Grant mechanism is specified for answers that differ by mechanism.

ELIGIBILITY
Eligible Organizations
1. Are NIH intramural scientists eligible to apply?
   • K08 No, the NIH Intramural Program is not an eligible applicant organization. At the time of award, the candidate must have a full-time appointment at the applicant institution.
   • K01 No, the NIH Intramural Program is not an eligible applicant organization. At the time of award, the candidate must have a full-time appointment at the applicant institution.
   • K22 & K99/R00 Yes, the NIH Intramural Program is an eligible applicant organization.
2. Are foreign institutions eligible to apply for the Tobacco Control Regulatory Research K08, K01, K22 or K99/R00?
   • No.
Eligible Individuals

3. Under what conditions may persons in tenure-track positions apply to these K01, K08, K99/R00 or K22 FOAs?
   - Individuals who are in tenure track positions may not apply for either the Tobacco Control Regulatory Research Pathway to Independence (K99/R00) or Transition (K22) awards, since the purpose of both is to allow the awardee to secure a tenure track position. Potential applicants to the Tobacco Control Regulatory Research Scientist (K01) or Clinical Scientist (K08) awards who are in tenure track positions are still eligible if at the time of application they have not been and are not currently the PI on an NIH research project (R01), program project (P01), center grants (P50), sub-projects of program project (P01), sub-projects of center grants (P50), other career development awards (K–awards), or the equivalent. (FAQ added 8/12/13)

4. Are NIH Intramural Research Program (IRTA) trainees eligible to apply for the TRSP career awards?
   - Postdoctoral trainees in the IRTA program are eligible to apply for the K99/R00 or K22 career awards. IRTA trainee applicants must of course also meet the other eligibility criteria for these tobacco regulatory research career awards. (FAQ added 8/6/13)

5. Are foreign individuals eligible to apply as Principal Investigators for the Tobacco Control Regulatory Research K08, K01, K22 or K99/R00?
   - By the time of award, the individual must be a citizen or a non-citizen national of the United States or have been lawfully admitted for permanent residence (i.e., possess a currently valid Permanent Resident Card USCIS Form I-551 or other legal verification of such status). Individuals on temporary or student visas are not eligible.

6. How do I determine if my years of research experience since I received my terminal research or clinical doctorate are within the specified years allowed (within 2-7 for the K22 and within 4 years for the K99)?
   - The critical issue is the number of years of the applicant’s research experience since the terminal doctorate was obtained. Under special circumstances, individuals who received terminal doctorates more than the specified number of years in the FOA may be eligible. For example, a clinical faculty member who does not hold an independent research faculty position or individuals who have experienced a career interruption may need to request consideration of their unique situation. Examples of qualifying interruptions would include a complete or partial hiatus from research activities for child rearing; an incapacitating illness or injury of the candidate, spouse, partner, or a member of the immediate family; relocation to accommodate a spouse, partner, or other close family member; pursuit of non-research endeavors; and military service. Potential applicants with clinical non-research positions or who have had research career interruptions should consult with NIH staff at the earliest possible stage.

7. How do I decide between applying for a K99/R00 and a K22 award in Tobacco Control Regulatory Research?
• Under the K99/R00, applicants must be within 4 years of having received their doctorate and will receive 1-2 years of mentored training. In contrast, applicants to the K22 must be within 2-7 years of having received their doctorate and, if selected, must find an acceptable tenure-track or equivalent position within 12 months of notification of Intent to Commit Funds. However, the K22 award period does not include mentoring. If you are in the 2-4 years window, consider whether you will be sufficiently prepared to successfully apply as an independent investigator for an NIH-supported research project grant or its equivalent by the second year of your 3-year award.

8. Must I have a medical doctorate to apply for the Tobacco Control Regulatory Research K08?
• No, you do not necessarily need a medical doctorate, but you must have a clinical doctoral degree. Such degrees include, but are not limited to, the MD, DO, DDS, DMD, OD, DC, PharmD, ND (Doctor of Naturopathy), and DVM. Individuals with the PhD or other doctoral degree in clinical disciplines, such as clinical psychology, nursing and clinical genetics are also eligible.

