

**Questions and Answers for Tobacco Centers of Regulatory Science (TCORS)
RFA-DA-13-003**

Updated November 5, 2012

APPLICATION STRUCTURE & ORGANIZATION

1. What are the required components of a responsive application?
 - A. There are six required components:
 - i. at least *three* theoretically grounded, strong research projects with an integrated theme;
 - ii. an Administrative Core (and other cores as needed and justified);
 - iii. use of funds for developmental/pilot projects and time-sensitive research;
 - iv. a program for career development and training.

2. What is expected for the overall organization and order of sections in the application?
 - A. As indicated, the overall application and each individual section must follow the instructions in the PHS398 Application Guide, <http://grants.nih.gov/grants/funding/phs398/phs398.html> and will use the page limits as indicated in the Table of Page Limits http://grants.nih.gov/grants/forms_page_limits.htm. The recommended organization for the TCORS Center application is as follows (indicated page limits may not be exceeded):
 1. Entire Center (PHS398 Guidelines and forms)
 - a. Face Page
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel
 - c. Table of Contents for the Entire Application
 - d. Detailed Budget for Initial Budget Period
 - e. Budget for Entire Proposed Project Period
 - f. Biosketches (for the entire center, all cores and projects, 4 page max per person)
 - g. Resources, entire center
 - h. Checklist
 2. Overall Center Research Strategy (12 page limit)
 3. Research Projects (PHS 398 Research Plan)
 - a. Cover Page (1 page)
 - i. Title of Project
 - ii. Research Project Director (Principal Investigator), title, affiliation
 - iii. Other investigators, titles, affiliations
 - b. Detailed Budget for Initial Budget Period
 - c. Budget for Entire Proposed Project Period
 - d. Budget Justification
 - e. Specific Aims (1 page)
 - f. Research Strategy (12 pages)
 - g. Bibliography and References Cited
 - h. Protection of Human Subjects
 - i. Inclusion of Women and Minorities

- j. Targeted/planned Enrollment Table
 - k. Inclusion of Children
 - l. Vertebrate Animals
 - m. Select Agent Research
 - n. Consortium/contractual arrangements
 - o. Letters of Support
 - p. Resource Sharing
4. Administrative and other Cores
 - a. Cover Page (1 page)
 - i. Title of Project
 - ii. Research Project Director (Principal Investigator), title, affiliation
 - iii. Other investigators, titles, affiliations
 - b. Detailed Budget for Initial Budget Period
 - c. Budget for Entire Proposed Project Period
 - d. Budget Justification
 - e. Core unit Structure, Administration, and Services (6 page total)
 5. Developmental/pilot research component
 - a. Cover Page (1 page)
 - i. Title of Project
 - ii. Research Project Director (Principal Investigator), title, affiliation
 - iii. Other investigators, titles, affiliations
 - b. Detailed Budget for Initial Budget Period
 - c. Budget for Entire Proposed Project Period
 - d. Budget Justification
 - e. Description (6 page limit)
 6. Research Training and Education Plan (6 page limit)
 - a. Cover Page (1 page)
 - i. Title of Project
 - ii. Research Project Director (Principal Investigator), title, affiliation
 - iii. Other investigators, titles, affiliations
 - b. Detailed Budget for Initial Budget Period
 - c. Budget for Entire Proposed Project Period
 - d. Budget Justification
 - e. Description (6 page limit)

The order of sections should be as presented above.

3. Can applicants provide a list of acronyms for the different sections of the application?
 - A. Yes, it is recommended that a glossary of terms/ acronyms for the different cores be included on the corresponding cover page for that section of the proposal.
4. What are the 12 pages titled, "Research Strategy" expected to address?
 - A. This section of the proposal is an opportunity for investigators to address the functioning and integration of the Center as a whole, including coordination and communication within the Center. It is in this section where investigators should demonstrate their ability to lead, manage and integrate components of the Center both conceptually and scientifically. It also is an opportunity to highlight the Center's theme

and relate it to compelling scientific questions as well as its relevance to the FDA's regulatory authority.

