Proposing an NIH HIV/AIDS Clinical Trials Network Study:
Background, Guidance & Additional Resources

This guidance document for current and future network behavioral and social science researchers as they propose new studies, request data sets for additional analyses, apply for scholar programs, and liaise with colleagues.

Below, please find information on the steps required to propose a National institutes of Health (NIH) HIV/AIDS Clinical Trials Network study. Included are links to web pages offering details on proposing a study to the various NIH networks and committees addressing behavioral and social science (BSS) questions. Additional resources are also included at the conclusion of the document.

Background: The Office of HIV/AIDS Network Coordination (HANC) works with the six NIH HIV/AIDS Clinical Trials Networks with the intent of creating a more integrated, collaborative and flexible research structure. The networks are an affiliated group of national and international medical research institutions and investigators that conduct clinical HIV/AIDS research to develop safe and effective drugs, prevention strategies, and vaccines. The networks include: the AIDS Clinical Trial Group (ACTG), the HIV Prevention Trials Network (HPTN), the HIV Vaccine Trials Network (HVTN), the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT), the International Network for Strategic Initiatives in Global HIV Trials (INSIGHT), and the Microbicide Trials Network (MTN).

HANC facilitates the trans-NIH institute, cross-network Behavioral Science Working Group (BSWG). The BSWG's overarching goal is to ensure that the NIH clinical trials networks benefit from state-of-the-science methods and procedures that optimize adherence to product and risk reduction counseling as well to minimize the risk of confounding user and product failures. Further, the BSWG 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.

NIH HIV/AIDS Clinical Trials Networks:

AIDS Clinical Trials Group (ACTG):

Network Background & Scientific Priorities:

The ACTG was established in 1987 and supports the largest network of expert clinical and translational investigators and therapeutic clinical trials units in the world, including sites in resource-limited countries. Clinical trials and laboratory studies conducted by the ACTG have made major contributions to optimizing antiretroviral therapy (ART), managing drug resistance, preventing and treating co-infections, evaluating acute and long-term toxicities, and demonstrating the importance of pharmacogenomics in predicting drug toxicities. Results of these studies have helped establish the paradigm for the management of HIV disease and form the basis of current treatment guidelines.

The mission of the ACTG is to develop and conduct scientifically rigorous translational research and therapeutic clinical trials in the U.S. and internationally that:

- Investigate the viral and immune pathogenesis of HIV-1 infection and its complications;
- Evaluate novel therapeutic agents and the most effective approaches and strategies for the use of existing agents to treat HIV-1 infection;
- Evaluate interventions and strategies to treat and prevent HIV-related opportunistic infections, co-infections, complications of therapies, and other HIV-1-related co-morbidities (e.g., tuberculosis and hepatitis);

- Publish and disseminate the findings from these studies to improve clinical care, prevent or delay HIV disease progression, and reduce or eliminate the morbidity and mortality associated with HIV-1 infection and its associated complications.

Opportunities & Proposal Process:

- Concept Proposal Form: Request to develop a new protocol
- Data Analysis Concept Sheet (DACS): Request to use existing data for new analyses.
- New Work Concept Proposal: Request to use existing lab specimens for new research purposes.
- CEPAC-ACTG Study Collaboration Proposal
- Minority HIV Investigator Mentoring Program (MHIMP)
- Questions can be directed to: ACTGCollaborations@s-3.com

Committees:

