

# Frequently Asked Questions and Answers Tobacco Centers of Regulatory Science for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (U54)

[RFA-OD-17-003](#)

Updated March 22, 2017

## Application Requirements

1. What are the Research Objective requirements for a **Tobacco Centers of Regulatory Science** (TCORS) application?
  - A. Applicants are required to: 1) identify an overall Integrative Theme for their proposed TCORS, and 2) propose a program of research that identifies no less than two of the Scientific Domains listed in the [RFA](#).
2. What type of Integrative Theme would be appropriate for a TCORS application?
  - A. The Integrative Theme may be organized around a number of tobacco regulatory research areas. Examples include: a specific scientific topic, a tobacco product, a level of analysis, or type of method(s). However, all TCORS applications should focus on areas with *significant gaps in knowledge* (i.e., where focused, collective, interdisciplinary efforts could make the greatest difference in reducing tobacco use and its adverse health consequences through the regulation of the manufacture, distribution, and marketing of tobacco products).
3. What are the Scientific Domains relevant for this application?
  - A. Applications must propose a program of research that includes no less than two of the following seven Scientific Domains across all projects: Toxicity, Addiction, Health Effects, Behavior, Communications, Marketing Influences, and Impact Analysis. Please see description of each Domain in the RFA.
4. Does each Research Project need to address two or more Scientific Domains?
  - A. No. Each research project must address one or more of the seven Scientific Domains. The Research Projects in an application must collectively address two or more Scientific Domains.
5. Would it be beneficial to propose a TCORS covering all Scientific Domains?
  - A. No. Addressing many or all Scientific Domains in one application may NOT be advantageous, as it could be difficult to present a focused proposal around a cohesive Integrative Theme.
6. What are the required Components for a TCORS Administrative Structure?
  - A. The following are the required Component Types specified in Part 2 Section IV of the application:
    - At least *three* fully developed hypothesis-driven Research Projects that contribute individually to the goals of the TCORS program and collectively to the Integrative Theme
    - An Administrative Core which includes a Rapid Response Program
    - A Career Enhancement Core

- Optional: other Center-named core(s) as needed and justified
7. Should the individual projects be considered as R01-like?
- A. Yes. The individual research projects could be thought of as R01s that are integrated and complementary to the larger TCORS goals, aims, and Integrative Theme.

### **Rapid Response Projects (RRPs)**

8. What are Rapid Response Projects (RRPs)?
- A. These projects are part of the Administrative Core of the TCORS application. Each TCORS awardee will be required to participate in yearly Rapid Response Projects (RRPs) in years 2–5 of the award. Time-sensitive topics for RRP will be identified by the NIH and FDA in collaboration with a Coordinating Center and TCORS Steering Committee. The NIH and FDA will have *final approval* of all proposed and identified RRP. The TCORS Administrative Core will be required to solicit, review, and select the RRP proposals put forth by their Center, and are also responsible for monitoring the progress of their TCORS RRP.
9. How many Rapid Response Projects (RRPs) will be anticipated per year?
- A. It depends on the research needs of the FDA and NIH. Beginning with the second year of the U54 TCORS award, applicants are required to set aside \$200,000 in direct costs per year to use for RRP, which will be reviewed by the Steering Committee for final approval by the NIH and FDA as described in question 7.

### **Career Enhancement Core**

10. What are the requirements of the Career Enhancement Core?
- A. The Career Enhancement Core will provide exposure to and experience in Tobacco Regulatory Science (TRS), including aiding students, fellows, scholars, new and early-stage investigators, and investigators new to TRS on their path toward becoming independent TRS investigators. Centers are expected to propose a plan for enabling appointees to develop independent research projects and to engage in professional development.
- B. Career/research enhancement activities are expected to include supervised research studies. The studies may either fall within the overall theme of the TCORS (or be conducted as inter-TCORS collaborative studies). All proposed pilot projects will require prior approval from the NIH and FDA CTP to assess responsiveness to FDA CTP Tobacco Regulatory Authorities before any expenditure of funds and/or work on the pilot project is initiated.
- C. This Core will provide the TCORS with a unique opportunity to create collegial and collaborative networks among investigators. TCORS are expected to develop mechanisms for establishing these networks and for sharing resources for development of TRS expertise, including existing curricula/courses, research opportunities, and the expertise of established investigators.
- D. Please note that self-standing institutional training/education/career development programs are *NOT appropriate* for this Core and must not be proposed. For example, TCORS cannot support institutional National Research Service Award (NRSA) programs, such as T32 Training Grants.

