Funding Opportunity Announcement

Improving Smoking Cessation Interventions among People Living with HIV

RFA-CA-20-035 (R01 Clinical Trial Optional)

RFA-CA-20-036 (R21 Clinical Trial Optional)

Webinar Questions & Answers

Q. I have questions about funding opportunity announcements (FOAs) RFA-CA-20-035 (R01) and RFA-CA-20-036 (R21). Who can I contact for more information?

A. For questions of a scientific nature, contact Dr. Annette Kaufman at the National Cancer Institute (kaufmana@mail.nih.gov), Dr. Redonna Chandler at the National Institute of Drug Abuse (redonna.chandler@nih.gov), or Dr. Rick Berzon at the National Institute on Minority Health and Health Disparities (rick.berzon@nih.gov; R01 mechanism only). All program directors can answer your questions and help you determine if your application will be responsive to the chosen RFA.

For questions about peer review, contact ncirefof@dea.nci.nih.gov. For questions about financial or grants management, contact Carol Perry at the National Cancer Institute (perryc@mail.nih.gov), Pamela Fleming at the National Institute of Drug Abuse (pfleming@nida.nih.gov), or Priscilla Grant at the National Institute on Minority Health and Health Disparities (pd38h@nih.gov).

Q. Are these applications being reviewed by a special emphasis panel?

A. All applications (R01 and R21) submitted in response to these Requests for Applications (RFAs) will be reviewed by a special emphasis panel convened by scientific review officer(s) working in the NCI Division of Extramural Activities. Reviewers will be chosen based on their expertise and other relevant qualifications, especially as related to research on human subjects in the context of HIV infection and tobacco use.

Q. Are foreign institutions or partners eligible to apply?

A. No. As stated in the RFAs, non-domestic (non-U.S.) entities (foreign institutions) and non-domestic (non-U.S.) components of U.S. organizations are not eligible to apply. Foreign components are also not permitted in applications and awards. Consult the scientific program contacts if you have further questions.

Q. Why is there only one application due date?

A. RFAs typically have only one application receipt (due) date. The funds associated with these RFAs have been approved and designated for FY 2021.

Q. Is there a limit on available funds or a set number of grants that can be funded under this opportunity?

A. For the R01 mechanism (RFA-CA-20-035), NIH intends to commit an estimated total of $2,000,000 in FY2019 to fund up to three awards. For the R21 mechanism (RFA-CA-20-036), NIH intends to commit an estimated total of $1,000,000 in FY2019 to fund up to three awards. There may be some shifts in where the money is allocated depending on the quantity of R01 and R21 applications and their performance in review. The funding reflects the total estimated funds (direct and indirect costs) the institutes are committing to projects funded through these RFAs.

Q. Can one organization or institution submit more than one application?

A. Yes. An organization or institution is welcome to submit more than one application if the research questions are distinct from one another. NIH will not accept duplicate or highly overlapping applications for consideration at the same time. Further information can be found in the RFAs under Section III, #3, Additional Information on Eligibility.

Q. Are new applicants who have not had prior NIH funding eligible to apply?

A. Yes. Applications from new and early-stage investigators are welcomed. One of the aims of this funding announcement is to encourage the development of new transdisciplinary teams that bring together expertise in HIV and tobacco. Investigators who are new to the NIH application process should, for mentoring and guidance purposes, consider working with a team of people who have experience with the NIH grants process. They are also encouraged to speak with the scientific program contacts at NIH for guidance.

Q. Does NCI give applications from early-stage investigators special consideration?

A. Yes. In accordance with NIH policy, early-stage investigators who submit applications in response to this RFA will have funding priority. For more information, go to https://grants.nih.gov/policy/early-investigators/index.htm.

Q. What type of exploratory work are you looking for in R21 applications/awards?

A. In contrast to the R01 mechanism, the R21 mechanism is for research exploration and development, and applicants are not expected to have and/or present pilot data. All applicants should consider carefully how their research would advance the science; refer to the RFA for further guidance.

Q. What is meant by evidence-based tobacco cessation intervention?

A. Evidence-based tobacco cessation interventions include both behavioral intervention (e.g., group or individual counseling) and Food and Drug Administration (FDA)-approved

pharmacotherapies. Please refer to the Public Health Service-sponsored 2008 U.S. Public Health Service Guideline for Treating Tobacco Use and Dependence. If you are unsure, please reach out to a scientific program contact before submission. Submitted applications that propose non-evidence-based tobacco cessation interventions will not be considered.

Q. Are telephone and mobile health (mHealth) platform interventions for tobacco cessation acceptable for this FOA?

A. Yes. We consider these types of interventions as responsive to the FOAs because an emerging evidence base supports the use of mobile health platforms, including telephones, apps, and text messaging services, for smoking cessation. Please contact the scientific program contacts for additional information or to discuss your specific aims.

Q. Would the use of an investigational new drug that is not yet approved for smoking cessation qualify as an intervention responsive to this FOA?

A. No. The focus of this RFA is to test existing evidence-based tobacco cessation interventions among people living with HIV (PLWH). If you would need to obtain approval for an investigational new drug (IND) from the FDA, the intervention would not be considered responsive.

Q. Can I use electronic cigarettes, very low nicotine cigarettes, and/or another tobacco product as part of the intervention?

A. No. Applications that propose to use these products would not be responsive to the RFAs because these are not evidence-based tobacco cessation interventions. For example, the Standardized Research E-Cigarette (SREC) does not currently satisfy FDA Center for Drug Evaluation and Research (CDER) requirements for nicotine cessation studies. To learn more, go to:
https://www.drugabuse.gov/funding/supplemental-information-nida-e-cig;
https://www.drugabuse.gov/sites/default/files/generalsrecwebinar508.pdf.