- The scientific priorities of the **Cure Transformative Science Group** (formally known as the 'HIV Reservoirs and Viral Eradication Transformative Science Group') are to fully characterize reservoirs of HIV-1 in patients on suppressive ART; identify and validate high-throughput, quantitative molecular markers of HIV-1 reservoirs to serve as surrogates for infectious virus recovery from latently-infected resting CD4+ memory T-cells and viral rebound after cessation of ART for use as therapeutic endpoints in interventional studies; better understand how virus eradication was achieved by allogeneic stem cell transplant from a CCR5 Δ32/Δ32 donor; better define the relationships between immune activation, immune exhaustion, and viral persistence in blood and tissues; and identify the most promising, new therapies for evaluation in pilot "proof-of-concept" studies with careful measurements of HIV-1 reservoirs before, during, and after dosing. With regard to the latter objective, candidate therapies should have been evaluated for preclinical "proof-of-concept" efficacy in ex vivo experiments with cells from patients on long-term suppressive. "Proof-of-concept" efficacy in SIV/macaque models of suppressive ART are also desirable. The **Antiretroviral Therapy Strategies Subcommittee** has responsibility for overseeing phase IIB-IV studies of ART, within the ACTG, both in the US and internationally.
- The **End-organ Disease and Inflammation Transformative Science Group** fosters collaborative efforts among virologists, immunologists, pharmacologists, and both clinical and laboratory researchers in the design of clinical trials of novel interventions targeting HIV-associated immune activation and inflammation, and/or end-organ diseases commonly associated with the aging process. The group also develops observational studies evaluating the causes and consequences of HIV-associated immune activation using existing data and samples in the ACTG specimen repository, studies other host targeted therapies designed to enhance immune recovery, and evaluates the influence of age and gender on the clinical consequences of HIV infection. The **Co-infections and Malignancies Subcommittee** is responsible for the development, implementation, and oversight of the ACTG research agenda related to the diagnosis, treatment and prevention of co-infections and malignancies associated with HIV infection, both in domestic and international settings.
- The **Hepatitis Transformative Science Group** provides effective therapy to all HIV patients co-infected with viral hepatitis and a platform for conduct of novel DAA trials in patients with HCV mono-infection
- The areas of highest priority for the **Neurology Collaborative Science Group** are on distal sensory peripheral neuropathy; HIV-associated cognitive impairment; the central nervous system as a reservoir of HIV infection; HIV-associated CNS opportunistic infections; and neurologic toxicities of ARV and other drugs.
- The **Tuberculosis Transformative Science Group** (TB TSG) is responsible for development, implementation, and oversight of the ACTG research agenda related to the treatment and prevention of tuberculosis with and without HIV co-infection. The primary objectives of the TB TSG are the evaluation of anti-TB new drugs and drug combinations; development of shorter treatment regimens; treatment of MDR/XDR tuberculosis; and optimal treatment of latent tuberculosis, including MDR/XDR tuberculosis infection. Additional aims include: optimizing treatment of tuberculosis for patients receiving combination antiretroviral therapy (ART); evaluation of drug-drug interactions involving anti-TB therapy and ART; improved TB diagnostics assays and biomarkers to predict and detect disease and to monitor response to therapy; evaluating TB vaccines for HIV infected adults; and developing novel clinical trial designs.
- **Underrepresented Populations Committee:** promotes and monitors the participation in trials of groups traditionally underrepresented in clinical research, and recommends policies and procedures to the ACTG Executive Committee to improve the representation of underserved populations and enhance participation by minority investigators. The committee also oversees the selection of candidates for the MHIMP.

- **Women's Health Inter-Network Scientific Committee** (WHISC) is a joint-committee with IMPAACT. It seeks to develop optimal strategies for the prevention and treatment of HIV disease and related complications among women and to determine the pathogenesis of manifestations that are unique to women.

HIV Prevention Trials Network (HPTN):

Network Background & Scientific Priorities:

The HPTN develops and tests the safety and efficacy of primarily non-vaccine interventions designed to prevent the acquisition and transmission of HIV. The HPTN was established in 2000, building on the work of the HIV Network for Prevention Trials (HIVNET). The HPTN carries out its mission through a strong network of expert scientists and investigators from both international and U.S. institutions and partnered with a leadership group comprised of three U.S.-based institutions. Through the coordination of the NIH Office of AIDS Research, other NIH institutes, such as the National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the National Institute of Child Health and Human Development (NICHD) and the John E. Fogarty International Center, collaborate with and support the HPTN.

The HPTN research agenda is focused primarily on the use of antiretroviral therapy for HIV prevention; treatment and prevention of sexually transmitted infections; treatment of substance abuse, particularly injection drug use; behavioral risk reduction interventions and structural interventions to reduce HIV transmission and acquisition.

HPTN studies evaluate new HIV prevention interventions and strategies in populations and geographical regions that are bearing a disproportionate burden of infection. This is intended to facilitate rapid scale-up of proven interventions and to have the greatest possible impact on the pandemic. In addition, the HPTN has refined and expanded its expertise in the development and validation of tools for the early detection of HIV infection. To maximize their quality and benefits, all HPTN studies are conducted in close partnership with the community.

Opportunities & Proposal Process:

- HPTN Scholars Program for early-career US minority investigators
- HPTN Study Capsule Template
- HPTN Concept Template
- HPTN Protocol Template
- HPTN Ancillary Study Application

Relevant Committees:

- **Behavioral Science Working Group's** principal focus is on the further identification, development, and evaluation of behavioral interventions associated with reducing risks of HIV through high-risk behavior.

