

FAQs About the ATN IV Initiative

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Funding Opportunity Announcement (FOA) Specific

1. What Institutes will be participating in this Adolescent Medicine Trials Network for HIV Intervention (ATN) IV Initiative?

Eunice Kennedy Shriver National Institute of Child Health and Human Development ([NICHD](#))
National Institute on Drug Abuse ([NIDA](#))
National Institute of Mental Health ([NIMH](#))
National Institute on Minority Health and Health Disparities ([NIMHD](#))

NICHD is the lead, NIDA, NIMH, NIMHD are co funders and partners.

2. What are the new components of the ATN?

ATN Research Program Grants (U19)

ATN Coordinating Center (CC) (U24)

3. What is the open date?

December 19, 2015 is the first date to submit an application

4. When are the letters of Intent due date?

December 19, 2015

5. What is the AIDS application due date?

January 19, 2016

6. When is review?

March 2016

7. What is the Council date?

June 2016

8. What is the earliest start date?

July 2016

9. What is the Purpose of this FOA?

The Network will have the capacity to develop and conduct innovative behavioral, community-based, translational, therapeutic, microbicide and vaccine trials in HIV-at-risk and HIV-infected youth ages 12 to 24 years, with a focus on the inclusion of minors.

10. What is the scope?

This initiative calls for cooperative, multi-program project grants with well-defined themes that may include a broad array of interventional studies, conducted collaboratively and independently, aimed at the reduction of new HIV infections among at-risk youth and improvements in numbers across the HIV care continuum among HIV-infected adolescents and young adults who are medically disenfranchised, of low socio-economic status, sexual and gender minority, and/or of racial/ethnic minority constituency including African American, Hispanic, and/or substance abusing youth.

11. What are the objectives?

Primary prevention studies will focus on efforts to interrupt HIV transmission in uninfected populations. This will be accomplished by supporting clinical trials and some formative work directly leading to such trials, evaluating HIV preventive vaccines, microbicides, pre-exposure prophylaxis (PrEP), and other combination biomedical and behavioral intervention modalities tailored for youth at greatest risk for HIV infection or transmission.

Studies focused on the HIV continuum of care for adolescents and young adults that examine behavioral and therapeutic interventions, at earlier stages of infection, to preserve health and function in HIV-infected populations and to prevent secondary transmission events.

This FOA will also support formative, test-of-concept/pilot clinical studies in HIV-infected and at-risk youth populations, if they are directly linked to a larger scale efficacy-level intervention for evaluation among these populations and proposed in the same application.

12. What are non-responsive topics?

- Formative biomedical, behavioral, or community level interventions lacking a clear developmental trajectory and link to large-scale efficacy or effectiveness evaluations
- Studies evaluating or comparing antiretroviral treatment strategy trials
- Standalone pharmacokinetic/pharmacodynamics evaluations of antiretroviral therapy (ART)
- Research focused only on neurocognitive dysfunction and HIV

13. What is the overall structure of the ATN IV?

The new ATN will be composed of several cooperative agreement program project grants (U19s = P01s) and a Coordinating Center U24.

14. What are the essential features of the New ATN?

(U19) Multi Program Project http://www.nichd.nih.gov/grants-funding/opportunities-mechanisms/mechanisms-types/research-mechanisms/Pages/u19_guide.aspx

The ATN is newly designed as a series of up to 5 U19s which supports a research program with a well-defined central theme, research focus, or objective(s).

- Each ATN U19 will include 3-4 R01 like Research Projects and may include 1 to 2 R21, R03 like pilot projects along with Core(s) necessary to support the projects.
- These research projects should directly focus on one or more aspects of primary prevention and/or the HIV continuum of care among adolescents in the United States.
- The U19 research effort will be facilitated by the sharing of ideas, data, and specialized resources, such as equipment, services, and clinical facilities.
- Each U19 application will include a proposal and process for the development of new protocols to be discussed and voted on by all members of the ATN executive committee.

The Research Projects proposed must be scientifically meritorious, and also complement one another, be synergistic, and support the program's overall theme. Thus, the program's overall scientific merit should be greater than the sum of its parts.