9. May I submit an application for a Tobacco Control Regulatory Research career award if I already have an application in for another career award?
• Two career award applications cannot be pending ‘concurrently.’ This means that the first application must have been reviewed and received a summary statement before the second application can be submitted. For example, if you have a career award application that would be scientifically reviewed at the end of October, you will not have your summary statement back in time for the RFA October 2 receipt date. (FAQ added 8/12/13)

10. Could I submit two or more career award applications that would be pending concurrently if they were on different topic areas or otherwise substantially different?
• No, the same guidance applies even if the applications are different. (FAQ added 8/12/13)

MENTORING

11. Do I need a mentor in order to apply for the Tobacco Control Regulatory Research K08, K01, K22 or K99/R00?
• K08 & K01 Yes. You must identify a primary mentor, or co-mentors, to develop your application. Note that at least one supervising mentor must have expertise in tobacco research as it relates to the regulation of tobacco products and FDA’s regulatory authorities.
• K22 No. The Transition Career Development Award in Tobacco Control Regulatory Research (K22) is designed to provide support for the initial 3 years of your first independent tenure-track faculty position. Since you will be independent, you will not have a mentor during the period of the award. The K22 candidate is not required to have expertise in tobacco regulatory research. However, the submitting institution is required to commit to assist in the candidate’s securing a tenure-track position to conduct tobacco regulatory research. Those who receive a Letter of Intent to Commit
Funds are eligible to apply for the award according to the procedures outlined in the FOA, which includes reasonable assurance by the applicant institution that it has the capacity to prepare the applicant for a career in tobacco regulatory science.

- **K99/R00** Yes. Before submitting the application, you must identify a primary mentor who will supervise the proposed K99 career development and research experience. You may identify a mentor and co-mentor to jointly supervise you. Note that at least one supervising mentor must have expertise in tobacco research as it relates to the regulation of tobacco products and FDA’s regulatory authorities.

12. Does the mentor’s experience in regulatory research have to have been funded by the FDA? That is, does the mentor’s experience have to involve specific tobacco regulations or is it acceptable for the mentor’s experience to be relevant to tobacco regulation?
- It is acceptable for the mentor’s experience to be relevant to tobacco regulatory science. As this is a relatively new field, it is not expected that all mentors will have FDA funding, or an extensive publication record specifically in tobacco regulatory science. (FAQ added 8/5/13)

**APPLICATION**

13. What letters are needed for mentored career award applications, and who needs to write them?
- Letters of Reference are needed from 3-5 persons who have supervised you and know your work. They may not also be mentors or consultants on your proposal. More detailed letters tailored to you are often seen as demonstrating that the writer knows you well. (FAQ added 9/3/13)
- Letters of Support are needed from anyone who has a key role in your project including mentor(s), consultants, and persons providing special materials (e.g. transgenic mice, ligands). It is recommended that they state their role in the project, what resources they will make available specifically to you, and in the case of a mentor take the opportunity to describe their impression of you. Some use institutional letterhead at the top of the first letter of support (from the primary mentor) and then not for subsequent ones in order to comply with space limitations. (FAQ added 9/3/13)
- A Letter of Institutional Commitment is needed that is usually written by the Department Chair. It describes the environmental resources and facilities as well as the institution’s commitment to your career. As with the other letters, this should ideally be tailored to you and should be fairly detailed in order to avoid the impression of a generic letter. This letter must be on institutional letterhead. (FAQ added 9/3/13)
- A cover letter will accompany your application. Application form instructions provide good information on what needs to be addressed, however your NIH Program Official (PO) may have additional suggestions. (FAQ added 9/3/13)
• It is recommended that you update all letter writers on your recent progress and accomplishments so that reviewers can talk about both how they saw you perhaps years ago and what kind of a scientist you are now. (FAQ added 9/3/13)

14. Is there a template for the written parts of the application?
• The forms and application instructions provide a template of sorts. The instructions require you to upload various sections, which you write offline and save in PDF files. (FAQ added 9/3/13)

15. Would you recommend that I look at examples of career award applications and review summaries as I prepare my application?
• This can be very helpful. However when using examples, be careful not to stray from the requirements of the specific Funding Opportunity Announcement (FOA) to which you are responding, e.g. the K01 FOA for Tobacco Regulatory Research and not the NIH parent K01 FOA. (FAQ added 9/3/13)
• Check with your university’s Office of Sponsored Programs or a similar office and with your mentor(s)/department for recent examples of funded K01 applications and their summary sheets from their review, so that you can see what to do and perhaps also some things to avoid. These should optimally be very recent examples, because NIH has been transitioning the format and method (electronic) of application submission. (FAQ added 9/3/13)
• Talk with the appropriate NIH institute contact listed at the bottom of your career award FOA for specific application guidance. (FAQ added 9/3/13)