HIV Vaccine Trials Network (HVTN):

Network Background & Scientific Priorities:

The mission of the HVTN is to enhance the discovery and drive the development of a safe and globally effective vaccine to prevent HIV. The HVTN does this through well-designed clinical research trials that objectively and ethically address the critical questions of the field. The network's clinical trial platform supports the evaluation of safety, immunogenicity, and efficacy of candidate vaccines as well as the design clinical trials that will provide clues on ways to enhance the effectiveness of new vaccines. HVTN promotes the use of new trial designs such as adaptive trial designs, which may help us get closer to a safe and effective vaccine more quickly. Current HVTN studies evaluate T-cell-mediated vaccines, vaccines that elicit neutralizing

antibodies (nAb) as well as those that elicit mucosal immune responses, and novel adjuvants to improve the breadth, quality, and magnitude of the body's immune response to HIV-1 immunogens.

The HVTN relies upon the collective wisdom and creativity of its investigators and collaborators and the HIV vaccine field at large to pursue studies that will move us closer to finding an effective HIV preventive vaccine. As such, HVTN welcomes the ideas of the scientific community regarding new proposals for HIV vaccine studies and related studies that are not currently being planned or pursued. The network is also interested in reviewing proposals for studies utilizing specimens and/or data collected during HVTN vaccine clinical trials that may further understanding of HIV vaccinology.

Opportunities:

- HVTN Study Proposal Flowchart
- Research and Mentorship Program (RAMP) Scholar Grant: Seeking African-American and Hispanic medical students interested in HIV vaccine research.
- NHP Early Stage Investigator Scholar Award: The Non-Human Primate (NHP) Early Stage Investigator (ESI) Scholar Program encourages investigators at the post-doctoral trainee, clinical instructor, or assistant professor level who are interested in HIV vaccine research to apply for this award.
- The SHAPe Programme: The South African/HVTN AIDS Vaccine Early Stage Investigator Programme (SHAPe) is a structured research, mentoring, and Ph.D. program seeking South Africans who have received an MBChB degree in the past 12 years.

Proposal Process:

- Review the HVTN Scientific Agenda. Does your proposal fit into or complement the agenda? How does the study fit with current concepts being developed at the HVTN?
- Prepare a brief synopsis of the idea. Use the Scientific Idea Submission Form to prepare a brief description of the proposal. The proposal will receive an initial review by HVTN leadership. You will be contacted within two weeks of your proposal submission if we require more information.
- Work with the network operations center. If further development is encouraged by HVTN leadership, HVTN will work with you to establish the appropriate team and guide you on moving the proposal forward. Leadership will also make sure that you will maintain involvement in the proposal as it moves forward
- Additional detail can be found here. Questions can be directed to vtn.research@hvtn.org.

Relevant Committees:

- **Social and Behavioral Working Group**: will address social and behavioral science scientific questions which have an impact on the design, implementation and interpretation of vaccine trials. The SBWG will identify social and behavioral science research priorities within the network to facilitate the integration of behavioral and social science work into existing and future HVTN efforts.

International Maternal Pediatric Adolescent AIDS Clinical Trial Group (IMPAACT):

Network Background & Scientific Priorities:

IMPAACT's mission is to decrease significantly the mortality and morbidity associated with HIV disease in children, adolescents, and pregnant women. Relevant network committees are detailed below and additional research area details can be found here.

The Primary Therapy Scientific Committee's (PTSC) agenda aims to optimize antiretroviral management of children from infancy through adolescence and into young adulthood. A major emphasis of the PTSC work is to determine the efficacy, safety, tolerance, pharmacokinetics (PK) and drug: drug interactions of existing and novel ARV agents and formulations alone and in combination across the pediatric age and developmental spectrum. Furthermore, the committee strives to define therapeutic approaches that provide reproducible efficacy while minimizing side effects. In addition, the PTSC recognizes the urgent need to

develop and standardize fixed dose combination preparations for pediatric populations to simplify treatment of the large numbers of children in high prevalence, under resourced settings and to facilitate adherence to treatment.

Opportunities & Proposal Process:

- General information
- Capsule Submission
- Concept Sheet: Request to use existing data for new analyses.
- New Works Analysis Concept Sheet: Request to use existing lab specimens for new research purposes.
- Data Analysis Concept Sheet
- Please submit the completed templates to: impaact.capsubmissions@fstrf.org. You will be contacted concerning the next steps.