11. Does it matter where the application budgets for payment for conferences? That is, can it be through the Administrative Core or through the Career Enhancement Core?
  - A. Either Core is acceptable. For instance, a TCORS may propose to use its Administrative Core to manage these funds for career enhancement conference participation. However, conference costs associated with career enhancement must be supervised through the center's Career Enhancement Core.
12. Can funds be requested to support pre-doctoral and/or post-doctoral candidates at NIH stipend levels and including tuition?
  - A. Yes, applicants may request funding to support pre-doctoral and/or post-doctoral candidates in their application. Note that pre-doctoral candidates will not be allowed to exceed (with salary and tuition combined) the current NRSA -0- level. Specific questions regarding an application's budget should be directed to the appropriate grants management contact listed in [Section VII of the RFA](#).
13. Can foreign students be supported in the U54 Career Enhancement Core?
  - 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 tobacco regulatory science, smoking prevention, and tobacco control.

## Eligible Applicants

14. Are foreign institutions eligible to apply?
  - A. No, foreign institutions *are not eligible* to apply, including Non-domestic (non-U.S.) Entities (Foreign Institutions) and Non-domestic (non-U.S.) Components of U.S Organizations. However, Foreign Components, as defined by the [NIH Grants Policy Statement](#) are allowed.
15. May applicants include NIH intramural researchers as part of the transdisciplinary/multidisciplinary team?
  - A. Yes. In general, NIH intramural researchers may collaborate or consult with extramural researchers who apply for a U54 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.
16. 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, applicants are not subject to a maximum allowable percentage of 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.

## Budget

17. 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 non-responsive.
18. 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 funding 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. How should applicants prepare budgets for future years of a TCORS?
- A. Applicants should follow the budget instructions in the [SF424 \(R&R\) Application Guide](#). The RFA states, a "*U54 center may not exceed \$4 million in total costs per year.*" Therefore, applicants should not request program expansion beyond that amount.

## Timeline

20. Should salary increases due to escalation or inflation be included in the application's budget?
- A. A. No, escalation or inflation costs should not be included in the application. Only costs required by the work needed for the study should be included. Changes in cost due to level of effort changes and fluctuations associated with the science performed will be honored. Applicants should request what is needed to complete the work proposed and grants management will make any necessary modifications in accordance with current funding guidelines if the application is selected for award. Specific questions regarding an application's budget should be directed to the appropriate grants management contact listed in [Section VII of the RFA](#).
21. What are the upcoming dates to keep in mind?
- A. Letters of Intent must be RECEIVED by May 19, 2017. TCORS Center applications must be RECEIVED by July 19, 2017.
22. Am I required to submit a Letter of Intent?
- A. A Letter of Intent is not required, and it does not enter into the review process. However, it allows NIH staff to estimate the potential review workload and plan the review. Investigators are encouraged to communicate with NIH scientific contacts to discuss their research ideas and specific aims prior to submitting applications, as all proposed research-specific aims must be within the regulatory authority of the FDA CTP and cover no less than two Scientific Domains described in the RFA in order to be deemed responsive to this FOA. Applications that are non-responsive will not be reviewed.

Suggested content of Letter of Intent:

- Descriptive title of proposed activity
- 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
- Specific Aims

23. Where do I send the letter of intent?

A. The Letter may be sent by email to: [TRSP@mail.nih.gov](mailto:TRSP@mail.nih.gov)

Or by regular mail to:

Tobacco Regulatory Science Program  
 Office of Disease Prevention  
 6100 Executive Boulevard  
 Room 3B01, MSC 7530  
 Bethesda, MD 20892-7530 (Use Rockville, MD 20852 for Express Mail)  
 Tel: 301-451-7464  
 Fax: 301-480-2230

24. When will awards be made?

A. Awards will be made in FY18

### **Other Applications Guidelines**

25. What are the application page limits?

A. All page limitations are described in the RFA. The Table of Page Limits must be followed, in addition to the following page limitations to the Research Strategy section of each component of the application:

- Overall (Overview of the Proposed Center): 12 pages
- Research Projects: 6 pages
- Administrative Core: 6 pages
- Career Enhancement Core: 6 pages
- Other Core(s): 6 pages

26. 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.