5. What are ways to organize the proposals and focus thematically?
 - A. Focus on areas where there are significant gaps in knowledge. Examples/options: organize around a tobacco product or constituent/ingredient (such as the FDA established list of [Harmful and Potential Harmful Constituents in Tobacco Products and Smoke](#)) and propose projects that examine biomarkers, toxicity, carcinogenicity, health consequences. Organize around a cross-cutting priority like vulnerable populations, communications, marketing, or economics. Centers are encouraged to study interactions across research foci, such as the variation of cultural and individual variables within a research topic, when possible.
6. Should the individual projects be considered as R01-like?
 - A. Yes. The Individual research projects can be thought of as three R01s that are integrated and complementary to the larger TCORS Center goals and aims.
7. What are the details for the inclusion of a plan for data sharing and data safety and monitoring and the inclusion of human subjects (women, children, and minorities)?
 - A. One Data Sharing and one Data Safety and Monitoring Plan should be included for the entire application. Include the human subjects' information for each individual project (there is no page limit). Each individual research project will be reviewed for the inclusion of women, children, and minorities as well as the overall TCORS application as a whole.
8. What makes a successful transdisciplinary center?
 - A. The success of a transdisciplinary center is influenced by a variety of contextual factors, such as, resources for communication, organizational policies, and interpersonal dynamics of team members. The NIH Web site devoted to Team Science provides a number of useful resources for TCORS applications (see <https://www.teamsciencetoolkit.cancer.gov/>). It includes references and information on enhancing transdisciplinary research collaborations, building teams with training and expertise in different fields, and managing productive and effective teams.
9. Can applicants include NIH Intramural researchers as part of the transdisciplinary team?
 - A. Yes. In general, NIH intramural researchers may collaborate or consult with extramural researchers who apply for a P50 award. However, NIH intramural investigators may not receive salary support through the grant award. See [Chapter 17 of the NIH Grants Policy Statement](#) for more information.
10. If the applicant proposes to collaborate with one or more organizations in carrying out the proposed research, is there a ratio or percentage of work that can be subcontracted from the applicant organization?
 - A. No, there is no set percentage or work that can be subcontracted from the applicant organization. NIH policy requires that the grantee is the one responsible and accountable for the performance of the grant. The grantee must perform a substantive role in the planned research and cannot simply be a conduit of funds to another party. This includes being able to provide appropriate oversight of all scientific, programmatic,

financial, and administrative matters related to the grant. However, depending on the nature of the science, it is possible that it would be appropriate for the consortia budget (i.e., subcontracts) to account for a larger portion of the requested budget. In short, there is no cap on subcontracts.

ELIGIBLE APPLICANT ORGANIZATIONS

11. 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.

12. 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.

PILOT PROJECTS

13. How detailed do the proposals for the within-center or cross-center developmental projects need to be?

- A. There is no need to include a full proposal for the developmental/pilot projects in the application. Applicants should frame ideas and research directions of interest, as well as the plans to propose, identify, and frame developmental/pilot projects in the TCORS application. The developmental/pilot projects will not start until the second year of funding. Collaborative projects may be across major research projects within a Center, across two or more Centers, or with scientists external to TCORS.

14. How many pilot projects will be anticipated per year?

- A. In funding years 02-05, it is expected that there will be up to five pilot projects per year awarded at each Center. Two of the pilot projects will be within Center research projects, and three will be cross-TCORS Center projects. All pilot projects will require approval by the TCORS Steering Committee prior to initiation of the project.

15. What is the recommended length of time for pilot projects?

- A. The recommended length for a pilot project is eight to twelve months, thus allowing the projects to be completed within one budget year.

CAREER DEVELOPMENT & TRAINING

16. What are the requirements of the career development and training plan?

- A. The research training and education plan must include pre-doctoral, post-doctoral, and/or cross-training of junior and established investigators in the field of tobacco

regulatory science. Such training should expose “appointees” to the multiple levels of research that address tobacco-related issues. The training and education program must be led by a Training Director who is an established investigator and who is senior in terms of mentoring appointees at the career levels proposed. Centers are expected to propose a plan for enabling appointees to develop independent research projects and for professional development. The application must propose a minimum of four appointees for training whose appointments are made no later than the second year of the grant award. Centers are expected to develop mechanisms for establishing networks and for sharing training resources. At a minimum, each Center must develop at least one course in their area of expertise/theme by the end of year two and make it available to other funded TCORS Centers by the end of year three.