Committees:

- The scientific and clinical priorities of the **Prevention Committee** are to evaluate: interventions to prevent mother-to-child HIV-1 transmission in the perinatal period and breastfeeding; safe, effective and feasible interventions to reduce incident HIV-1 infection in pregnant and breastfeeding women; and biomedical and behavioral interventions to reduce transmission of HIV-1 among adolescents.
- The **HIV/ARV Complications Committee's** agenda focuses on the evaluation of therapies to prevent/treat co-infections, HIV complications, and treatments; evaluation of safety, immunogenicity and efficacy of licensed childhood vaccines and novel non-HIV vaccines in HIV-infected youth; define the epidemiology, diagnostic methods, and therapies for neurodevelopmental and neuropsychiatric problems in HIV-infected youth; and long-term follow up of HIV-infected and exposed infants and children.
- The **HIV Treatment Committee** is charged with the evaluation of the PK/safety of new ARVs leading to optimal labeling and licensing, as well as drug-drug interactions; the evaluation of treatment strategies that have the potential to result in greater suppression of viral load, enhanced immune response, decreased morbidity, less toxicity, less drug resistance, more affordable regimens, and cost-effective assay monitoring; and to use ARV agents and novel treatment strategies to investigate HIV-1 pathogenesis and the reconstitution of the immune system.
- The **Vaccine Committee** is asked to: develop effective regimens to prevent breast milk transmission of HIV-1; Evaluate immune based therapy for possible maintenance of suppressed viral loads in infants, children, and adolescents who were HIV-1 infected prior to immunization; evaluate and implement an effective vaccine regimen to prevent sexual transmission of HIV-1; design studies addressing questions in the areas of immune response to HIV, HIV vaccines, or viral factors; and determine safety, immunogenicity and efficacy of vaccines for infectious diseases other than HIV.
- **Women's Health Inter-Network Scientific Committee's** (WHISC) mission is to foster the development of studies that address scientific questions pertaining to HIV infected women including but not limited to assessing optimal antiretroviral therapy (ART) over the course of their lifetime. Responsibilities include attention to: response to treatment and toxicities; assessing the impact of contraception and hormonal interventions on this population; optimizing diagnosis and management of opportunistic infections (OI) including prevention and treatment of HPV related disease, and evaluating strategies to improve adherence to lifetime therapy. The WHISC works to maximize the recruitment and retention of women into clinical trials and provide recommendations regarding reproductive health, contraception, and pregnancy issues. This committee is a joint-committee with ACTG.
- The **Cure Committee** seeks to: develop a definition including endpoints for functional cure versus viral eradication; test whether therapy with multi-class ART that includes agents that block virus entry/integration reduces/eliminates HIV reservoir establishment in acutely infected infants; identify groups of HIV-infected elite responders of early-treated children/youth likely to achieve cure or functional cure; and conduct clinical trials of immune modulatory agents, including therapeutic HIV vaccines, virus activation or target cell modification strategies to effect cure or functional cure in youth on long-term suppressive ART.
- The **Hepatitis Committee** is charged with the evaluation of ARVs, novel agents and vaccines for the treatment and cure of hepatitis infections; evaluation of strategies to prevent HBV, HCV and HEV infection applicable in developed and developing environments; the development of strategies for the diagnosis, evaluation and staging of liver disease among HIV-infected infants, children, adolescents and pregnant women with and without viral hepatitis infections; and the evaluation of the impact of hepatitis treatment on the pathogenesis of disease and long-term outcomes of both HIV and hepatitis infections

International Network for Strategic Initiatives in Global HIV Trials (INSIGHT):

Network Background & Scientific Priorities:

INSIGHT's mission is to define optimal strategies for the management of HIV and other infectious diseases through a global clinical research network. INSIGHT was created in 2006 by merging two existing NIH-funded clinical research trial groups: The Evaluation of Subcutaneous Proleukin® in a Randomized International Trial (ESPRIT) and the Terry Berin Community Programs for Clinical Research on AIDS (CPCRA). The synergy and success of the INSIGHT organization can be best demonstrated by the enrollment of the two largest HIV treatment trials to date, the Strategies for Management of Anti-Retroviral Therapy (SMART) study and ESPRIT. In 2009, INSIGHT commenced recruitment to the START (Strategic Timing of AntiRetroviral Therapy) study. Subsequent to the unblinding of the SMART findings in 2006, multiple successful projects have been completed, providing a better understanding of why intermittent provision of antiretroviral therapy (ART) was associated with excess morbidity and mortality. A similar exercise has been initiated for ESPRIT, the results of which were unblinded in January 2009.
ESPRIT, SMART and START aim to provide definitive evidence to a clinical research question. By design, these studies have included several thousand study participants followed within the trial over several years. Follow-up included as a priority careful ascertainment of relevant clinical endpoints. INSIGHT is also conducting two influenza studies.

Suitable research proposals have a design that aims either to provide a definitive answer to a research question (contained within the area of the vision as formulated i.e. infectious diseases) or aims to provide an answer that is critical to inform design of future more definitive research projects. These might be vanguard trials or observational studies.

The suitability of a project will be viewed relative to the following criteria/imperatives:

- Fits with INSIGHT mission;
- Significant impact on clinical practice;
- Applicability to the global population and expands into resource poor countries;
- Scientific merit and novelty of research;
- Operational feasibility and using the current large network of clinical sites;
- Building relationships with research foundations;
- Expanding into other infectious disease clinical and laboratory research;
- Developing/establishing strategic alliances/partnerships; and
- Research building on already achieved results from previous INSIGHT studies is encouraged. Most new studies will be expected to include randomization as part of their design.

Opportunities & Proposal Process:

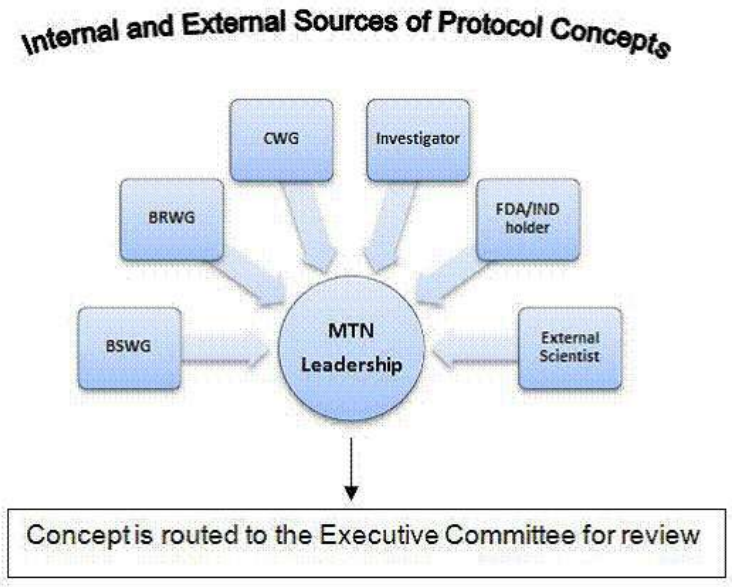
- Proposal form
- Proposal submission guidance

Microbicide Trials Network (MTN):

Network Background & Scientific Priorities:

MTN was established in 2006, with co-funding from the NIH's National Institute of Mental Health and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). The MTN brings together international investigators and community and industry partners devoted to reducing the sexual transmission of HIV through the development and evaluation of products used orally or applied topically. MTN-affiliated researchers and partners work within a unique infrastructure specifically designed to facilitate the research required to support licensure of these products for widespread use. MTN was designed to identify promising candidate microbicides and provide the necessary safety and efficacy testing in an efficient and cost effective manner to support the progression of safe, effective products to licensure. With the

belief that the best clinical research program involves an open submission process for study concepts and a timeline-driven protocol development and implementation process, the MTN accepts concepts for new protocols from all interested parties.



Because the network focuses on development of new drug entities for prevention, the types of studies which are within the scope of the MTN are those that fill gaps in the development product pathway toward licensure (classic Phase 1 safety and acceptability studies, Phase 2 expanded safety studies and Phase 2B/3 effectiveness studies), bridging studies to other populations (adolescents, pregnant or lactating women, post-menopausal women), and ancillary studies which provide data on adherence, biomarkers of efficacy, or evaluation of alternative formulations. Concepts arise from a variety of sources and MTN reviews all study concepts that are submitted for consideration. Importantly, many study concepts are submitted by researchers or organizations outside of the network, most frequently by product Investigational New Drug (IND) holders based upon FDA request for safety or efficacy data. Other protocol concepts are submitted from members of the Biomedical Science Working Group (BSWG), Behavioral Research Working Group (BRWG) or Community Working Group (CWG), from site investigators, or by members of the Network Laboratory. Provided that the proposed study fits into the mission of MTN, the concept is routed to the Executive Committee (EC) for review, and approval is based on a tally of written ballots.

Opportunities & Proposal Process:

- Proposals should be submitted to MTN co-PIs Sharon Hillier or Ian McGowan. Additional details can be found here.

Relevant Committees:

- **Behavioral Research Working Group**: will develop and implement the MTN behavioral science agenda through participation of BRWG members on each MTN protocol for which there is a behavioral component and to set priorities for behavioral research on microbicides within the MTN.

Affiliated Research Groups & General Resources:

Adolescent Trials Network (ATN):

Network Background & Scientific Priorities:

The primary mission of the ATN is to conduct U.S.-based research, both independently and in collaboration with existing research networks and individual investigators, in HIV-infected and HIV-at-risk pre-adolescents, adolescents, and young adults up to age 25 years. Prevention research, not the development of antiretroviral therapy trials, remains a large focus of research for pre-adolescents. Much of the research activity of the ATN focuses on collaboration with the Clinical Trials Networks supported by other institutes of the NIH, including but not limited to NIAID and the National Cancer Institute (NCI) through coordination of research. The ATN has the capacity for developing and conducting selected behavioral, community-based translational, prophylactic, therapeutic, microbicide and vaccine trials based on and adding to the information developed

through the Adolescent Medicine HIV/AIDS Research Network (1994-2001) and the earlier years of the Adolescent Medicine Trials Network (2001-2011). The ATN is funded by the National Institute of Child Health and Human Development.

The ATN brings expertise and resources to collaborative protocol development that ensures feasible and acceptable study design as well as experience in recruiting and retaining this unique population. This initiative calls for a broad array of intervention studies aimed at the primary, secondary, and tertiary prevention of HIV infection in pre-adolescents, adolescents, and young adults at clinical sites and in their surrounding communities. These include pilot phase and formative studies as well as selected larger efficacy level interventions, with appropriate collaboration from other networks when needed. Comparative effectiveness and operational research, including program evaluation research, may also be conducted when necessary and feasible. This network designs, develops, and conducts multiple common clinical trials as well as pertinent formative and translational research studies collaboratively or independently when needed. The ATN strives to bring the required numbers of subjects into rigorously designed common protocols and thus address pressing research questions in youth more quickly than individual centers acting alone.

The ATN offers expertise and infrastructure to collaborative protocol development that will ensure feasible and acceptable study design as well as experience in recruiting and retaining this unique population. The network investigators are strongly committed to developing the best scientific knowledge possible and are committed as individual professionals and as a group to improving the health and quality of life of HIV-infected and other high-risk adolescents. The network welcomes the opportunity to consider collaborative proposals from other basic science and clinical investigators.

The ATN offers three key features to collaborators in the field of adolescence and HIV infection:

- Leadership by experts with behavioral, clinical, therapeutic, epidemiologic, laboratory, and statistical expertise to set research priorities;
- Resources for collaborative protocol development to ensure feasible and acceptable study design; and
- Experience in recruiting and retaining the adolescent population in clinical trials.

Opportunities & Proposal Process:

- Investigators interested in collaborating with the ATN will develop a brief description of the proposed study in a short encapsulated format, i.e., a Protocol Concept Capsule (PCC), following the development procedure in Step One, Initiation of a Protocol Concept, of the ATN Policy for Study Concept Plan Development. Additionally, the investigators will identify who will collect the data, manage the data, and be responsible for providing the Executive Committee with data analysis. The collaboration supports the overall purpose of the Network and is within the prioritized scientific agenda as established by the Executive Committee. Queries can be submitted to atnwebmaster@westat.com.
- ATN Mentoring Program for Doctoral-Level Scholars Interested in Youth-Focused HIV Research Careers

ClinicalTrials.gov: Searchable clinical trials database that includes results from many recent trials (e.g., A5202).