27. May 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.

### **Responsiveness**

28. How do I know if my application is responsive to the RFA?

A. Multiple aspects of the application contribute to a determination of responsiveness, including the following requirements:

- *Identification of an overall Integrative Theme*
- *A program of research that addresses no less than two of the seven Scientific Domains listed in the RFA*
- *All Specific Aims across Research Projects must fall within the regulatory authority of the FDA Center for Tobacco Products*

- *No aim(s) may address the non-responsive research topics outlined in the RFA*

As such, applicants are strongly encouraged to contact the Scientific/Research Contacts 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, the NIH and FDA. Applications that are incomplete and/or nonresponsive will not be reviewed.

29. In general, what areas of research are **not within the FDA CTP's regulatory authority**?

A. [The Family Smoking Prevention and Tobacco Control Act](#) gives the 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, the 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 policies
- Regulating tobacco growing

30. Within the list of priorities under the Scientific Domain "Impact Analysis," the [RFA](#) states that one priority is "evaluation of policies at the state and community level that fall within the FDA CTP regulatory authorities." Which types of policies fall within, versus outside of, FDA CTP regulatory authorities?

A. As noted in the previous question, the CTP's regulatory authorities do not extend to setting tax rates or clean indoor air policies. As such, studies evaluating the impact of a tobacco tax increase or smoking ban are not responsive. Similarly, as the CTP does not have authority over the sale of tobacco cessation medications, a study evaluating the impact 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.**

31. Are public opinion polls about tobacco regulations responsive to FDA CTP regulatory authorities?

A. No. Unlike state or local policymaking, where public support can be an important factor in the adoption and implementation of policies, public opinions cannot be used to support federal regulations.

32. Within the Scientific Domains "Toxicity" or "Health Effects," is a research proposal which investigates the mechanisms and/or etiology of tobacco-related disease responsive?

A. It depends. Mechanistic and/or etiologic research is largely relevant to disease prevention or treatment, neither of which is within the 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/Research Contact and to consider submitting a Letter of Intent.

33. Within the Scientific Domain “Addiction,” is a treatment intervention study designed to compare the effectiveness of various tobacco products on tobacco cessation considered responsive?

A. No. The CTP’s regulatory authority does not extend to regulating therapeutic uses of tobacco products, as this authority rests with other Centers within the 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, the 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.**

34. Within the Scientific Domains “Toxicity” or “Health Effects,” is a research proposal in which the primary outcome informs treatment of disease considered responsive?

A. No. The CTP does not regulate products or support development of clinical 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.\*

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

35. What additional areas of research will be considered non-responsive for TCORS applications?

A. The list of non-responsive research topics includes, but is not limited to, the topics outlined in the RFA, which are listed below. We recommend that applicants seek the input of one or more Scientific Research Contacts listed in the RFA regarding the responsiveness of their aims.

- Studies of short-term health effects and/or acute toxicology/clinical pharmacology testing of early-generation ENDS products
- Mechanistic studies/basic science of disease development, unless biomarkers of harm with predictive value for disease development associated with tobacco product use is an outcome
- Short-term studies of the acute effects of reduced-nicotine-content cigarettes
- Graphic health warnings for cigarette packages and advertisements
- Communicating harmful and potentially harmful constituents to the public
- Impacts of marketing restrictions on adults
- Descriptive studies of demographics and/or risk perceptions that describe only exposure to advertising without linking exposure to tobacco use behaviors

## Review

36. Are decisions appealable?
- A. **No. Funding decisions are not appealable** because this FOA is a one-time issuance with no opportunity for a re-review or additional receipt dates.
37. Will individual projects receive scores? Is it possible for the overall application to receive funding even if one project does not receive a favorable score?
- A. Yes, 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 as long as the Center still has 3 active projects).
38. Will these applications be reviewed by a standing study section?
- A. No. These applications will be reviewed by a single Special-Emphasis Panel (SEP) convened specifically to address the science proposed in the applications.
39. Will there be reviewers reviewing individual projects who will not 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. Consequently, applicants are encouraged to construct each core as separate and self-contained.

