Pre-Application Webinar: Advancing Adolescent Tobacco Cessation Intervention Research - FAQs

Advancing Adolescent Tobacco Cessation Intervention Research RFA-CA-22-042 (R34 Clinical Trial Option) and RFA-CA-22-043 (R01 Clinical Trial Required)

Frequently Asked Questions

SCOPE

Which tobacco products are included in the scope of the R34 and R01 RFAs?
Cessation interventions are needed for the broad range of tobacco products, with particular interest in interventions targeting the products most commonly used by adolescents: ENDS, cigarettes, and cigars/little cigars/cigarillos. Additionally, interventions may focus on concurrent use of multiple tobacco products (e.g., dual and poly tobacco product use) and/or take into account the use of multiple tobacco products.

Is an intervention that tests a smoking cessation medication with behavioral counseling responsive to this RFA?
This RFA is intended to focus on behavioral interventions for tobacco cessation among adolescents. However, pharmacotherapy may be included as an adjunct to the behavioral intervention.

What types of study designs are responsive to the R01 RFA?
Intervention development and testing using a clinical trial design is a requirement of the R01 RFA. Proposed clinical trials should be designed to estimate the effect of an intervention on tobacco cessation outcomes with at least one control or comparison group. Applications that propose purely observational or descriptive research will be considered non-responsive to the R01 RFA.

For proposed interventions designed to prevent escalation, are cessation outcomes expected and/or responsive?
Yes, and as specified in the R01 RFA, a minimum of a 6-month primary cessation endpoint is required for all studies.

Can an application focus on developing interventions to treat adolescents who use cannabis daily and occasionally use tobacco?
The RFA is intended to fund projects that focus on developing and testing tobacco cessation interventions for adolescents, and the primary endpoint of the intervention being developed and tested must be tobacco abstinence. Studies that include cannabis use endpoints (including cessation of cannabis) should describe the relationship of cannabis use to tobacco use, and why addressing cannabis co-use is important for tobacco cessation.

Are applications focused on interventions to treat co-use of tobacco and alcohol responsive to this RFA?
The RFA is intended to fund projects that focus on developing and testing tobacco cessation interventions for adolescents, and the primary endpoint of the intervention being developed and tested must be tobacco abstinence. Studies that include alcohol use endpoints (including

cessation of alcohol use) should describe the relationship of alcohol use to tobacco use, and why addressing alcohol co-use is important for tobacco cessation.

Are vaping cessation randomized controlled trials (RCTs) responsive if they involve digital interventions?
Yes, an RCT designed to test a digital intervention to treat adolescent ENDS use (vaping) would be responsive to the R01 RFA.

If a smartphone app for delivering an adolescent tobacco cessation intervention is already developed but it needs further testing for feasibility and acceptability with the target population, can I apply under the R34 RFA?
Yes, the R34 RFA is intended to accommodate projects that need further refinement and testing for appropriateness for the study population and aspects of feasibility with the study population (e.g., ability to reach, recruit, retain adolescents into the study and engage with the intervention).

I conduct adolescent tobacco cessation intervention research in another country. Would a study entirely conducted in another country be responsive to this RFA?
Foreign institutions and components are eligible to apply to both the R34 and R01 RFAs. However, if the study is conducted in another country, the applicant will need to provide a strong justification for how the cessation intervention and the results of the study will be applicable to U.S. adolescents who use tobacco.

The target age range is noted as 14-20 years. Would an intervention targeted at college students age 18-24 be responsive to this RFA?
To be responsive to this RFA, interventions should be targeted to individuals in the mid- to late adolescent period (approximately 14-20 years old). Applications may address ages that are slightly younger or older than this range, however the mid- to late adolescent period must be included. Applications explicitly focused on intervening only with young adults (age 18-24) would not be considered responsive to this RFA. Applicants who are unsure whether their target population is within scope are strongly encouraged to consult with the Scientific Contacts listed on the RFA.