(U24) Data and Coordinating Center (CC)

A separate award, which will facilitate cross-U19 and external collaborations (including management and allocation of resources) for all ATN U19s and will coordinate logistical needs for the network, is described in more detail under a separate solicitation for the ATN CC (U24).

ATN Executive Committee (EC)

The ATN EC will have representation from each U19 and ATN CC U24 PD(s)/PI(s), NIH, and other selected experts, to help develop cross-U19 collaborations and collaborations with other networks and investigators and prioritize emergent science as the research landscape evolves. In consultation with NIH, the EC will also consult with an external Ethics Advisory Panel (EAP).

Single Institutional Review Board (sIRB)

In order to reduce the burden on local IRB's, streamline the protocol approval process, and standardize the oversight of human subjects' protection in the ATN studies, the use of a single IRB is strongly encouraged.

External Advisory Group (EAG)

An independent EAG will be convened to review the scientific progress and activities across the Network with the goal of maintaining the highest level of scientific progress and relevance of proposed and ongoing projects. The EAG may recommend new directions as appropriate. Members will have the scientific expertise but not be affiliated with components of the ATN U19s. The EAG will meet yearly at an ATN National Meeting coordinated by the ATN CC. Following these meetings, the EAG will make recommendations in writing regarding scientific progress and activities of the network to the NIH and the ATN EC.

15. What is the budget for a U19 Program Project?

Budgets of up to \$2.5 million per year in direct costs may be requested per U19.

16. What is the maximum project period?

5 years

17. What are the critical features of the U24 ATN Data and Coordinating Center (CC)?

The ATN CC funded under this FOA will provide operational and logistical support infrastructure to a series of U19 Cooperative Research Program awards, funded under a separate FOA, to support a research program with a well-defined central theme, research focus, or objective(s) for the ATN. The award funded under this FOA and the companion FOA will use cooperative agreement mechanisms (see Section VI.2 Cooperative Agreement Terms and Conditions of Award). Close and substantial interactions between the NIH, and the ATN U24 and U19 awardees, are required to accomplish the objectives of the ATN and of this FOA.

All funds for cross-network collaborative and emerging high-priority study protocols to be conducted by the Network's U19s and other external collaborations **will be awarded to the ATN CC in the Notice of Grant Award (NOA) as restricted protocol-related expenses**. The use of these funds will require prior discussion and approval from NICHD. Upon approval the funds will be released for studies either in increments or full amounts for approved ATN protocols to the ATN CC.

- The ATN CC is responsible for the monitoring and distribution of protocol funds to the ATN U19s.
- The application should provide a performance-based, centralized, equitable, and efficient method for coordinating the distribution of funds with actual subject accrual.
- Full and transparent collaboration, including appropriate sharing of all necessary tools, materials, technologies and other essential methodologies necessary for protocol and program development, implementation and monitoring between the ATN CC and each of the ATN U19 Programs is a critical requirement for the success of the Program.

- Critical features and functions of the CC include, but are not limited to:
 - Administrative management and coordination of external collaborations with the network
 - Operational support for cross-network U19 protocols, collaborations and other projects (e.g. conduct of trainings, development of manuals of operation, network public relations, maintenance of network website, communications and conference calls, convening committees and meetings, etc.)
 - Data management and innovative analytic methodology
 - Training on a breadth of research related topics (e.g. regulatory/IND, safety reporting, GCP/GCLP, HSP, etc)
 - Management of resources and execution performance-based subcontracts (e.g. material distributors, specimen storage, pharmaceutical vendors, U19 investigators, other collaborators, etc.)
 - Provision of a regulatory infrastructure for cross-network U19 protocols, collaborations and emerging projects (e.g. site performance monitoring, quality assurance procedures and protocol registration)
 - Provision of mechanisms and metrics to monitor subject screening, recruitment, retention, and dropout, and procedures for adjustment if enrollment targets are not being met
 - Provision of a detailed system for regular tracking and reporting of study progress, including a description of performance metrics, milestones, timelines, and quality-control measures to keep the study on track and on budget and which includes strategies to identify and mitigate problems as they arise
 - Provision of a data sharing policy with explicit plans, procedures, milestones, and timelines to make the data and bio specimens available for access and analysis by the research community as appropriate

18. What is the budget for the management (e.g. overhead) of the U24 Coordinating Center?

Budgets of up to \$250,000 per year in direct costs may be requested.