## Post-Award Management & Reporting

40. What does collaboration across all funded Centers and cross-site scientific working groups mean?
- 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 conducting 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 possible 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.
41. Will you consider any administrative supplements or competitive revisions?
- A. Administrative supplements and/or competitive revisions may be considered if the FDA identifies a need.
42. 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.
43. Are the reporting requirements for TCORS the same as other NIH grants?



- A. No. In addition to the standard NIH reporting requirements, grants awarded using CTP funds are required to also submit an Interim Progress Report six (6) months after the start of the budget year.
44. 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, the 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 the statute, Congress must appropriate the funds before the FDA can obligate them. The tobacco industry has no control over CTP funding decisions. The FDA uses some of these funds to award research grants.

## Resubmission

45. 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 considered new applications, not resubmissions (A1s).
46. Can components of my TCORS application be simultaneously submitted for consideration in response to other Tobacco Control Regulatory Research Funding Opportunity Announcements? For example, could I submit one or more of my TCORS projects as individual R01s?
- A. Yes. You may submit applications to existent FOAs. However, note that if the TCORS is funded, the individual R application will be withdrawn

## Research Resources

47. What is the PhenX Toolkit, and why does the RFA encourage its use?
- A. The [PhenX Toolkit](#) is a web-based catalog of freely-available standard measures that can be easily incorporated into research studies. The measures span many scientific domains, and include Specialty Collections in Tobacco Regulatory Research (TRR). As noted in [NOT-OD-17-034](#), the TRR Collections provide a common set of recommended measures that, when incorporated across studies, will facilitate data sharing, comparing, and integration, as well as replication and validation of findings. The measures that are included in the PhenX Toolkit were identified by working groups of experts within each of the scientific domains, followed by outreach to the relevant scientific communities to establish a consensus for the prioritized, recommended measures. PhenX measures are typically well-established, broadly validated measures that are low-burden to the participant and investigator. The TRR Collections include standard measures like the Fagerstrom Test for Nicotine Dependence and questions found in large and/or nationally representative surveys like the Population Assessment of Tobacco and Health (PATH) and the National Youth Tobacco Survey (NYTS). For more information about the TRR Collections in the PhenX Toolkit, see the [TRSP website](#).
48. Will the government make available reduced-nicotine-content cigarettes (research grade) for a research project that would be part of a U54 grant?
- A. A limited supply of reduced-nicotine-content (RNC) cigarettes for research is available through the National Institute on Drug Abuse (NIDA) Drug Supply Program. Please visit their website to review their application process <http://grants.nih.gov/grants/guide/notice-files/NOT-DA-14-004.html>.

49. What will be the availability of confidential information obtained by the FDA, for example, specific tobacco product(s) and constituent reporting?
- A. Several laws govern the confidentiality of tobacco product information submitted to the 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 the FDA's implementing regulations. The 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.
50. If a scientific study proposes to make ANY change to a currently marketed tobacco product (e.g., manipulating the size of the product; putting the tobacco product in different colored packaging), then an investigational tobacco products (ITP) request is recommended by the FDA (Reference: [Draft Guidance Use of Investigational Tobacco Products](#)). What information is required in the ITP request?
- A. The information needed in an ITP request may vary depending on the proposed ITP and the type of study. The FDA needs to determine whether the product is a tobacco product, whether the tobacco product is within our current jurisdiction, whether the tobacco product is an ITP, and whether the study products will be provided to human subjects. For example, if one makes a change in labeling of a commercially marketed tobacco product and it will not be used by human subjects, no ITP request is needed. If one makes a change in labeling of a commercially marketed tobacco product and there will be actual use by human subjects, then the FDA recommends that an ITP request come to the CTP for review, but it is likely that chemistry, engineering, and manufacturing will not be needed. If you have questions about ITP, please contact Debbie Cordaro ([debbie.cordaro@fda.hhs.gov](mailto:debbie.cordaro@fda.hhs.gov)).

NIH Guide FOA: <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-003.html>

NIH-FDA Tobacco Regulatory Science Program Website:  
<https://prevention.nih.gov/tobacco-regulatory-science-program>