

Questions and Answers for NIH Revision Applications for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (P30)

RFA-OD-12-077

1/29/13

APPLICANT ORGANIZATION

1. How many years must be left on my P30 in order to apply?
 - A. Applicants may request support for up to 2 years, not to exceed the remaining number of years on the parent grant and/or the funded extension per the Notice of Award, and/or the no-cost extension. If a no-cost extension is needed on the parent grant to incorporate the project period of the revision, the no-cost extension must be in place before the revision application is submitted.

2. Our current P30 will end in early 2014. Since we are confident that we are going to be funded for another cycle, can we extend our revision into the new award period
 - A. No, centers can only apply for the period left on their current award (plus time from a No Cost Extension, if that is feasible). Please check with the NIH program official for your center regarding the period of time that you are eligible for revision award funding.

3. Timing is such that my P30 is not eligible to submit a revision application at this time. Will this RFA be reissued?
 - A. FDA must assess what research is supported through this and other funding opportunity announcements before making decisions about future FOAs. Investigators are encouraged to consider related FOAs that are currently active (and may be found at <http://prevention.nih.gov/tobacco/>).

4. How many applications per P30 award are allowed?
 - A. Only one application per P30 award is allowed. However, an institution that has multiple P30s may submit multiple applications (but only one application per P30).

5. Does the Principal Investigator (PI) on the Revision Application need to be the same person as the PI of the parent P30?
 - A. Yes, the PI of the parent must be PI on the revision application. However, the PI of the parent grant need not be lead or substantially involved in the revision project(s).

REQUIRED RESEARCH PROJECTS

6. How many projects may I propose?
 - A. All applicants responding to this FOA must propose one to four research projects that respond to one or more areas of research interest defined above.

7. Do the projects need to be integrated or thematically related?
 - A. No. This is left to the investigators' discretion. The one to four projects may be self-standing or mutually thematically related.

8. Must all the projects be like R01s?

- A. No. At the applicant's discretion, the scope of the proposed projects may be similar to typical R01 projects and/or pilot or small projects (R21 and R03).

BUDGET

9. Are modular budgets acceptable?
- A. No, modular budgets will not be accepted regardless of total costs. Detailed budgets must be submitted.
10. Is there a budget cap on revision applications?
- A. Yes. Revision applications may not exceed \$1,000,000 in total costs per year, and application budgets need to reflect actual scope and needs of the proposed project(s).
11. Will there be administrative cuts to any funded applications?
- A. There are no plans for across-the-board administrative cuts. However, there may be cuts recommended in response to issues raised by reviewers in summary statements. Details regarding individual budgets will be determined when funding decisions are being made.

LETTER OF INTENT (DUE 2/26/13)

12. What information should be included in the letter of intent?
- A. The letter of intent is strongly encouraged and should include:
- Parent grant number
 - Descriptive title of proposed research
 - Description of how findings generated from each project are anticipated to inform the manufacture, distribution and/or marketing of tobacco products related to FDA regulatory authority
 - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
 - Names of other key personnel
 - Participating institution(s) Number and title of this funding opportunity
 - Number and title of this funding opportunity

RESPONSIVENESS

13. How do I know if my application is responsive to this funding opportunity?
- A. This is a critical question, as applications must propose research that is within the regulatory authority of the FDA Center for Tobacco Products (CTP) in order to be considered for funding. In fact, all the scientific aims of a proposal must fall within FDA CTP's purview. As such, applicants are strongly encouraged to contact their NIH Program Officials (listed in the PAR under Scientific/Research Contacts) for feedback about responsiveness prior to submitting an application. Upon receipt, applications will be **evaluated for completeness** by the Center for Scientific Review **and responsiveness** by CTP, FDA and components of participating organizations, NIH. **Applications that are incomplete and/or nonresponsive will not be reviewed.**

14. FDA/CTP has regulatory authority over the manufacture, marketing and distribution of tobacco products. What are some examples of these authorities?