BUDGET
16. What are allowable salary and research costs for awarded Tobacco Control Regulatory Research K08, K01, K22 or K99/R00, and are there any other costs?
• K08, K01 & K22 The opportunity provides annually up to $90,000 toward the salary and $60,000 toward research development costs of the career award recipient. Indirect costs, also known as Facilities & Administrative (F&A) costs, are reimbursed at 8% of modified total direct costs.
• K99 Up to $90,000 per year toward the salary and up to $60,000 per year toward research development costs are allowed for the K99 phase. Intramural scientist applicants should not request salary and related fringe benefits. Indirect costs, also known as Facilities & Administrative (F&A) costs, are reimbursed at 8% of modified total direct costs. The total cost for the independent investigator (R00) phase may not exceed $249,000 per year. This amount includes salary, fringe benefits, research support allowance, and applicable F&A costs. Indirect costs will be reimbursed at the extramural sponsoring institution’s indirect cost rate.

17. What is the basis of determining the salary of the Tobacco Control Regulatory Research award recipient?
• K08, K01 & K22 At the time of award, the candidate must have a “full-time” appointment at the applicant institution. The award requires the candidate to devote a
minimum of 9 person-months (75% of full-time professional effort) to conducting tobacco regulatory research. The remaining effort may be devoted to other research pursuits and activities consistent with the objectives of the award. Note that the K22 submitting institution is distinct from the institution to which the K22 will be awarded and it is the sponsoring institution at the time of award where the candidate must have a full-time position.

- **K99/R00** The K99 salary must be justified by the applicant as consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities. The R00 salary should be based on the person-months effort to be devoted to the R00. For both the K99 and R00 phases, candidates must devote a minimum of 9 person-months (75% of full-time professional effort) to conducting tobacco regulatory research. The remaining effort may be devoted to other research pursuits and activities consistent with the objectives of the award.

18. Will there be administrative cuts to any funded Tobacco Control Regulatory Research K08, K01, K22 or K99/R00 applications?

- Each NIH Institute establishes its own funding policies (see [http://grants.nih.gov/grants finanzi al/index.htm](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.

19. Can mentors be paid from the budget?

- As stated in the RFAs, salary for mentors, secretarial and administrative assistants, etc., is not allowed. (FAQ added 8/5/13)

**K22 INSTITUTIONAL COMMITMENT**

20. What is the emphasis of the institutional commitment requirement of the submitting institution?

- **K22** The submitting institution must assure that they can provide an environment that is conducive to the applicant’s success in securing a tenure-track assistant professor faculty position, or its equivalent, in a domestic academic institution.

21. What are the important issues in addressing the institutional commitment requirement of the sponsoring institution?

- **K22** Before the NIH issues the Notice of Award, the sponsoring institution will need to provide a description of the institutional environment. The emphasis here is quite different, because the K22 award recipient will be dependent upon these resources for the next three years in order to launch a career in tobacco regulatory research. Sponsoring institutions should provide a full description of the resources that will be made available to the award recipient and demonstrate a solid commitment to his or her scientific and career development and his or her progression to independence for a career in tobacco regulatory science.
ATTENDANCE/PRESENTATION AT MANDATORY MEETINGS

22. Am I required to attend the annual participant workshop every year of my Tobacco Control Regulatory Research K08, K01, K22 or K99/R00 award?
   - Yes. Even in your first year when you may have little to share, you will have the opportunity to meet with Tobacco Regulatory Science Program (TRSP) career awardees and with NIH and FDA staff. Once your research is underway, presentations will allow you to showcase your research and see what others are doing. At all of these meetings you will learn more about the TRSP program overall and the direction of tobacco regulatory research.

23. Am I expected to also attend a scientific conference or workshop each year of my Tobacco Control Regulatory Research K08, K01, K22 or K99/R00 award?
   - Yes. In addition to your annual participation in the participant workshop, you are expected to attend and present your research results at a conference or workshop appropriate to furthering your tobacco regulatory research career.

TRAVEL

24. Must funds from the award be used for travel to the two required meetings per year?
   - Yes

RESPONSIVENESS

25. How do I know if my application is responsive to this funding opportunity?
   - 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 RFA 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.

26. How is responsiveness assessed once my application is submitted to NIH?
   - CTP and NIH together assess applications for responsiveness. Your application abstract and specific aims are used to make this determination, so it is important that you are clear about your proposed scientific aims and how they may potentially inform CTP’s regulatory authority. Staff reviewing your application will not try to infer how your research falls within CTP’s regulatory authority beyond what is stated in the abstract and specific aims. If your application is deemed responsive, it will undergo scientific peer review by experts convened specifically for this FOA (by the NIH Center for Scientific Review). If your application is deemed nonresponsive, it will be withdrawn prior to evaluation of its scientific merit, i.e., peer review.
27. FDA/CTP has regulatory authority over the manufacture, marketing, and distribution of tobacco products. What are some examples of these authorities?