Office of HIV/AIDS Network Coordination (HANC):

HANC offers various resources for behavioral and social scientists (BSS) interested in collaborating with the NIH HIV/AIDS Clinical Trials Networks:

- Behavioral Science Interest Group (BSIG): The BSIG is a listserv connecting BSS, Network Leaders, protocol team members, community members, and advocates. HANC circulates a weekly digest noting funding announcements, relevant presentations, tools and measures, and articles of interest saved to the BSIG Resource Center.
- BSIG Resource Center and Document Library: A password protected forum to share ideas; post relevant articles; house network CRFs and behavioral measures; gather and address BSS needs; and collaborate on related topics. PDFs of articles etc. are available to all BSIG members.

- BSIG Rx Connect: Investigators pose research and technical questions to one another using the BSIG listserv. HANC facilitates the discussions and documents the suggestions for future queries.
- BSIG Topics of Interest Webinar Series: HANC curates a webinar series addressing BSS research concerns. Recent presentations included the HIV epidemic in the U.S. MSM population, conducting research using social media
- Behavioral Science Working Group: The overarching goal is to ensure that the 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 BSWG 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 BSWG features representatives from each participating network, as well as the relevant data coordinating and operations centers, community partners and key NIH staff. These representatives serve as liaisons to their respective entities and enlist assistance from additional staff for specific BSWG tasks as indicated.
- BSWG Report Library: Recommendations, guidance, and detailed reports emerging from annual BSWG meetings as well as focus groups considering risk assessment, neurocognitive assessments, and behavioral data capture technologies.
- Public BSS Publications Library: An important resource for behavioral and social scientists as well as those interested in relevant topics in HIV social and behavioral research. Each entry includes PubMed IDs, article abstract, and a link to the full text (if available).
- Youth Prevention Working Group (YPRWG): The cross-network/trans-Institute was formed in the winter of 2012. The group consists of representatives from the networks, the Adolescent Trials Network (ATN), DAIDS, NIAID, NIMH, NIDA, and NICHD. The group is interested in coordinating sharing of network adolescent research agendas; addressing the challenge of conducting trials across multiple networks, considering tangible outcomes such as dropping the mean age of network volunteers, validating existing tools, considering adolescent issues early on in design process, reviewing relevant informed consent documents, and collating a set of core competencies.
- Other HANC projects addressing behavioral research concerns follow:
    - Community Partners is made up of community representatives from the NIH Networks community groups and network staff, and other external community advisors. Community Partners represents community research needs and priorities to the HIV/AIDS Clinical Trials Network Leadership Operations Group (NLOG) and Strategic Working Group (SWG) and other advisory groups or committees as needed/requested. CP provides input to NIH research plans as they relate to scientific agendas, ethical conduct of clinical trials, community education, community training and communication/information dissemination in a manner that ensures respect for community priorities and continued community participation.
    - The Legacy Project works nationally to increase awareness of and build support for HIV prevention and treatment clinical and behavioral research by addressing factors that influence participation of historically underrepresented communities. The Legacy Project achieves its core mission through ongoing and strategic engagement, collaboration, education, and scientific investigation. With a team of diverse, skilled and devoted staff, the Legacy Project works to cultivate and enhance partnerships and relationships among the NIH HIV/AIDS Clinical Trials Networks and research sites, research and academic institutions, governmental agencies, community-based organizations and affiliates, while ensuring a commitment to capacity building for communities and populations most impacted by the HIV epidemic in the United States.

Pediatric HIV/AIDS Cohort Study (PHACS):

Network Background & Scientific Priorities:

The PHACS network was established in 2005 to address two critical pediatric HIV research questions: the long-term safety of fetal and infant exposure to prophylactic antiretroviral (ART) chemotherapy, and the effects of perinatally acquired HIV infection in adolescents. The goals of this network are to: create a body of data to understand more fully the effect of HIV on sexual maturation, pubertal development, and socialization of perinatally HIV-infected pre-adolescents and adolescents; acquire more definitive information regarding long-term safety of ARV agents when used during pregnancy and in newborns; Ensure a mechanism is in place to estimate the upper bounds of risk for children associated with the use of ARVs in their HIV-infected pregnant mothers as recommended in the Public Health Service Guidelines to prevent perinatal HIV transmission; and ensure that the follow-up of these populations continues.

Opportunities & Proposal Process:

- Guidelines for development of a sub-study or data analysis capsule can be found here.
- Pease contact the Behavioral and Neurological Disease Working group through the PHACS Coordinating Center at phacscc@tulane.edu or phacscc@fstrf.org.

NIAID: Laboratory and scientific resources: http://www.niaid.nih.gov/labsAndResources/pages/default.aspx?wt.ac=tnLabs.