A. The Family Smoking Prevention and Tobacco Control Act gave FDA responsibility for and authority to, among other things:

- Restrict cigarettes and smokeless tobacco retail sales to youth
- Restrict the sale and distribution tobacco products, including advertising and promotion, as appropriate to protect public health
- Review modified risk tobacco products, such as those marketed for use to reduce harm, prior to their introduction to the market
- Adjust warning labels for cigarettes and smokeless tobacco products in order to promote greater public understanding of the risks of tobacco use
- Establish standards for tobacco products (for example, setting limits on harmful and potentially harmful constituents and nicotine levels) as appropriate to protect the public health
- Review new tobacco products prior to their introduction to the market

For more information, see “Overview of the Family Smoking Prevention and Tobacco Control Act” at

<http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM246207.pdf>

15. In general, what areas of research are not within FDA/CTP’s regulatory authority?

A. The Family Smoking Prevention and Tobacco Control Act gives FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by youth. In general, CTP’s regulatory authorities do NOT extend to the following:

- Setting tax rates for tobacco products
- Regulating therapeutic products, such as those marketed to treat tobacco dependence
- Setting clean indoor air polices
- Regulating tobacco growing

16. What are FDA/CTP’s research priorities?

A. FDA/CTP has identified [research priorities](#) for new scientific evidence that can inform their regulatory actions. However, this RFA is focused **only** on the following ten FDA/CTP interest areas.

1. Nicotine dependence threshold among youth and adults and impact of nicotine reduction on tobacco product use behavior (e.g., topography, compensation, switching, multiple use, initiation, cessation, relapse)
2. Cigar (small, large, cigarillos) initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence and toxicity
3. Smokeless tobacco initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence and toxicity
4. E-cigarettes initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, toxicity

- 5. Other tobacco product (e.g., hookah, pipes, dissolvables) initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, toxicity
- 6. The impact of tobacco product characteristics, (e.g., ingredients, constituents, components, additives such as flavors, and labeling and marketing) on initiation, especially among youth and other vulnerable populations
- 7. Toxicity thresholds for each of the 20 harmful and potentially harmful constituents identified in the March 2012 Guidance for Industry <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297752.htm>
- 8. Statistical modeling of the public health impact of FDA/CTP regulation of potential modified risk tobacco products, e.g., product standards, communications regarding risks of tobacco products
- 9. Consumer perceptions of tobacco products including the impact of labeling and marketing
- 10. Effective communication strategies regarding harmful and potentially harmful constituents and risks of tobacco products

Only applications proposing research projects/pilots relevant to one or more of these ten areas will be considered for funding.

17. Is a treatment intervention study designed to compare the effectiveness of various tobacco products on tobacco cessation considered responsive?
- A. No. CTP's regulatory authority does not extend to regulating therapeutic uses of tobacco products as this authority rests with other Centers within FDA. Examples of research projects that would be considered responsive include an observational study to examine the natural history of whether participants quit smoking cigarettes while using a different tobacco product, and assessing if communications regarding the health consequences of using tobacco products have an impact on usage rates.* In many of its key regulatory areas, CTP is charged with assessing the impact of tobacco products on the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products as well as the increased or decreased likelihood that existing users of tobacco products will stop using such products; and the increased or decreased likelihood that those who do not use tobacco products will start using such products.

**** The examples provided are illustrative and should not be viewed as definitive or comprehensive.***

18. Is a treatment intervention study designed to evaluate the effectiveness of a treatment for tobacco dependence (medications and/or behavioral counseling) on tobacco cessation considered responsive?
- A. No. CTP's regulatory authority does not extend to evaluation of interventions designed to promote cessation. Although a section of the Tobacco Control Act addresses medications to treat tobacco dependence (Sec. 918), this section of the Tobacco Control Act is under the authority of FDA's Center for Drug Evaluation and Research.

**** The examples provided are illustrative and should not be viewed as definitive or comprehensive.***

19. Is a research proposal in which the primary outcome informs treatment of disease considered responsive?
- A. No. CTP does not regulate products or interventions intended for the treatment of disease, for example pharmacotherapy for treatment of cancer or emphysema or screening, physical activity or dietary interventions for heart disease.
20. Is a research proposal which investigates the mechanisms and/or etiology of tobacco related disease responsive?
- A. Depends. Mechanistic and or etiologic research is largely relevant to disease prevention or treatment, neither of which is within CTP's regulatory authority, so would not be considered responsive. These types of research may in some cases be responsive, but only if the outcomes of the research inform the mandate of the FDA CTP. For example, research comparing the mechanistic processes or underlying disease etiology of different tobacco products or their constituents may be considered responsive. As such it is important to discuss your research concept with an NIH Scientific Contact.