- The Family Smoking Prevention and Tobacco Control Act gave FDA responsibility for and authority to, among other things:
  - Restrict cigarette and smokeless tobacco retail sales to youth.
  - Restrict the sale and distribution of 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.


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

- 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.

29. Is a treatment intervention study designed to compare the effectiveness of various tobacco products on tobacco cessation considered responsive?

- 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.

30. 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?
   • 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.

31. Is a research proposal in which the primary outcome informs treatment of disease considered responsive?
   • No. CTP does not regulate products intended for the treatment of disease, for example pharmacotherapy for treatment of cancer or emphysema. *

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

32. 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?*
   • 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.

33. What types of biomarker research may be appropriate for FDA/CTP funding?
   • 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 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.

34. What types of research on nicotine and/or nicotinic receptors are appropriate for consideration of funding by CTP?
• 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.

35. What types of international research would be considered responsive?
• 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 or disease risk of a tobacco product 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.

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

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

* The examples provided are illustrative and should not be viewed as definitive or comprehensive.
37. Is CTP interested in graphic health warning research given that the U.S. government did not seek Supreme Court review of the court decision that blocked the implementation of graphic health warnings on cigarette packages and advertising?

- FDA is committed to funding and conducting research on graphic health warnings so that it may fulfill its statutory requirement to issue a rule requiring graphic health warnings on cigarette packages and advertisements. Of particular interest would be research to provide further evidence that graphic health warnings are effective, to inform the development of new graphic health warnings, or to inform the development of methods for assessing the effectiveness of graphic health warnings. This research may be conducted using the images proposed by FDA in June 2011, images used internationally, or new images.*

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

REVIEW

38. Will applications be reviewed by the NIH Center for Scientific Review (CSR) or by study sections organized by participating NIH Institutes and Centers?

- Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by CSR.

AWARD SELECTION

39. On what basis are applications selected for funding?

- 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.

40. What is the selection and award process for the K22?

- If the application receives a meritorious score for scientific merit and then is favorably reviewed for relevance to the mission of the FDA CTP, a Letter of Intent to Commit Funds will be issued to the candidate. He/she will then have up to 12 months to identify and secure a tenure-track assistant professor faculty position, or its equivalent, in a domestic academic institution. Upon securing a tenure-track faculty position, or its equivalent, an updated application with a revised budget will be submitted by the (new) sponsoring institution to the NIH. Detailed instructions for submitting a revised budget will be included with the Letter of Intent to Commit Funds. NIH, in conjunction with the FDA CTP, will review the new updated application to ensure that all programmatic requirements have been met prior to issuance of the award.

POST-AWARD MANAGEMENT & REPORTING

41. Which NIH Institute/Center (IC) will manage my award?

- It depends on the nature and scope of the research projects proposed. Applicants may request assignment to a particular IC in their cover letter, but NIH will make the final determination regarding IC assignment.
42. What does A-110 (Shelby Amendment) mean and how does it relate to this FOA?
   - 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/).

43. Are the reporting requirements for these awards the same as other NIH grants?
   - 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.

44. Are policies and procedures different for these awards?
   - Yes. This includes exclusion from Streamlined Noncompeting Award Procedures (SNAP), and all carryover requests require prior approval.

45. Some researchers are under limitations with respect to accepting funds from the tobacco industry. How will these FDA research awards be funded?
   - 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. FDA uses some of these funds to award research grants. The tobacco industry has no control over CTP funding decisions.

RESUBMISSION

46. Can any unfunded applications in response to this RFA be resubmitted?
   - This RFA has only one receipt date; consequently, amended applications are not allowed. However, applicants may submit new applications to relevant FOAs issued by NIH Institutes and Centers.

RESEARCH RESOURCES

47. Will the government make available reduced nicotine content cigarettes (research grade) for a research project grant?
   - 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-13-002.

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

- 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.

- 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 the PATH website.

49. What will be the availability of confidential information obtained by the FDA, for example, product and constituent reporting?

- 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.
Applicants should follow the instructions in the SF424 (R&R) Application Guide, except where instructed in the funding opportunity announcement to do otherwise.

Tobacco Control Regulatory Research Career Award Funding Opportunity Announcements: