interest Group (BSIG) continues to produce a bi-weekly newsletter informing recipients of recently published articles, upcoming meetings related to behavioral and social sciences, funding opportunities, and available new resources that may be useful to the BSIG members work.
- The Behavioral Science Consultative Group (BSCG) is planning a webinar series for 2019. The first webinar will likely be held in January and it will be hosted by Dr. Rivet Amico (UMich). Dr. Michele Andrasik (HVTN) and Dr. Jessica Haberer (Harvard/MGH) will present on the first webinar. Dr. Andrasik will present on the AMP Study and Dr. Haberer will discuss the work she contributed to the PHOENix Study. The presentation will include ways that the BSCG’s work has contributed to the AMP and PHOENix studies. Future webinars will be planned after the first one is held.
- The BSCG has submitted a paper to the journal “AIDS and Behavior” that will be published in 2019. The paper is a qualitative data analysis using data from MTN’s VOICE D trial.
- The BSCG will hold a face-to-face meeting on June 20, 2019 at the conclusion of IAPAC’s Adherence 2019 Conference in Miami, Fl. The BSCG will produce a report at the conclusion of the meeting.
- BSCG members Dr. Rivet Amico and Dr. Jessica Haberer will continue providing effort for the PHOENix Study.
- The Youth Prevention Research Working Group (YPRWG) is planning to host two to three webinars in 2019.
- The YPRWG will submit an abstract for a satellite symposium to IAS 2019. The symposium will highlight NIH-sponsored multi-center international adolescent prevention research. The symposium will likely include participants from network studies.
- Greg Davis, Project Manager of the BSWG, BSCG, YPRWG, and BSIG, will likely attend the following conferences in 2019: Adherence 2019, IAS 2019 (if the YPRWG’s satellite symposium abstract is accepted), and the CFAR SBSRN Meeting.

**Communications Working Group**

- Provide network updates and content around major studies for inclusion in the monthly HANC newsletter.
- Catalog and share network submissions to major HIV/AIDS research conferences, including HIVR4P, CROI, AIDS/IAS, and USCA, on the HANC website.

**Community Coordination**

- Develop FAQ sheets to promote Community Partners resources and training materials
- Promote and disseminate slide deck focused on Study Modifications and the importance of community engagement
- Continue partnership with CRAG in developing TB/HIV presentations, materials, best practices
- Continue working with PHOENix Study Protocol Team on developing community messaging materials and resources
- Submit a manuscript for publication with the network-level community impact survey data
- Host or co-host community-focused workshops/presentations on ongoing network research and community engagement activities
- DRAFT a White Paper to highlight the collaboration of CRAG and CP in addressing issues around TB/HIV co-infection from a community perspective
Develop a multi-network CAB lessons learned/best practices document (protocol review, CAB orientations, CAB meetings, etc.)

Present to ATN Youth CAB Face-to-Face Meeting in April 2019 as part of formalizing engagement with ATN Youth CAB

Complete webinar series focused on HIV & Aging

Identify opportunities for improvement and work in collaboration with DAIDS and Network Leadership to ensure dissemination of research results (NIAID to share press releases with HANC to share with CP, communities and sites)

Work directly with DAIDS Cross-Network Transgender working group to promote the Transgender Training Curriculum for HIV Research with the Networks and other groups to encourage global adoption and implementation of the recommendations

Submit abstracts to host workshops/presentations at national and international meetings/events to engage communities and promote work and activities of Community Partners, including our collaboration efforts with TBTC CRAG

Data Management Center Coordination

The IT Best Practices Working Group (ITBPWG) will finalize and publish a revised version of the “Information Technology Best Practice Standards at NIH HIV/AIDS Clinical Research Networks’ Study Sites and Site Affiliated Laboratories”.

The Data Management Center Working Group (DMCWG) will produce an annual report on changes to data management evaluation metrics and standards.

The DMCWG will continue to refine and finalize the Safety Data Reconciliation policy for reconciliation of adverse events in the DAERS and safety database.

Evaluation Coordination

Create, review, and maintain the Community Indicator Survey (CIS) library, a compilation of all CIS questions asked across the networks.

Share experiences around software programs for real-time reporting of evaluation metrics, with plans for a presentation from the HVTN around the network’s use of Tableau.

Track developments in DAIDS policies related to protocol deviation reporting.

Financial Disclosure Database

Provide coordination with Network Regulatory Affairs Coordinators to update investigator, company, and site coordinator lists to use for the HANC-facilitated annual solicitation.

Review and update the Financial Disclosure and Conflict of Interest Guidelines SOP to ensure compliance with Federal policies.

Work closely with Freelock to maintain the database/ensure stability of database.

Laboratory Coordination

Complete full review and update of all standard operating procedures contained within the ACTG/IMPAACT Laboratory Manual.

Support new LTC member training by facilitating a series of training webinars that demonstrate how to populate the Lab Processing Chart and maintain webinar recordings on the HANC website.