17. What are the guidelines for paying trainees?
 - A. Applicants may refer to the NIH training grant standards for payment of trainees. The 2012 stipends are posted in the NIH Guide: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-033.html>
18. What is the suggested or required length of a trainee appointment?
 - A. There is no required length for trainee appointments – in part due to variability across schools, departments and disciplines. However, there is a minimum requirement for the Center to support a minimum of four appointees.
19. May the TCORS center cover 100% of a pre-doctoral trainee’s tuition and fees, as well as a stipend?
 - A. Yes, as long as the trainee meets the requirements of their center training program and is an appointee of that program.
20. If already-funded F31 students are included in the training program, can the center provide an institutional allowance for payment for conference attendance (registration and travel costs)?
 - A. They can use the center grant to supplement fellowship-funded trainees for training purposes, if the trainees are training appointees of the center grant and therefore also meet its training program requirements. However, in the context of the center grant, TCORS funds would not be called an institutional allowance as that is a term used in fellowships.
21. Does it matter where the application budgets for payment for conferences? That is, can it be through the Administrative Core or through the training program?
 - A. Centers may propose to use their administrative core to manage these funds for training appointee conference participation. However, conference costs associated with training must be supervised through the center’s research training program, which may be situated in a separate core. Correspondingly, conference payments for center trainees must be recorded as a training expense.
22. Can foreign students be supported in the P50 training program?
 - A. Just as foreign applicants must justify that they have a unique resource, applicants who propose to train foreign appointees should address the special opportunity offered by their inclusion. In addition, applicants should describe how having foreign appointees in

their program will contribute to the NIH-FDA TCORS goal of developing the workforce in the regulatory science of smoking prevention and tobacco control.

23. What is meant by the Training and Education plan requirement for "at least one course in (our) area of expertise/themes by the end of year 2" and to "make it available to other funded Centers in the TCORS program no later than the end of year 3." Reference is made to curricula, webinars, and short courses in the guidelines, as well. Does the TCORS program envision these as formal semester-long courses as are offered at universities?
- A. The TCORS program does not have a formal requirement regarding the details of the course, as we want to remain open to both the ingenuity of the investigators, and to the collaborative process that we expect to unfold once the Centers are funded. We envision this course as an opportunity for the training appointees in each of the Centers to avail themselves of the expertise across Centers to receive more comprehensive training in tobacco regulatory science. Possible offerings that would fulfill this requirement include a week-long short course, a university course with distance learning options, or a series of webinars over the course of six months to a year that are made available to training appointees within the TCORS program. Alternatively, materials for a semester-long course could be developed, including lectures and suggested supporting materials, which could be shared with mentors at other Centers to use in their coursework, or even made broadly available to instructors teaching tobacco related science at other institutions. This is an opportunity to utilize and showcase the expertise of your faculty and also to focus on the themes chosen for your Center.

BUDGET

24. What is the budget cap? Will applications that exceed the budget cap be considered?
- A. The budget cap is \$4M in total costs per year (for five years). Proposed budgets *cannot* exceed the budget cap, and applications exceeding the budget cap risk being returned as nonresponsive.
25. 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.
26. How should applicants prepare budgets for future years of a TCORS?
- A. Applicants should follow the budget instructions in the PHS SF424 application guide, which states that actual institutional-based compensation should be requested and justified at time of application and that these requested amounts may be adjusted at the time of the award. Please see the SF 424 application guide page I-77 discussion on institutional base salary and the [NIH Grants Policy Statement Glossary](#) for the definition of institutional base salary. The RFA states, a *P50 center may not exceed \$4 million in total costs per year*. Therefore, applicants should not request significant program expansion beyond that amount.

TIMELINE

27. What are the upcoming dates to keep in mind?
- A. Letters of Intent must be RECEIVED by October 15, 2012. TCORS Center applications must be RECEIVED by November 14, 2012.
28. When will awards be made?
- A. Awards will be made in FY13, before the end of September 2013.

