Questions and Answers for Administrative Supplements for Tobacco Regulatory Research on the Role and Impact of Flavors in Cigarettes, Cigars, E-Cigarettes and Smokeless Tobacco

PA-14-320

September 18, 2014

ELIGIBLE APPLICANT ORGANIZATIONS

1. Are applicant organizations holding National Institutes of Health (NIH) parent grants that are not supported through the Center for Tobacco Products, Food and Drug Administration (CTP FDA), eligible to apply?

    A. Yes, any NIH investigator with an active R01, P01, P50, U01, U19, or U54 grant/cooperative agreement issued by one of the participating Institutes listed in this funding opportunity announcement (FOA) may apply for an administrative supplement provided the following conditions are met:

    - The topic of the administrative supplement must be related to the research priorities that are identified in the FOA, conducted under the original NIH award ("parent" award), and related to tobacco products;
    - Efforts proposed and funds requested in the administrative supplement application must expand on the original study design and be relevant to FDA regulation of tobacco products;
    - The parent award must remain active during the entire funding period of this supplement; and
    - The principal investigator (PI) for the supplement must be the PI of the parent award.

2. Are NIH parent grants held by foreign institutions eligible to apply?
    A. Yes, foreign institutions are eligible to apply, including "Non-domestic (non-U.S.) Entities (Foreign Institutions), Non-domestic (non-U.S.) components of U.S Organizations, and Foreign Components, as defined by the NIH Grants Policy Statement." NIH grants policy does not prohibit a foreign for-profit institution from applying for this funding opportunity announcement provided that the conditions listed in the FOA (see #1 above) are met. However, foreign applicants must demonstrate that the proposed research is not possible to pursue with domestic research, and that it can directly contribute to the U.S. FDA's regulatory authority over the manufacture, marketing and distribution of tobacco products.

3. Are tobacco companies eligible to apply to this funding opportunity?
    A. Yes. As stated in the funding opportunity announcement, for-profit organizations are eligible to apply, provided that the conditions listed in the FOA (see #1 above) are met.

ADDITIONAL INFORMATION ON ELIGIBILITY

4. Can applicant organizations submit more than one application?
    A. Yes. Applicant organizations may submit more than one application, provided that each is sufficiently distinct from any other administrative supplement currently under consideration by the awarding NIH Institute. (added 8/20/14)

5. May investigators submit more than one supplement application per parent grant award?
    A. The rules for multiple administrative supplements may differ across Institutes. However, it is not advisable to submit more than one request for a given parent award because you would be competing against yourself. A better strategy might be to tie research questions together into a single cohesive supplement application. (added 8/20/14)

6. May investigators on sub-projects of eligible grants, such as P50s and U54s, submit a supplement application?
    A. No, the administrative supplement application must be submitted through the parent grant's institution and PI. Investigators on sub-projects should work with the PI of the parent grant to submit an appropriate application. As stated in the funding announcement, "The Program Director/Principal Investigator (PD/PI) for the supplement must be the PD/PI of the parent award… For supplements to parent awards that include multiple PDs/PIs, the supplement may be requested by any or all of the PDs/PIs (in accordance with the existing leadership plan) and submitted by the awardee institution of the parent award. Do not use this administrative supplement application to add, delete, or change the PDs/PIs listed on the parent award. Visit the Multiple Program Director/Principal Investigator Policy in the SF424 (R&R) Application Guide for more information." (Added 8/25/14)

APPLICATION SUBMISSION

7. Should applications be submitted electronically or through paper?
    A. Paper submission or electronic submission of an application depends on the policy of the IC and the grant mechanism of the parent award (R01, P50, etc.). To confirm the appropriate method of submission, potential applicants should consult with the grants management specialist assigned to the parent award (found on the notice of grant award for the parent award) or the financial/grants management contacts listed on the funding announcement. If possible, applicants are encouraged to submit applications electronically. (added 9/12/2014)

8. Who should paper applications be sent to?
    A. If possible, applicants are encouraged to submit applications electronically. However, in those cases where a paper- based application is to be submitted, paper-based applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. The grantee institution, on behalf of the PD/PI of the parent award, must submit the request for supplemental funds directly to the awarding component that supports the parent award. Submit a signed, typewritten original of the application, including the checklist, to:

Tobacco Regulatory Science Program
6100 Executive Blvd, Room 3B01
Rockville, MD 20892 (use Rockville, MD 20852 for Express Mail)
Telephone: 301-451-7464
Email: TRSP@mail.nih.gov

On the face page of the application form, note that your application is in response to a specific program announcement, and enter the title and number of this announcement. (added 9/18/2014)

PAGE LIMITATIONS

9. Is there a page limit on applications?
    A. Yes. All page limitations described in the Application Guide and the Table of Page Limits must be followed, with the following exceptions or additional requirements:
        - Research Strategy not to exceed 6 pages for P01, P50, U19, U54, R01, U01
        - Biographical Sketches not to exceed 2 pages for P01, P50, U19, U54, R01, U01.

RESEARCH OBJECTIVES AND SCOPE

10. How do I know if my application is responsive to this funding opportunity announcement (FOA)?
    A. This is a critical question, as *each* of the specific aims in the application must meet the following criteria to be considered responsive:
        i. address one or more of the three interest areas listed in the FOA,
        ii. be within the scope to the parent grant's specific aims, ***and***
        iii. fall within the scope of the FDA's regulatory authority.

    As such, applicants are strongly encouraged to contact the Scientific/Research Contacts listed in the PA for feedback about responsiveness prior to submitting an application. Upon receipt, applications will be **evaluated for responsiveness** by FDA CTP and components of participating organizations, NIH. **Only complete *and* responsive applications will be reviewed.** (added 9/5/2014)

11. What are the research interest areas for this funding opportunity announcement (FOA)?
    A. Although FDA/CTP has identified research priorities for new scientific evidence that can inform their regulatory actions, this FOA is focused on the following 3 FDA CTP topics related to **flavors and flavorings in cigarettes, cigars (including little cigars and cigarillos), e-cigarettes, and smokeless tobacco**.

    Only applications proposing research projects relevant to one or more of these 3 topics may be considered for funding:
        - Characteristics (e.g., smell, taste, color on the packaging, name on the packaging) that influence people's perceptions that a tobacco product contains a characterizing flavor, regardless of whether a tobacco product is labeled as flavored
        - Characteristics (e.g., ingredients, additives) that impact sweetness in tobacco products
        - Impact of flavor and sweetness on use behaviors such as, (a) experimentation, initiation, and progression to regular use among youth and young adults; (b)

transition from smokeless tobacco products to combustible tobacco products, including dual use; (c) use of tobacco products by former smokers; or (d) perception and attractiveness among users and nonusers.(added 9/5/2014)

12. Are the three research topics listed in the funding opportunity announcement (FOA) the only research on flavors that is responsive to this funding opportunity announcement?

    A. Yes, applications submitted in response to this PA must address at least one of the three topics identified in the FOA. However, the NIH and the FDA acknowledge and understand that the research needs regarding flavors in tobacco products are broader than what is specified in the funding announcement. As such, investigators with research questions regarding flavors that are not addressed by this FOA are encouraged to apply to other NIH FOAs and through NIH parent announcements (e.g., PA-13-302, PA-13-303, PA-13-304).

13. Is research on flavors in water pipes (hookah) responsive to this funding opportunity announcement?

    A. No. This funding opportunity focuses on the role and impact of flavors in cigarettes, cigars, e-cigarettes, and smokeless tobacco. As stated above, the NIH and the FDA acknowledge and understand that the research needs regarding flavors in tobacco products are broader than what is specified in the funding announcement. As such, investigators with research questions regarding flavors that are not addressed by this FOA are encouraged to apply to other NIH FOAs and through NIH parent announcements (e.g., PA-13-302, PA-13-303, PA-13-304). (added 8/20/14)

AWARD SELECTION

14. On what basis are applications selected for funding?
    A. Funding priority is given to applications that propose supplement activities that increase or preserve the parent award's overall impact within the original scope of award. Applications will be selected for funding based on scientific merit, current research priorities, and availability of funds.

POST-AWARD MANAGEMENT & REPORTING

15. Are the reporting requirements for these awards the same as other NIH grants?
    A. No. An Interim Report will be due at six (6) months following the project start date, as well as the annual progress report. It is critical that CTP funds be used only to support research that is responsive to the FDA's authority to regulate the manufacture, marketing, and distribution of tobacco products. Any proposed change in scope or specific aims requires pre-approval.

16. Are policies and procedures different for these awards?
    A. Yes. This includes exclusion from Streamlined Noncompeting Award Procedures (SNAP) and all carryover requests requiring prior approval.

17. Some researchers are under limitations with respect to accepting funds from the tobacco industry. How will these FDA research awards be funded?

    A. As mandated in the Tobacco Control Act, FDA is authorized to collect fees from tobacco product manufacturers and importers for its activities related to the regulation of the manufacture, distribution, and marketing of tobacco products. Although the tobacco user fees are specified in statute, Congress must actually appropriate the funds before the FDA can obligate them. The tobacco industry has no control over CTP funding decisions. The FDA uses some of these funds to award research grants.

NIH-FDA Tobacco Regulatory Science Program Web site: http://prevention.nih.gov/tobacco/