**** The examples provided are illustrative and should not be viewed as definitive or comprehensive.***

21. Is a research proposal in which the primary outcome identifies differential effects of various tobacco products on disease risk, incidence, or progression of disease considered responsive?*
- A. Yes. This proposal identifying differential effects of various tobacco products on disease would be responsive. Examples might include:
- pulmonary function testing outcomes following use of various combustible tobacco products
 - oral manifestations following use of various tobacco products, especially new and emerging tobacco products

**** The examples provided are illustrative and should not be viewed as definitive or comprehensive.***

22. What types of biomarker research may be appropriate for FDA/CTP funding?
- A. Proposals identifying biomarkers of specific tobacco product exposure and/or disease and those with the potential to differentiate exposure of differing tobacco products could be considered responsive. Examples* include:
- Biomarkers to measure exposure to new and emerging tobacco products
 - Biomarkers of disease (e.g., cancer, cardiovascular disease, pulmonary disease, reproductive and developmental effects) that can be associated with specific measures of tobacco exposure
 - Development of a nonclinical biomarker of disease coupled to traditional toxicology and/or pharmacology studies to provide a relevant framework for the regulatory application
 - Studies linking biomarkers of disease in nonclinical models that translate to biomarkers that are measurable in the clinical setting

- Magnitude of changes in biomarkers of that translates into clinically meaningful impacts on human health outcomes
- Novel biological and physiological markers (including genetic and epigenetic markers) that are predictive of smoking-related and smokeless tobacco-related adverse health outcomes

Biomarker proposals in which the primary focus is to inform treatment would not be responsive.

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23. What types of research on nicotine and/or nicotinic receptors are appropriate for consideration of funding by CTP?
- A. If the research provides information on outcomes such as motor activity, memory, or neuronal responses to particular ligands, the research is likely not appropriate. Research to rapidly screen tobacco constituents for activity at the nicotinic receptor to determine their dependence potential would be considered responsive.*

**** The examples provided are illustrative and should not be viewed as definitive or comprehensive.***

24. Are studies on the impact of state and local tobacco control policies responsive?
- A. It depends upon the specific policies being examined, and whether they fall under the purview of the FDA CTP. Studies evaluating the impact of a tobacco tax increase are not responsive, as CTP does not have regulatory authority regarding tax rates on tobacco products. Similarly, CTP does not have authority over the sale of tobacco cessation medications, so, for example, a study evaluating the effectiveness for tobacco cessation of providing free nicotine replacement therapy would not be considered responsive. Studies evaluating the impact of a tobacco advertising restriction, a ban on the sale of flavored tobacco products, or restrictions on the sale of single serving products, however, may be considered responsive (but must fit within the 10 research priorities identified for this RFA).*

**** The examples provided above are illustrative and should not be viewed as definitive or comprehensive.***

AWARD SELECTION

25. On what basis are applications selected for funding?
- A. FDA CTP makes the ultimate decision on funding and will select applications for funding based on scientific merit, current research priorities and availability of funds and FDA CTP current research priorities

POST AWARD MANAGEMENT & REPORTING

26. What does A-110 (Shelby Amendment) mean and how does it relate to this FOA?

- A. The Shelby Amendment tasks the Office of Management and Budget (OMB) to change OMB Circular A-110 so that all federally-funded research data can be accessed through the mechanisms set forth in the Freedom of Information Act (FOIA). With regard to this FOA, the research findings generated may be used to provide scientific evidence informing the regulation of the manufacture, distribution, and marketing of tobacco products to protect public health. If research data are cited publically in support of regulation, institutions of higher education, hospitals, and other non-profit organizations are subject to the Freedom of Information Act (FOIA) as outlined in Revised Circular A-110 (http://www.whitehouse.gov/omb/circulars_a110/).
27. Are the reporting requirements for these awards the same as other NIH grants?
- A. No. An Interim Report will be due every six (6) months following the project start date, as well as the annual progress report and all reports at the time of grant close-out. It is critical that CTP funds be used only to support research that is responsive to FDA's authority to regulate the manufacture, marketing and distribution of tobacco products. Any proposed change in scope or specific aims requires pre-approval.
28. 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.
29. 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 FDA can obligate them. The tobacco industry has no control over CTP funding decisions. FDA uses some of these funds to award research grants.

RESEARCH RESOURCES

30. Will the government make available reduced nicotine content cigarettes (research grade) for a research project grant?
- A. A limited supply of reduced nicotine content (RNC) cigarettes for research is available through the NIDA Drug Supply Program. This supply is dependent on availability of funds and need. To determine if there is adequate supply for your research needs, please provide the following information prior to submission of your research application: 1] a brief description of your project, 2] the estimated number of RNC cigarettes required at specified nicotine content doses, and 3] a timeline for when those RNC cigarettes are needed. This information should be sent via email attachment to Dr. Hari Singh (hsingh1@nida.nih.gov). For more information see the Notice of Availability of Nicotine Research Cigarettes through NIDA's Drug Supply Program, [NOT-DA-12-002](#).

NIH-FDA Web site: <http://prevention.nih.gov/tobacco/>