Questions and Answers for Tobacco Control Regulatory Research
PAR-12-267 (R01)
PAR-12-268 (R03)
PAR-12-266 (R21)
Updated September 18, 2012

ELIGIBLE APPLICANT ORGANIZATIONS

1. Are NIH intramural scientists eligible to apply?
    A. Yes, the NIH Intramural Program is an eligible applicant organization.

2. Are 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.

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. It is the responsibility of the NIH peer review and council recommendations to identify the merit and quality of applications, as well as FDA's consideration of the relevance of the application to program priorities, to determine the entity's success in securing funding for research.

BUDGET

4. Are modular budgets acceptable?
    A. No, modular budgets will not be accepted regardless of total costs. Detailed budgets must be submitted.

5. Is there a budget cap on R01 applications?
    A. Applicants requesting $500,000 or more in direct costs in any year (excluding consortium F&A) must contact NIH program staff at least 6 weeks before submitting the application and follow the Policy on the Acceptance for Review of Unsolicited Applications that Request $500,000 or More in Direct Costs as described in the SF 424 (R&R) Application Guide.

6. Will there be administrative cuts to any funded applications?
    A. Each NIH Institute establishes its own funding policies (see http://grants.nih.gov/grants/financial/index.htm for current policies). All grants selected for pay must adhere to the assigned Institute's policies. In addition, 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.

RESPONSIVENESS

7. How do I know if my application is responsive to this funding opportunity?
    A. Applicants are strongly encouraged to contact their NIH Program Officials (listed in the PAR) 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 components of participating organizations, NIH. Applications that are incomplete and/or nonresponsive will not be reviewed.

8. 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

9. 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

10. Is a treatment intervention study designed to compare the effectiveness of a tobacco product and 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 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 has 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**.*

11. Is a research proposal in which the primary outcome informs treatment of disease considered responsive?
    A. No. CTP does not regulate products intended for the treatment of disease. However, if the primary outcome of a research project identifies differential effects of various tobacco products on disease risk, incidence, or progression of disease, then the proposal would be considered responsive.***** Examples 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**.*

12. 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.

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

13. 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**.*

14. What types of international research would be considered responsive?
    A. In general, if study results can be generalized to the U.S. (based on the products tested and the population being sampled), it would be considered responsive. Studies evaluating toxicity, disease risk in humans would likely be responsive if a similar product is planned to be or is marketed in the U.S. Studies assessing consumer behavior and/or perceptions may or may not be responsive, since consumer behavior and perceptions may be driven by a number of factors unique to a specific country.

15. Are studies on the impact of state and local tobacco control policies responsive?
    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. 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.*****

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

POST AWARD MANAGEMENT & REPORTING

16. Which NIH Institute/Center (IC) will manage my award?
    A. It depends on the nature and scope of the research projects proposed. Applicants may request assignment to a particular Institute in their cover letter, but NIH will make the final determination regarding Institute assignment.

17. 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/).

18. Are the reporting requirements for these awards the same as other NIH grants?
    A. No. An Interim Report will be due at the end of 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.

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 FDA can obligate them. The tobacco industry has no control over CTP funding decisions. FDA uses some of these funds to award research grants.

RESUBMISSION

20. Can any unfunded applications in response to this PAR be resubmitted?
    A. An application that has been previously submitted, but was not funded, may be resubmitted for consideration. NIH will accept only a single amendment to the original application (A1).

RESEARCH RESOURCES

21. 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).

22. What is the PATH Study and what are its aims?

A. In October 2011, the Food and Drug Administration (FDA) and the National Institutes of Health (NIH) announced a joint national, prospective, longitudinal cohort study of tobacco users and those at risk for tobacco-product use to monitor and assess their tobacco use and the resultant health impacts. The initiative, called the Population Assessment of Tobacco and Health (PATH) Study, represents the first large-scale NIH-FDA collaboration on tobacco regulatory research since Congress granted FDA the authority to regulate tobacco products under the Family Smoking Protection and Tobacco Control Act (FSPTCA). Scientific experts at the National Institute on Drug Abuse (NIDA) and FDA's Center for Tobacco Products (CTP) will coordinate this effort via a research contract awarded to Westat in Rockville, MD. The PATH Study will prospectively follow almost 60,000 people who are users of tobacco products and those at risk for tobacco-product use ages 12 and older in the United States. The study will a) examine what makes people susceptible to tobacco-product use; b) evaluate initiation and use patterns including use of new products, dual use, poly use, and switching of tobacco products; c) study patterns of tobacco-product cessation and relapse ; d) evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes; and e) assess differences in attitudes, behaviors, and key health outcomes among racial/ethnic, gender, and age subgroups. The PATH Study will also collect biospecimens from adults to analyze biomarkers of tobacco use and disease processes.

23. What will be the availability of the PATH data in terms of timing and content?

    A. It is anticipated that the PATH baseline restricted use file and codebook will be available by late summer 2015. Details, when available, will be posted to PATH website, PATHstudyinfo.nih.gov, which is currently under construction.

24. When will PATH biospecimens and biospecimen data be available?

    A. It is anticipated that PATH biospecimens and biospecimen data will become available by late summer 2015. Details, when available, will be posted to PATH website, PATHstudyinfo.nih.gov, which is currently under construction.

25. What will be the availability of confidential information obtained by the FDA, for example, product and constituent reporting?
    A. Several laws govern the confidentiality of tobacco product information submitted to FDA, including sections 301(j) and 906(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Trade Secrets Act, and the Freedom of Information Act, as well as FDA's implementing regulations. FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR Part 20. Regarding the reporting of constituents, the FD&C Act requires tobacco product manufacturers and importers to report quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products or tobacco smoke by brand and sub-brand. The FD&C Act also directs the Agency to publish a list of HPHCs by brand and by quantity in each brand and sub-brand, in a format that is understandable and not misleading to a layperson.

NIH Guide FOA:

R01, http://grants.nih.gov/grants/guide/pa-files/PAR-12-267.html

R03, http://grants.nih.gov/grants/guide/pa-files/PAR-12-268.html

R21, http://grants.nih.gov/grants/guide/pa-files/PAR-12-266.html

NIH-FDA Web site: http://www.cancercontrol.cancer.gov/nih-fda/