19. What is the budget for the protocol-related expenses (e.g. reimbursable through performance-based subcontracts to sites) of the U24 Coordinating Center?

Budgets of up to \$2 million per year in direct costs may be requested.

20. What is the maximum project period

5 years

Application Content

21. What are the **required** components of the U19 application?

- Overall component
- Management Core
- Analytic Core
- Research Projects (3-4)

22. What are the **optional** components of the U19 application?

- Scientific Core (s)
- Pilot Project (s) (1-2)

23. What should be included in the application regarding potential sites for youth recruitment?

- A plan to address youth recruitment needed for the proposed studies and estimated/projected number of youth available for recruitment
- Tables demonstrating previous success with recruitment and retention in studies
- Performance measure and monitoring plans of all sites under the proposed Program
- Plans, processes, timelines, milestones, and site performance monitoring

24. Can subject recruitment venues (SRVs) have relationships with more than one U19?

YES; these can also change with evolving needs of projects during the project cycle.

25. Can new SRVs join after the award has been made?

YES; performance and other need-based modifications to subcontracts are allowed, but need consultation with NIH.

26. Must I ensure community relationship-establishment and engagement?

YES; this is a **requirement** in your application and should be done before work is planned and should be an integral part of ongoing network research activities.

27. Does a Community Advisory Board (CAB), alone, fulfill the requirement on community engagement?

NO; a youth CAB must be constituted at the local level and is an additional requirement in your application. Local youth CAB(s) must be engaged at the beginning, before work is planned and should be an integral part of ongoing network research activities.

28. When might it be beneficial to include a Scientific Core(s)?

When a Program Project includes more than 1 research projects that would benefit from a common/unique source of resources and support (e.g., central lab)

29. Does/do the optional a pilot project(s) need to link up to a larger scale trial?

Yes. This FOA will also support formative, test-of-concept/pilot clinical studies (Pilot Projects) in HIV-infected and at-risk youth populations, if they are directly linked to a larger scale efficacy-level intervention for evaluation among these populations and proposed in the same application.

30. Can any research in neurocognitive dysfunction among youth impacted by HIV be proposed under this FOA?

YES; research on this topic that addresses specific barriers to achievement of the main objectives of the FOA (e.g. reducing the curve of new infections or improving achievement of milestones along the HIV CoC in youth) are responsive.

31. How will new or emergent scientific priorities or gaps be addressed?

There will be a kick-off meeting after all awards have been made. The ATN EC (U19 PI/PDs, U24 PI/PDs, NIH collaborators and community membership) will convene to expeditiously review the network agenda and U19 projects, consider what the needs are and devise a plan to address these through emergent priority protocols.

32. Will external projects (e.g. R01s) be considered after the ATN cycle begins?

YES; the ATN EC will develop policies and procedures for such collaborations at the kick-off meeting

33. Is the inclusion of perinatally HIV-infected adolescents allowed?

YES; as long as the work proposed fits within the objectives and scope of the FOA, this is allowable.

34. During the 5-year ATN project cycle, can any of the Research Projects be defunded, changed or not allowed to continue forward?

YES; the ATN EC and NIH are responsible for ongoing monitoring and evaluation of the progress of all research conducted in the Network. Based on performance, the EC can make

recommendations to the NIH to best align resources that maximize and ensure appropriate and expeditious completion of project objectives.

35. What does the \$250,000 in direct costs for the ATN CC (U24) cover?

The ATN CC Scope of Work includes operational support, regulatory infrastructure, data management and innovative analytic methodology, tracking and reporting of study progress, etc., *to support cross network and emerging high-priority study protocols only, **not** the U19 Research Projects that are included in the applications to this FOA.*

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Application Review

36. How will the review of the U19 and U24 applications be conducted?

A special emphasis panel (SEP) with the relevant content expertise will be convened by the NICHD/NIH.

37. What are the foci of review for a Cooperative Program Project (U19)?

- U19 Multi-Program Project as an **integrated Network and collaboration** of Projects and Cores oriented around a central theme, and overall merit of the program
- Individual Research Projects and any optional Pilot Projects
- Each individual Core

38. What are the review criteria for these FOAs?

Standard NIH peer review system criteria plus RFA-specific criteria will be used. There are additional criteria for the U19 on the Program Project as an Integrated Effort.

