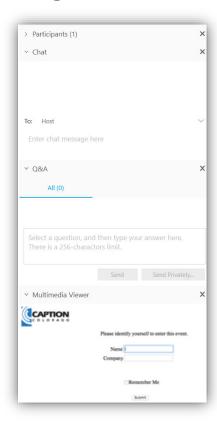
# Webinar on Request for Applications (RFA) Improving Smoking Cessation Interventions Among People Living with HIV

RFA-CA-18-027 and RFA-CA-18-028



#### Using WebEx and webinar logistics



- All lines will be in listen-only mode
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Michele Bloch, M.D., Ph.D. Chief Tobacco Control Research Branch National Cancer Institute

### Webinar Overview

Improving Smoking Cessation Interventions among People Living with HIV



# Speaker and Technical Expert

Annette Kaufman, Ph.D., M.P.H.
 National Cancer Institute

 Rick Berzon, Dr.P.H, P.A.
 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 <u>not</u> 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

# NIH Research Project Grant (R01)

# NIH Exploratory/Developmental Grant (R21)

- 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

- 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



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

## Request for Applications

Improving Smoking Cessation Interventions among People Living with HIV

#### 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



#### 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

## 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

Nicotine & Tobacco Research, 2016, 2177–2184 doi:10.1093/ntr/ntw126 Review Advance Access publication May 31, 2016





Review

Smoking Cessation for People Living With HIV/ AIDS: A Literature Review and Synthesis

David M. Ledgerwood PhD, Russell Yskes MD

Department of Psychiatry and Behavioral Neurosciences, Wayne State University School of Medicine, Detroit, MI

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

## **RFA Details**

Improving Smoking Cessation Interventions among People Living with HIV

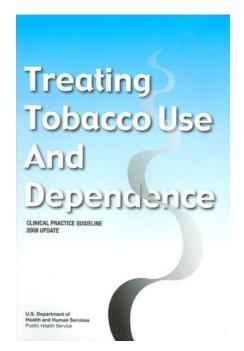
#### All projects must include:

- 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



Michele Bloch, M.D., Ph.D. Chief Tobacco Control Research Branch National Cancer Institute

# 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 <u>not</u> be addressed.



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Today's webinar and list of Q&As (both leading up to and following the webinar) will be posted online: <a href="mailto:cancer.gov/brpwebinars">cancer.gov/brpwebinars</a>



www.cancer.gov/espanol