PAGE LIMITS

29. What are the application page limits?
- A. Research strategy is limited to 12 pages.
Administrative core is limited to 6 pages.
Each additional core is limited to 6 pages.
Each research project component is limited to 12 pages.
Developmental/pilot research component is limited to 6 pages.
Research training and education plan is limited to 6 pages.
30. Should descriptions of affiliated Centers be included in the appendix?
- A. No, DO NOT use the appendix as a way to circumvent the page limits.

RESPONSIVENESS

31. How do I know if my application is responsive to the RFA?
- A. Applicants are strongly encouraged to contact their NIH Program Officials (listed in the RFA) 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.
32. 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>

33. 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
34. 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.***

35. 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.***

36. 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.***

37. 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.***

38. 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.

39. 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.***

REVIEW

40. Are decisions appealable?
- A. For this FOA, because it is a one-time issuance, there can be no appeals to the review because there will not be a re-review or additional receipt dates. That is, the FOA is not being reissued. Funding decisions are not appealable.
41. Will individual projects receive scores and is it possible for the overall application to receive funding even if one project does not receive a favorable score?
- A. Individual projects will be reviewed and scored. There will also be an overall score, which will reflect that independent review plus the reviews of each section. Individual project scores will have an effect on the overall score. However, it is possible for an award to be made at a partial level (e.g., by dropping one project).
42. Will these applications be reviewed by a standing study section?
- A. These applications will be reviewed by a single special emphasis panel convened specifically to address the science proposed in the applications.
43. Will there be reviewers reviewing individual projects that won't have access to the overarching description?
- A. Reviewers will be assigned specific sections of each application to review. Though they will have access to the entire application, it should not be expected that reviewers must refer to sections outside of their assignment to review the part they are assigned.

POST AWARD MANAGEMENT & REPORTING

44. What exactly is meant by collaboration across all funded Centers and cross-site scientific working groups?
- A. Each Center funded under this announcement is expected to participate with the other Centers within the TCORS program on a regular basis to share information, assess scientific progress in the field, identify new research opportunities, participate in one or more cross-site scientific working groups, and form inter-center collaborations to promote discovery, address research gaps, and resolve areas of scientific disagreement. TCORS applicants will ideally demonstrate an interest in and capacity for the conduct of ad hoc time-sensitive research projects. Because we do not know which applications will be funded, applicants are not expected to provide a detailed proposal of

collaborative projects. Once the Centers have been awarded, investigators and members of the TCORS Steering Committee will identify key research opportunities that will link well across the Centers and provide excellent cross-Center research projects.

45. Will you consider any administrative supplements or competitive revisions?
A. These are options for the future if the FDA determines there is a need.
46. 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.
47. Will there be a coordinating center as mentioned in the earlier Notice of Intent to Publish?
A. We are still considering this option. If so, there will be a separate FOA.
48. 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 from TCORS funding 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/).
49. Are the reporting requirements for TCORS the same as other NIH grants?
A. No. An Interim Report will be due midway between regular annual reports.
50. 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

51. Can any unfunded applications in response to the TCORS FOA be resubmitted?
A. Unfunded applications may be submitted to a future FDA/NIH announcement or an NIH announcement. If so, these are new applications, not resubmissions (A1s).
52. Can components of my TCORS application be simultaneously submitted for consideration in response to the Tobacco Control Regulatory Research Funding Opportunity Announcements

(FOAs) [PAR-12-267](#) (R01), [PAR-12-268](#) (R03), and [PAR-12-266](#) (R21)? For example, could I submit one or more of my TCORS projects as individual R01s?

- A. Yes. You may submit applications to these FOAs for the November 1, 2012 receipt date. Note that if the TCORS is funded, the individual R application will be withdrawn. If you are unable to make the November 1 deadline, you may submit for receipt dates in subsequent years (2013, 2014 and 2015).

RESEARCH RESOURCES

53. Will the government make available reduced nicotine content cigarettes (research grade) for a research project that would be part of the P50 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).

54. 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.

55. 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.

56. 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.
57. 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: <http://grants.nih.gov/grants/guide/rfa-files/RFA-DA-13-003.html>

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