Q. How should these applications relate to NIH HIV/AIDS Research Priorities?

A. Applications should reflect elements of the highest NIH priorities. Study aims, hypotheses, frameworks, and data collection/analyses should integrate HIV and consequences of smoking with smoking cessation. Assessment of HIV/AIDS immune status (e.g., CD4 cell count) is a requirement of these RFAs. Applications may also consider smoking-related health consequences, and collect data reflecting comorbidities (e.g., cardiovascular disorders, pulmonary disorders, malignancies associated with smoking and/or HIV infection). For more information, see NIH Guide Notice NOT-OD-20-018. The FY2021-2025 NIH Strategic Plan for HIV and HIV-Related Research is also very helpful.

Q. What are primary research topics and questions of interest to NIMHD?

A. NIMHD is especially interested in smoking cessation interventions that are most effective among subgroups of PLWH with disproportionately high smoking rates. These populations include African-American men, American Indians/Alaska Natives, rural residents, sexual and gender minorities, people with mental illness and/or other substance use disorders, people of low socioeconomic status (SES), and people who are medically underserved or uninsured. For example, considering the diversity among PLWH, in terms of culture, country of origin, English language proficiency, socioeconomic status, race/ethnicity, and more, how can existing evidence-based smoking cessation interventions be adapted to best reach and be effective in specific groups?

Q. What are primary research topics and questions of interest to NIDA?

A. NIDA is interested in research that examines how best to facilitate linkage of care for managing HIV and tobacco cessation, including the cessation of electronic cigarettes. Applicants are encouraged to identify interventions that create sustainable solutions to address retention and re-engagement in care. These approaches may include, but are not limited to: adapting and implementing evidence-based cessation treatments in diverse HIV settings, addressing barriers that hinder access to integrated treatment interventions, and uncovering policy interventions that would serve to improve the outcomes of cessation or prevention efforts at both a clinical and population level.

R. What should I do if I have an R01 application that might be of interest to more than one participating NIH institute?

B. The RFAs are co-sponsored by NCI, NIDA, and NIMHD; however, for review purposes, all applications will be assigned to NCI. You can request NIMHD or NIDA as a secondary assignment in your cover letter when you submit your application. NCI should be your primary contact for post-review questions.

Q. Will a list of the members of the Special Emphasis Panel (SEP) be made available?

A. Reviewers are selected after applications are received and are chosen to ensure they are not in conflict with the applications that they review. The date(s) on which the relevant SEP will meet to discuss the applications will be indicated in the applicants' eRA account folders for their applications. The roster for the SEP should become available for applicants to see at https://public.era.nih.gov/pubroster/rosterIndex.era about 30 days before the scheduled review meeting.

Q. Is an intervention with strong pilot data (but no large-scale trial) considered "evidence-based?"

A. Evidence-based means that there is an accumulation of published research that supports the effectiveness of the intervention. Please contact Dr. Annette Kaufman (NCI) via email for guidance.

Q. Given the exploratory and developmental nature of the R21 mechanism, could you discuss the requirements of empirically-supported interventions and need for a control group in that context?

A. A control group is required to determine whether a modification or enhancement to an evidence-based tobacco cessation intervention is working beyond a standard of care. For both R01 and R21 applications, we expect there would be a control group or comparison group for the intervention being tested.

Q. Can you define cessation abstinence? Does it mean abstinence from cigarettes, all tobacco products, all combustible tobacco products? Does it require abstinence from e-cigarettes?

A. This RFA is focused on cigarette smoking cessation, and the cessation endpoints should include both quit attempts and sustained abstinence from cigarette smoking. However, you should plan to assess the use of other tobacco products (including e-cigarettes). Biological verifications of abstinence, which would detect other tobacco product use, are encouraged, but not required.

Q. Would a project comparing evidence-based implementation strategies to increase uptake of smoking cessation treatment among PLWH be considered responsive?

A. Yes, as long as the project includes an intervention with a control group. Applicants are encouraged to contact Dr. Annette Kaufman (NCI), Dr. Rick Berzon (NIMHD), and/or Dr. Redonna Chandler (NIDA) to discuss their projects during the preparation phase of the application process.

Q. Could a project compare two different pharmacotherapies?

A. Yes, a project could compare two different FDA-approved pharmacotherapies in PLWH. Little research has been done to examine the possible interactions between tobacco cessation pharmacotherapies and antiretroviral therapy (ART) (e.g., how these medications may be tolerated by PLWH). However, NCI does not intend to support the development of new pharmacotherapies for use in PLWH through this RFA.

Q. Will a pilot trial conducted in an R21 be considered a "clinical trial" for administrative purposes?

A. NIH has revised the definition of a clinical trial. We anticipate that all applications submitted to this RFA should be designated as clinical trials.

Q. Will funded grantees be asked to attend grantee meetings?

A. Yes. NIH will convene annual grantee meetings to enable R01 and R21 grantees to discuss their research, develop common measures, etc. The RFAs include language on budgeting for attendance at an annual grantee meeting.

Q. What can an applicant do if he or she is unsuccessful in applying (e.g., by not applying on time, by submitting an incomplete application, by not having his/her successfully submitted application selected for award, or for any other reason)?

A. Applicants can apply to the NIH Parent R01 program announcements: https://grants.nih.gov/grants/guide/pa-files/PA-20-183.html (Parent R01 Clinical Trial Required) or https://grants.nih.gov/grants/guide/pa-files/PA-20-185.html (Parent R01 Clinical Trial Not Allowed). For R21s, please consult a scientific program contact.