

Frequently Asked Questions and Answers for [PA-15-183](#)

Administrative Supplements for Tobacco Regulatory Research on Tobacco Flavors and Flavorings

April 10, 2015

ELIGIBLE APPLICANT ORGANIZATIONS

1. Are applicant organizations holding National Institutes of Health (NIH) parent grants that are not supported through the Food and Drug Administration (FDA) Center for Tobacco Products (CTP) eligible to apply?
 - A. Any NIH investigator with an active R01, P01, P30, P50, U01, U19 and U54 grant/cooperative agreement issued by NCI, NHLBI, NIAAA, NIDCR, NIDA and NIEHS (any of the six Institutes participating in this [funding opportunity announcement \(FOA\)](#)) may apply for an administrative supplement through this [FOA](#), 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 of participating institutes 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 announcement \(FOA\)](#)?
 - A. Yes. As stated in the funding opportunity announcement, for-profit organizations are eligible to apply, provided that the conditions listed in the funding opportunity [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.
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 supplemental requests from the same parent grant would be competing against one another. A better strategy might be to tie research questions together into a single cohesive supplement application.
6. May investigators on sub-projects of eligible grants, such as P50s and P01s, 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."

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.
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 Program Director/Principal Investigator (PD/PI) of the parent award, must submit the request for supplemental funds directly to the awarding component that supports the parent award. In addition, if submitting a paper application, please send 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.

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, P30, P50, U19, U54, R01, U01](#)

ABSTRACT REQUIREMENTS

10. Do I need to submit an abstract for the administrative supplement or can I submit the same abstract from the parent grant?
- A. As stated in the [funding opportunity announcement \(FOA\)](#), “A project summary/abstract for the supplement should be submitted that is distinct from the project summary/abstract for the parent award.”

RESEARCH OBJECTIVES AND SCOPE

11. 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 of the two interest areas listed in the [FOA](#),
 - ii. be within scope of the parent grant’s specific aims, *and*
 - iii. fall within scope of FDA CTP’s regulatory authority.

As such, applicants are strongly encouraged to contact the [scientific research contacts](#) listed in the [FOA](#) for feedback about responsiveness prior to submitting an application. Upon receipt, applications will be **evaluated for responsiveness** by the Food and Drug Administration (FDA) Center for Tobacco Products (CTP) and components of participating organizations, NIH. **Only applications that are within scope of the parent grant, responsive to the [FOA](#) and FDA CTP’s regulatory authority, and complete will be reviewed.**

12. Should I contact my program official to make sure that the administrative supplement proposal is within scope of the parent grant before submitting it?
- A. It is highly recommended that the principal investigator (PI) of the parent grant discusses the proposed project with the program official of the parent grant before submission to confirm that the intended administrative supplement application falls within scope of the parent grant. Please note that supplement applications not within the scope of the parent grant *will not be* reviewed.
13. What are the research interest areas for this [funding opportunity announcement \(FOA\)](#)?
- A. The purpose of this funding opportunity is to generate data regarding the following two topics related to flavors and flavorings in cigarettes, cigars (including little cigars and cigarillos), and e-cigarettes. *Only applications proposing research projects relevant to one or both of the following two topics will be considered for funding:*

- 1) When tobacco product flavorings and additives are heated or burned, what chemicals are formed from the thermal degradation processes (pyrolysis and/or oxidation), including chemicals that are on the FDA's established [Harmful and Potentially Harmful Constituent list](#), as well as any other toxic chemicals not on the list? What are the levels of the chemicals that are formed?
 - 2) What in vitro assays are capable of comparative toxicological assessments that can examine the harm potential between different flavorings commonly used in cigarettes, cigars and e-cigarettes; comparing the flavorings after burning or heating (at temperatures achieved by conventional pyrolysis and non-conventional heating methods, such as ones used in aerosol formation)?
14. Are the two research topics listed in the [funding opportunity announcement \(FOA\)](#) the only research on flavors and flavorings in cigarettes, cigars (including little cigars and cigarillos), and e-cigarettes that is responsive to this [FOA](#)?
- A. Yes, applications submitted in response to this FOA must address at least one of the two topics identified in the FOA. However, the NIH and the FDA acknowledge and understand that the research needs regarding flavors and flavorings in cigarettes, cigars (including little cigars and cigarillos), and e-cigarettes are broader than what is specified in the funding announcement. As such, investigators with research questions regarding flavors and flavorings 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](#)).

AWARD SELECTION

15. On what basis are applications selected for funding?
- A. Applications will be selected for funding based on scientific merit, current FDA CTP research priorities, and availability of funds.
16. How will applications be reviewed?
- A. Administrative supplement applications will be reviewed by the program official of the parent grant and other NIH and Center for Tobacco Products (CTP) scientists. In addition, applications will be evaluated using the criteria listed in the [funding opportunity announcement \(FOA\)](#).

POST-AWARD MANAGEMENT & REPORTING

17. 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 the Food and Drug Administration (FDA) Center for Tobacco Products (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.
18. 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.

19. 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 FDA Center for Tobacco Products (CTP) funding decisions. CTP uses some of these funds to award research grants.

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