Webinar on Request for Applications (RFA) Improving Smoking Cessation Interventions Among People Living with HIV

RFA-CA-18-027 and RFA-CA-18-028
Using WebEx and webinar logistics

- All lines will be in listen-only mode
- Make sure icons are selected for them to appear as a drop down option
- Submit questions at any time during the presentation by typing into the Q&A feature on the right hand side of the WebEx interface.
  - Select Host and a moderator will ask the questions on your behalf
- Closed captioning available by selecting the Media Viewer Panel
- This webinar is being recorded
Webinar Overview

Improving Smoking Cessation Interventions among People Living with HIV

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Speaker and Technical Expert

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  National Cancer Institute

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  National Institute on Minority Health and Health Disparities
Agenda

- Grant information
- Request for Applications (RFA)
  - Goal and purpose
  - Background
  - Details
- Questions
  - Questions about specific aims or grant application details will not be addressed.
Request for Applications (RFA)

- Identifies
  - specific receipt date(s)
  - estimated amount of funds earmarked for the initiative
  - number of awards likely to be funded
  - any specific criteria for scientific peer review

- Applications received in response to a particular RFA are reviewed by an Institute’s Scientific Review Group
## Grant mechanisms – R01 and R21

<table>
<thead>
<tr>
<th>NIH Research Project Grant (R01)</th>
<th>NIH Exploratory/Developmental Grant (R21)</th>
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<tbody>
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<td>Used to support a discrete, specified, and circumscribed research project</td>
<td>Encourages new, exploratory, and developmental research projects by providing support for early stages of project development</td>
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<td>NIH's most commonly used grant program</td>
<td>Sometimes used for pilot and feasibility studies</td>
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<td>No specific dollar limit unless specified in Funding Opportunity Announcement (FOA)</td>
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<td>Advance permission required for $500K or more (direct costs) in any year</td>
<td>Combined budget for direct costs for the two-year project period usually may not exceed $275,000</td>
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- **NIH Research Project Grant (R01)**
  - Used to support a discrete, specified, and circumscribed research project.
  - NIH's most commonly used grant program.
  - No specific dollar limit unless specified in Funding Opportunity Announcement (FOA).
  - Advance permission required for $500K or more (direct costs) in any year.
  - Generally awarded for 3-5 years.

- **NIH Exploratory/Developmental Grant (R21)**
  - Encourages new, exploratory, and developmental research projects by providing support for early stages of project development.
  - Sometimes used for pilot and feasibility studies.
  - Limited to up to two years of funding.
  - Combined budget for direct costs for the two-year project period usually may not exceed $275,000.
  - No preliminary studies are required.
Request for Applications

Improving Smoking Cessation Interventions among People Living with HIV

Annette Kaufman, Ph.D., M.P.H.
Program Director
Tobacco Control Research Branch
National Cancer Institute
Award details

- **RFA-CA-18-027** (R01)
  - $2,000,000 in FY 2019 to fund up to 3 awards (NCI, NIMHD)

- **RFA-CA-18-028** (R21)
  - $1,000,000 in FY 2019 to fund up to 3 awards (NCI)
Goal and purpose

- **Goal**: Support studies to improve smoking cessation treatment among people living with HIV (PLWH) in the U.S.

- **Purpose**: Support R01 and R21 grants that systematically test existing evidence-based smoking cessation interventions (e.g., combination of behavioral and pharmacological) and/or to develop and test adaptations of existing evidence-based smoking cessation interventions among PLWH.
Background

Improving Smoking Cessation Interventions among People Living with HIV
Cancer among PLWH

- Antiretroviral therapy (ART) has led to a decline in AIDS-related mortality and increased life expectancy

- Non-AIDS-defining cancers are the leading non-AIDS cause of death

- Lung cancer is the leading cause of cancer death
  - Diagnosed a decade or more earlier
  - 94% of diagnoses could be prevented by eliminating cigarette smoking

Altekruse, et al., 2017; Mani et al., 2012; Nakagawa, et al., 2013; Shiels, et al., 2011; Shiels et al., 2017; Smith et al., 2014; Yanik, et al., 2016
Tobacco use among PLWH

- Over 1.1 million people in the U.S. are living with HIV (2015)
  - An estimated 40% smoke cigarettes

- PLWH who use tobacco suffer greater morbidity and mortality
  - Life expectancy is reduced by at least 16 years

- Diversity of the population

Jamal, et al., 2016; Mdodo, et al., 2015; Petoumenos & Law, 2016
Tobacco cessation challenges for PLWH

**Patient**
- Lower cessation rates
- HIV-related barriers to cessation

**Provider**
- Tobacco use is inadequately addressed
- Tobacco use treatment is not a priority

**System/Contextual**
- Cessation treatment is not standard of care
Literature review

- Few studies have assessed the efficacy of tobacco cessation treatments
- Lack rigorous methods
RFA Details

Improving Smoking Cessation Interventions among People Living with HIV
All projects must include:

- Consistent with the highest HIV/AIDS research priorities as identified by NIH (see NOT-OD-15-137)
- At least one control or comparison group
- Detailed assessment of cigarette smoking and cigarette smoking history among study participants, including other tobacco products
- Cessation endpoints/characteristics
- Markers of HIV/AIDS immune status (e.g., CD4 cell count) and, if feasible, examination of HIV/AIDS related co-infections and/or co-morbidities
- Design for dissemination
Responsive = Evidence-based

- Treating Tobacco Use and Dependence: 2008 Update
- FDA approved pharmacotherapies
- Behavioral interventions
  - Group counseling
  - Individual counseling
  - Telephone counseling
  - Mobile health platforms
Non-responsive = Non-evidence-based

- Other products
  - Products that would require a submission of an IND (investigational new drug) application (e.g., e-cigarettes, Cytisine)

- Other therapies
  - Complementary and alternative therapies (e.g., hypnotherapy, acupuncture, yoga)
Non-responsive projects (continued)

- Applications or research projects focused on biological mechanisms or disease processes
- Studies that do not test an intervention that is intended to reduce cigarette smoking among PLWH
- Observational studies
- Studies that lack a control or comparison group
- Studies that employ non-evidence-based tobacco cessation interventions
- Studies that do not provide a detailed assessment of cigarette smoking and cigarette smoking history
Important information

- Applications will be evaluated by reviewers with relevant expertise in tobacco control and HIV
- R01’s maximum project period is 5 years, which require preliminary studies
- R21’s are 2-year grants, which are considered exploratory and do not require preliminary studies
- Non-domestic (non-U.S.) Entities (Foreign Institutions) are not eligible to apply
Important dates

- Open date (earliest submission date): December 8, 2018
- Letter of intent: 30 days prior to the application due date
- Application due date: January 8, 2019
- Earliest start date: September 2019

- Start the process early! Allow time for registration in the system for Award Management, eRA Commons, and Grants.gov
Questions?

Type into the Q&A panel on the right hand side of the interface and press “send”

Questions about specific aims or grant application details will **not** be addressed.

Michele Bloch, M.D., Ph.D.
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Today’s webinar and list of Q&As (both leading up to and following the webinar) will be posted online: cancercontrol.cancer.gov/brpwebinars