Update shared documents on the LTC online portal, including the Laboratory Technologists Workload Tracking Sheet, Lab Processing Chart (LPC) Template, Protocol Support Training Resources and Standardized Wording documents for use in LPC development.
• Review and revise the LTC meeting attendance tracking file and current methods for transferring and storing it on the LTC Portal.
• Attend and support face to face laboratory sessions at the 2019 ACTG and IMPAACT Annual Meetings.
• Complete and disseminate the DCLOT/LFG cross-network terminology guidelines for laboratory audit action plans.
• Facilitate cross-network dissemination and implementation of changes to the Good Clinical Laboratory Practice guidelines.
• Coordinate LFG/DCLOT collaboration to develop and maintain standard cross-network analyte naming conventions.
• Coordinate with CPQA leadership to plan and facilitate an ongoing webinar series focused on lessons learned from FDA, EMA and industry audit experiences.
• Coordinate with IMPAACT Network Laboratory Center to regularly update vendor pricing, ordering details, and product information for Fetal Bovine Serum for ACTG and IMPAACT laboratories on the HANC webpage.
• Facilitate ongoing communication between members of the laboratory working groups and the NIAID/Division of AIDS, Statistical and Data Analysis Center, Data Management Center, Operations Center, and Clinical Site members.
• Continue to provide virtual communication platform and participate in laboratory working group teleconferences and webinars to assure synchronous activities among stakeholders, including ad hoc calls for leadership and/or collaborators.
• Continue to provide software and document development support to laboratory working groups and provide a website for maintaining group documents, agendas and minutes.

Legacy Project

• In partnership with HPTN and HVTN representatives, host community-focused workshop on Be the Generation at the 2019 African American MSM Leadership Conference on Health Disparities and Social Justice.
• Develop and broadcast a podcast on HIV research and community engagement in collaboration with research and community stakeholders in the HIV response.
• Host community-focused webinars on HIV prevention, treatment, and cure clinical research advances in collaboration with the NIH HIV/AIDS clinical trials networks.
• Develop and broadcast a podcast on HIV research and community engagement in collaboration with research and community stakeholders in the HIV response.
• Host or co-host community-focused workshops/presentations on ongoing network research including cure, PrEP, TasP, microbicides, and vaccines at meetings/events focused on key populations impacted by the domestic HIV epidemic.
• Host a community-focused webinar on Molecular HIV Surveillance and HIV phylogenetics research in collaboration with CDC representatives and HIV researchers.
• In partnership with Community Partners, host webinars focused on issues and research related to HIV & Aging.
• Oversee publication of the quarterly Be The Generation e-newsletter, BTG News, in collaboration with the HPTN, HVTN, and MTN.
• Update and promote the BTG HIV Prevention Research and Basic Scientific Literacy Modules.
• Collaborate with DAIDS, WHRC, Community Partners and the NIH HIV/AIDS Clinical Trials Networks and other stakeholders with the development and implementation of the Transgender Training Curriculum for HIV Research.
• Host a community-focused webinar on Native American engagement in HIV/AIDS clinical trials.
HIV/AIDS Network Coordination 2019 Work Plan

- Review and update the guidance document for engaging Native American communities based on the experiences of the Native American Engagement in HIV Clinical Research Project.
- Seek funding to convene a Legacy Project/WHRC face-to-face meeting in 2019 to discuss and develop engagement strategies for the upcoming HIV research networks 2020-2027 funding cycle.

Site Management Coordination
- Disseminate DAIDS policies, memos, SOPs for comment and/or general distribution to network operation center and/or clinical research sites as requested.
- Solicit site-level feedback and perspective on site management issues, processes, and monitoring. Relay concerns and emerging problems to relevant DAIDS offices, including OCSO and OPCRO.
- Track development and evolution of policies and projects impacting site operations, including the Age and Identity and Co-Enrollment Prevention policy, Protocol Funding Distribution mechanism, electronic distribution of investigator brochures, and cross-network protocol deviation form.

Training Resources
- Upload recordings of HANC-hosted webinars as completed.
- Review and update links and content on the “Resources” page of the HANC website on a quarterly basis.

Women's HIV Research Collaborative (WHRC)
- Submit an abstract on the feasibility and acceptability of screening for intimate partner violence in HIV research to the International Workshop on HIV and Women preceding CROI 2019.
- If accepted, present an oral presentation on the feasibility and acceptability of screening for intimate partner violence in HIV research to the International Workshop on HIV and Women preceding CROI 2019.
- Conduct a webinar on the feasibility and acceptability of screening for intimate partner violence in HIV research.
- Publish a community-focused blog post to summarize and reflect on a webinar on the feasibility and acceptability of screening for intimate partner violence in HIV research.
- Develop and disseminate a slide set on HIV prevention research modalities relevant to transgender and cisgender women.
- Develop and disseminate a slide set on HIV cure research relevant to transgender and cisgender women.
- Submit at least one abstract to the United States Conference on AIDS.
- Create and disseminate a fact sheet on NIH-funded HIV/AIDS research relevant to transgender and cisgender women for National Women and Girls HIV/AIDS Awareness Day.
- Conduct a webinar exploring the links between mental health, trauma, gender, and HIV acquisition.
- Revise or advocate for the revision of antiquated stigma scales and quality of life scales used in HIV research.
- Recruit new WHRC members from historically underrepresented backgrounds.

HANC Activity Updates
- Monthly HANC Newsletter
- Maintain all the NIH/Network contact lists on the HANC portal.