- Coordination, cohesiveness and synergy among the Research Projects and Cores as they relate to the common theme of the project?
- Clear advantages of conducting this research as a Program Project rather than through separate Research Projects?
- Mechanisms proposed for regular communication, coordination and collaboration among investigators within the Program Project **AND** with potential investigators within the Network?
- Effective administrative structures for the day-to-day management of the Program Project?

39. After NIH peer review and National Advisory Child Health and Human Development Council (NACHHD) review of U19 applications, what will NIH funding decisions consider?

- Scientific and technical merit of the proposed project as determined by scientific peer review
- Availability of funds
- Relevance of the proposed project to program priorities
- Compliance with data and resource sharing policies as appropriate
- NIH discretion with application selection to ensure a synergistic range of topics are addressed (i.e., prevention approaches and specific parts of the continuum of care, diverse populations, and geographic distribution) to form a collaborative Network of multi-program projects

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General FAQs

40. What is a U19?

A U19 is the cooperative agreement form of the P01, a research Program Cooperative Agreement:

- To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach.
- A cooperative agreement research program generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective.
- Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.
- The investigators have primary authorities and responsibilities to define research objectives and approaches, and to plan, conduct, analyze, and publish results, interpretations and conclusions of their studies.
- Each research project is usually under the leadership of an established investigator in an area representing his/her special interest and competencies.
- Each project supported through this mechanism should contribute to or be directly related to the common theme of the total research effort.

- The award can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort.
- These scientifically meritorious projects should demonstrate an essential element of unity and interdependence.

41. What is a P01?

A research program project grant:

- Support for integrated, multi-project research projects involving a number of independent investigators who share knowledge and common resources
- Each project contributes or is directly related to the common theme of the total research effort, thus forming a system of research activities and projects directed toward a well-defined research program goal
- Specific dollar limit unless specified in FOA

42. What is a U24?

A U24 is a cooperative Agreement of an R24 Resource-Related Research Projects-- Cooperative Agreements to support research projects contributing to improvement of the capability of resources to serve biomedical research

43. What is an R24?

A research-related Research Project used in a wide variety of ways to provide resources to research projects or to enhance research infrastructure

44. Will ATN IV participate in protocols supported by other Networks or individual grants?

Yes. ATN has a history of participating in protocols initiated by other networks and funded by individual awards. ATN also has a history of participating with other federal agencies such as CDC and HRSA.

45. Will ATN IV continue to support Protocols developed or initiated during the previous cycle.

This is subject to the deliberations of and prioritization by the EC.

46. Will data generated by the ATN be available to interested researchers outside the network?

Yes

47. Is there a process for obtaining access to these data?

Yes; for an example, see [NICHD DASH](#).

48. How will a network of independent U19s operate efficiently and communicate with each other to achieve desired results in a timely fashion?

- Although each U19 will have its own Research Projects addressing ATN pertinent research and clinical questions, each U19 PI(s) and U24 PI(s) as well as Research project PIs and core PIs will meet on a regular basis to discuss both scientific and logistic matters important to the ATN.
- In addition the Network will be guided by an EC composed of NIH collaborators, community membership, U19 PIs and U24 PIs.
- There will be a startup meeting after the successful applicants are funded.

49. Will sites and their investigators be able to contribute and shape the science of ATN?

YES; all applicants are encouraged to forge close partnerships with candidate sites as they consider participating in each U19. Relationships that meaningfully and substantively contribute (e.g. protocol conceptualization, development, leadership, analysis and data dissemination through publications, etc) to the scientific agenda of ATN are also encouraged.

50. What is expected from the Data and Coordinating Center (CC) (U24)?

- The ATN CC will provide the ATN's infrastructure and organizational support for the Network's cross-U19 collaborative Program Projects and other external collaboration needs.
- This will include but not be limited to: participant accrual, staff and site training, quality assurance procedures including necessary site monitoring, the operation and integrity of the cross-U19 and other collaboration study databases.
- Additionally, as determined by the ATN EC and NIH, the ATN CC will provide funding to the ATN U19s for high priority study protocols and collaborations that emerge as major scientific gaps in the rapidly evolving HIV/AIDS research landscape.