

INTERVENTIONS TO PREVENT
ELECTRONIC NICOTINE DELIVERY
SYSTEMS (ENDS) USE AMONG
ADOLESCENTS (R01 - CLINICAL TRIAL
OPTIONAL) – RFA-DA-21-009

Pre-Application Webinar

August 17, 2020

1:00 – 2:00 pm



**National Institute
on Drug Abuse**
The Science of Drug Abuse & Addiction

Participating Agencies

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

NATIONAL CANCER INSTITUTE (NCI)

DIVISION OF PROGRAM COORDINATION, PLANNING AND
STRATEGIC INITIATIVES, OFFICE OF DISEASE PREVENTION (ODP)

OFFICE OF BEHAVIORAL AND SOCIAL SCIENCES RESEARCH
(OBSSR)



Funding Opportunity Purpose

This funding opportunity seeks to support

1. Research to test the efficacy or effectiveness of interventions to prevent initiation and/or escalation of electronic nicotine delivery systems (ENDS) use among adolescents;
2. Research on the impact of tobacco control policies, including ENDS-specific policies, on adolescent ENDS use behavior.

Particularly, for prevention intervention research (e.g., school, community, and clinic-based), collaboration with stakeholders and likely program adopters is required to ensure feasibility for implementation, scalability, dissemination and sustainability.

For this FOA, individuals as young as 12 and as old as 18 encompass the core target age range. Justification for the specific age or age range of the target population is required, including studies that propose targeting youth outside the core age range.



NIDA interest areas include but not limited to:

- Research on interventions to prevent initiation and escalation of ENDS use among adolescents, for example:
 - Studies testing the efficacy/effectiveness of novel social network strategies that leverage peer leaders or other social influencers;
 - Interventions to prevent the escalation of ENDS use among adolescents already experimenting with e-cigarettes or other ENDS devices
 - Studies that leverage digital technology (e.g., smart phone technologies, mobile apps) and social media for prevention of adolescent ENDS use
- Research on the impact of tobacco control and ENDS-specific policies on adolescent ENDS use outcomes – for example:
 - Studies examining the impact of tobacco control and ENDS-specific policies (e.g., federal, state, local) on ENDS use behaviors (e.g., initiation and escalation of use)
- Studies may focus on prevention of ENDS containing nicotine, THC, flavorings or other substances, independently, or their co-use



NCI interest areas include but not limited to:

- Studies that develop and test prevention interventions that address determinants of risk and protective factors (e.g., perceptions of risk/benefit, parent/peer influences, media and advertising influences)
- Intervention research to prevent initiation and escalation of ENDS use among youth, either ENDS use alone, or in the context of dual/poly-tobacco product use (concomitant use of ENDS and other tobacco products), especially escalation to smoked tobacco products
- Studies investigating effective approaches for employing digital health technologies and social media to prevent youth ENDS use
- Studies to understand the impact of ENDS-specific policies on prevention of initiation and escalation of youth ENDS use (e.g., smoke-free or ENDS-free policies, point-of-sale or other retail policies, ENDS product pricing policies) and interactive effects with other tobacco control policies
- Studies investigating health care providers' advice and practice aimed at youth ENDS prevention



OBSSR and ODP Interests:

- OBSSR/ODP are supporting the goals of NIDA and NCI
 - Applicants should not try to tailor their aims to OBSSR or ODP, but rather, should focus on the goals as stated in the RFA.
 - Applicants are encouraged to seek guidance from NIDA and NCI scientific contacts regarding responsiveness of proposed specific aims.
- OBSSR/ODP will play a co-funding role post review; they will not be involved in the pre-submission process.
 - OBSSR/ODP intends to supplement the RFA set-aside money to help NIDA and NCI support as many meritorious grants as possible at the time of pay.
 - Decisions about OBSSR/ODP co-funding will be made by NIH staff post-review and may not be requested by applicants in advance.



Review FOA for Specific Details and Instructions

- Section I – FOA Description
- Section II – Award Information
- Section III – Eligibility Information
- Section IV – Application and Submission
- Section V – Application Review Information
- Section VI – Award Administration Information
- Section VII – Agency Contacts
- Section VIII – Other Information



Key Dates

Letter of Intent Due Date: September 19, 2020

Application Due Date: October 19, 2020 (this is a Monday)

AIDS Application Due Date: Not applicable to this FOA

Scientific Merit Review: March 2021

Advisory Council Review: May 2021

Earliest Start Date: July 2021



Award and Eligibility Information

- Award Information:
 - The FOA will support New Applications
 - The FOA is Clinical Trial Optional – accepting applications that either propose or do not propose clinical trials (as specified in the FOA)
 - Funds Available and Anticipated Number of Awards:
 - NIDA intends to commit \$1,000,000 to fund 1-3 awards
 - NCI intends to commit \$1,000,000 to fund 1-3 awards
 - Application budgets are limited to \$500,000 direct costs per year.
 - The maximum project period is 5 years
- Eligibility:
 - Refer to the FOA for specific information on eligible applicants, eligible individuals, required registrations, and other eligibility information



Review Information

- Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system
- Applications will be assigned to a Special Emphasis Panel organized by NIDA
- The Review meeting will be held in March 2021
- Review criteria described in Section V of the FOA will be considered in the review process (starred criteria contain additions specific to the FOA)
 - Significance*
 - Investigators
 - Innovation
 - Approach*
 - Environment
 - Additional Review Criteria: Study Timeline and Milestones



Non Responsive Applications

- Applications that do not propose (1) research to test the efficacy or effectiveness of interventions to prevent initiation and/or escalation of ENDS use among adolescents; and/or (2) research on the impact of tobacco control and ENDS-specific policies on adolescent ENDS use outcomes will be considered non-responsive and will not be reviewed.
- Applications that do not include a study timeline with milestones will be considered non-responsive and will be withdrawn without review.



Questions

Some initial questions we received and answers:

- Q – Do we need to submit a letter of intent?
A letter of intent is requested 30 days in advance of the application due date but it is not required, is not binding, and does not enter into the review of a subsequent application. The information it contains allows IC staff to estimate the potential review workload and plan the review.
- Q – Is the focus of the RFA on the development or evaluation of a prevention program, or both?
A-For intervention research, the RFA is interested in studies to test the efficacy or effectiveness of the intervention. This could include testing the efficacy of a novel intervention.
- Q—Is there more interest in school-based interventions?
A—The RFA is not specific to school-based research.



Key Contacts

- Program Officials
 - Belinda Sims, NIDA – bsims@nida.nih.gov
 - Rachel Grana Mayne, NCI – Rachel.Mayne@nih.gov
- Review
 - Dharmendar Rathore, NIDA - dharmendar.rathore@nih.gov
- Grants Management
 - Garlin Hallas, NIDA – garlin.hallas@nih.gov
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