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

August 25, 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)

PAGE LIMITATIONS

7. 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

8. 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,
9. 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

10. 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

11. 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.

12. 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.

13. 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.