APPLICATION INFORMATION

Can you talk a bit more about what you are looking for from projects involving community-based participatory research?
Applications may focus on many different types of settings and systems, including community-based organizations that serve adolescents, their families, or their schools. In terms of partnership or collaboration with a stakeholder, the FOA indicates interest in research that will have relevance to the setting or system that is targeted, that is, where the intervention is likely to be adopted. Involving members of the community as part of the research team is a way to integrate this perspective into the work.

Are there any specific measurement-related requirements for R01 applications?
All studies must include a comprehensive assessment of tobacco product use including, but not limited to, the product(s) being targeted for cessation. At minimum, tobacco product

use should be assessed at baseline and at the primary study endpoint. A 6-month cessation primary endpoint is also required. Biological verification of tobacco abstinence is strongly encouraged.

Does my R01 application need to have a primary cessation endpoint, even if the focus of the intervention is on disrupting escalation?
Yes, all R01 applications must be designed to estimate the effect of an intervention on tobacco cessation outcomes, with at least a 6-month cessation primary endpoint. Applications that do not target cessation explicitly (e.g., applications that target reduced tobacco product use) will be considered non-responsive to the FOA.

Can you provide more information on the NIDA NACDA guidance on Tobacco Industry Funding of Applicants?
As specified in the RFAs, NIDA's NACDA guidance are points to consider with regard to existing or prospective sponsored research agreements with tobacco companies or their related entities and can be found here: https://nida.nih.gov/about-nida/advisory-boards-groups/national-advisory-council-drug-abuse-nacda/points-to-consider-regarding-tobacco-industry-funding-nida-applicants.

Do I need to choose NCI or NIDA when I submit my application?
Applications submitted in response to this RFA are not required to choose an IC when the application is submitted. Applicants may indicate their preferred Institute, but the final decision as to Institute assignment will be made by NIH.

Can a new application to the October 2023 receipt date that is not funded be sent later as a resubmission?
No. Once the RFA has expired, the application cannot be sent as a resubmission. Rather, it will need to be submitted as a new application to a different funding opportunity announcement (FOA). For clarity, these RFAs have two receipt dates – January 2023 and October 2023. Applicants who submit in January 2023 will be allowed to resubmit for the October 2023 receipt date. In the resubmission, applicants can specifically address reviewer comments from the first submission. After the October 2023 receipt date, resubmissions are not allowed. Instead, applicants will need to submit the proposal as a new application to a different applicable funding opportunity announcement. Please feel free to reach out with any resubmission questions after the last submission and review cycle for these RFAs.

REVIEW & SCORING

Will applications to this RFA be reviewed by standing study sections?
No. Applications will be evaluated for scientific and technical merit by a special emphasis panel convened by the NCI Division of Extramural Activities.

Can you provide more information on the likely expertise of the reviewers on the SEP?
The review will be conducted by NCI's Division of Extramural Activities. Reviewer expertise will likely include adolescent development, adolescent tobacco use, tobacco cessation, nicotine addiction and treatment, polytobacco product or poly-use with other substances, cancer prevention and control, behavioral and social sciences.

Will standard NCI paylines be applied to these awards?
Applications will receive an overall impact score but not a percentile. Standard NCI paylines will not apply.

BUDGET & TIMELINE

How many grants do the NCI and NIDA intend to fund?
Together, NCI and NIDA intend to fund at total of 10 awards across two receipt dates, across FY23 and FY24, and across both the R34 and R01 mechanisms.

What is the maximum duration and total direct costs allowed for R01 awards?
The maximum project period is 5 years. As noted in the RFA, direct costs in any single year should reflect the actual needs of the proposed project. However, total direct costs are limited to $3,150,000 over a 5-year project period. This budget maximum is calculated based on $630,000 direct costs per year, for a five-year grant. However, applications may deviate from that amount per year according to the needs of the project so long as the total direct cost is not more than $3,150,000 for the entire project period. Total costs are not specified as individual institutions' indirect costs vary.

What is the maximum duration and total direct costs allowed for R34 awards?
Applicants may request direct costs of up to $450,000 over a three-year project period. Although variation from year to year is permissible, in no case may any year be more than $225,000 in direct costs, and total direct costs for the entire project period may not exceed $450,000.