

Dear Colleagues:

As you may have seen, NICHD recently released a notice of intent to publish a funding announcement for the ATN Scientific Leadership Center (SLC). While the details contained in that notice: <https://grants.nih.gov/grants/guide/notice-files/NOT-HD-21-043.html> are limited, it does state that the SLC should plan to include **5-8 Research Projects**.

To maximize our ability to submit a responsive application, we are reaching out broadly to solicit the submission of new research concepts that fit within the ATN priority research areas as described in notice and included below.

“The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), with other NIH Institutes and Centers (ICs), the National Institute on Drug Abuse (NIDA) and the National Institute of Mental Health (NIMH), intends to promote a new initiative by publishing a Funding Opportunity Announcement (FOA) to solicit applications for a research program cooperative agreement to support the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) to develop and conduct innovative behavioral, community-based, translational, therapeutic, microbicide and vaccine trials in youth ages 13-24 years at-risk for HIV and living with HIV, with a focus on the inclusion of minors. This FOA will encourage a more focused, clinical research agenda, with increased emphasis on registrational trials of biomedical interventions. Among the areas of research encouraged in this initiative are studies to investigate HIV priority areas of undiagnosed HIV infection, persistent new infections, poor HIV care engagement, poor ART adherence, viral suppression, and adverse HIV health outcomes from COVID-19, as well as research designed to improve the translation of existing knowledge of strategies for the prevention and treatment of HIV/AIDS.”

Given the limited time, we are requesting that all concepts (max 5 pages including references) be submitted by **September 27, 2021**, to lisa_hightow@med.unc.edu. Concepts will be reviewed and prioritized, and investigative teams will be notified of decisions by October 4, 2021. In the event that similar concepts are submitted, the review committee may suggest for various teams to work together in development of a full proposal.

Concepts are welcomed from ATN and non-ATN affiliated investigators; inclusion of junior investigators is encouraged. Please note that clinical trials with preliminary data are preferred over developmental projects.

Should you have any questions, please don't hesitate to reach out to either of us. We look forward to hearing from you.

Sincerely,

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CONCEPT SHEET

(NOT TO EXCEED 5 PAGES, including references)

STUDY TITLE

INVESTIGATIVE TEAM

Specify lead and co-investigators. Provide brief discussion of roles, responsibilities. Specify inclusion of junior investigators and their role.

SUMMARY OF PURPOSE AND RATIONALE

This should include introduction and background literature to set the context of the proposed research. Include any supportive preliminary data.

STUDY AIMS/OBJECTIVES

Describe study aims and objectives

STUDY DESIGN

Specify the type of study proposed. If registrational drug trial, specify any product related considerations (e.g., Is an IND needed? Are there any agreements in place with pharmaceutical companies to provide product?)

DESCRIPTION OF THE INTERVENTION

Describe intervention, specify study arms, including control if applicable. Specify levels (e.g., individual, interpersonal, community, structural) intervention is targeting as well as more specific domains within each level.

OUTCOMES AND ANALYSIS

Specify the primary outcomes and secondary outcomes and overview of potential analysis plan. Identify if statistical expertise is included within study team or will need to be provided through statistical core.

STUDY POPULATION

Specify sample size, the principal inclusion and exclusion criteria, recruitment source (s), and other salient characteristics.

STUDY SITES

Specify the approximate number/type of sites and site capacity required to successfully conduct the study.

TIMEFRAME AND APPROXIMATE YEARLY BUDGET:

Specify expected duration of start-up, accrual and follow-up, and any contingencies for development/implementation (e.g., final product selection/dosage to await results of ongoing studies). Provide an approximate yearly budget.

RELEVANCE TO ATN

Specify how this study addresses priority areas within the field of adolescent HIV. How will this study advance science, contribute to a change in policy or practice or have a significant public health impact?