

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-17-006](#)

Updated July 11, 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. There is a very big overlap between toxicity and health effects, so most people who are addressing one are automatically addressing the other. It's a concern given that addressing too many priorities is considered non-advantageous. Can they be combined?
 - A. As there is overlap across several of the [Scientific Domains](#), it will be necessary for the applicant to determine which domain (s) best represent the focus of their research proposal(s). It is not necessary to include all Scientific Domains each Research Project *could* conceivably address; rather, applicants should indicate how the primary aim(s) of the Research Projects are integrated into an overall theme for your center.

7. 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
8. Do principal investigators (PIs) for the overall TCORS and individual projects need to have R01s in order to apply to this RFA?
 - A. No. Having an R01 is not a requirement for PIs in order to apply to this RFA. As stated in the RFA, any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Note that reviewers will be assessing whether the PD(s)/PI(s), collaborators, and other researchers are well suited to the project.
9. 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)

10. 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.
11. 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.
12. What's the difference between pilot projects and rapid response projects (RRPs)?
 - A. *Rapid Response Projects (RRPs)* provide a mechanism for TCORS to respond to novel, time-sensitive research questions that can advance the field of tobacco regulatory science. RRP fall within the scope of the Administrative Core. Topics to be addressed through RRP will be identified in years 2–5 by the NIH, FDA, and the TCORS Steering Committee members (i.e., topics for RRP are not generated by individual TCORS). All TCORS applications must set aside \$200,000 in direct costs in years 2–5 for this purpose. Every effort will be made to ensure that each TCORS will have RRP for each

year of the set-aside. The timeline for solicitation and selection of RRP projects is intended to coincide with the project periods, hence the start of the RRP in year 2. As such, TCORS should expect to use their \$200k set-aside each year on RRP. *Pilot projects* are intended to serve as career enhancement opportunities for students, fellows, scholars, New and Early-Stage Investigators, and/or investigators new to tobacco regulatory science (TRS). Pilot projects fall within the scope of the Career Enhancement Core and should focus on research experiences and related activities that will enhance development of TRS expertise. Pilot project topics are developed, proposed, and selected by the individual TCORS, but they must be approved by the NIH and FDA for responsiveness before implementation. As with all TCORS research, pilot project aims must fall within the scope of FDA regulatory authorities.

13. Can institutional funds be used to support the RRP?
 - A. No. Co-mingling of funds in CTP-awarded grants is **not** allowed. Therefore, institutional funds may **not** be used to support RRP. As stated in the RFA, applications should include a budget set-aside of up to \$200,000 in direct costs each year in years 2–5 for RRP.
14. Are pilot projects and rapid response projects limited to postdoctoral scholars/fellows only?
 - A. No. Pilot projects and rapid response projects are not limited to a specific type of investigator. It will be up to the TCORS to decide who is best suited to meet the program's objectives and conduct the research.

Career Enhancement Core

15. 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, postdoctoral 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 participants to develop independent research projects and to engage in professional development.
 - B. Supervised research studies are expected to be a substantial component of the career/research enhancement activities. 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 full-time year-round research training such as that supported under institutional National Research Service Award (NRSA) training grants.

16. 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?
- 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 managed through the center's Career Enhancement Core.
17. Can funds be requested to support pre-doctoral and/or post-doctoral candidates at NIH stipend levels and including tuition remission?
- A. Yes, graduate students and post-doctorates performing TCORS research may be supported by the program. Note that awards funded under the Career Enhancement Core will be made through NIH's research authority as opposed to training authority. As such the support must be through salaries rather than stipends and should be consistent with NIH's policy for graduate student compensation ([NOT-OD-02-017](#)). Specific questions regarding an application's budget should be directed to the appropriate grants management contact listed in [Section VII of the RFA](#).
18. We understand that the Career Enhancement Core cannot be a self-standing institutional training/education/career development program, but are the terms "training" and "education" appropriate for use in describing the aims of this core?
- Yes, as applicable, "training" and "education" may be used to describe activities in this core. Note that this RFA does not ask for formal training, but rather asks for career enhancement activities. Your application needs to address what the RFA requires. You may use any terminology you wish to describe career enhancement activities.
19. Could participants of the Career Enhancement Core, such as graduate students, postdocs, etc., take advantage of existing training or educational programs at their institutions (e.g., T32 or R25)?
- A. Given the description of the Career Enhancement core that was included in the [FOA](#), several potential scenarios would be anticipated in which students and postdocs might be involved in TCORS activities:
- Students or postdocs might be working as research assistants/research associates in conjunction with one of the proposed TCORS research projects. In this scenario, they would be paid from TCORS funds and be "employees" of the university.
 - T32 trainees, "F" fellows, or K12/KL2 scholars might obtain pilot research funds from the TCORS, and consult with and/or work with TCORS investigators on their research projects. In these situations, they would continue to be supported by the grant they were appointed to (or fellowship they received) and they would not draw any additional compensation from the TCORS center.

Eligible Applicants

20. 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.

21. 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.
22. 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.
23. Can a single scientist serve as an investigator on more than one U54 application?
- A. Yes, an investigator may serve as an investigator on more than one U54. However, applicants are encouraged to carefully consider the effort they will carry in these large grants as level of effort will be taken into consideration. NOTE: Key personnel of the CASEL awardee team cannot include key personnel from the research team of a TCORS awardee.
24. Is a subcontract or collaboration with a foreign entity to study a new tobacco product expected to be reviewed by the FDA in a test market in their country eligible for funding as a subcontractor or collaborator?
- A. Yes, as long as the product meets the definition of a tobacco product and therefore would be regulated as a tobacco product under the FDA's regulatory authorities if sold in the United States. Justification for foreign collaboration would need to be included as well as applicability to the United States.

Budget

25. 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.
26. 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.

27. 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

28. Should salary increases due to escalation or inflation be included in the application's budget?
- 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](#).
29. 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.
30. 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
31. If an applicant sends a letter of intent (LOI) in early May and obtains feedback that part of the application is off target or non-responsive, can they resubmit a revised LOI?
- A. Yes, it is recommended that applicants communicate with the appropriate scientific contact listed in [Section VII. Agency Contacts](#) as early as possible. Also, it is important to note that an LOI is not required, not binding, and does not enter into the review of an application.

32. Where do I send the letter of intent?

- A. The letter may be sent by email to: 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

33. When will awards be made?

- A. Awards will be made in FY18

Other Applications Guidelines

34. 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: 12 pages
 - Administrative Core: 6 pages
 - Career Enhancement Core: 6 pages
 - Other Core(s): 6 pages

35. Does the specific aims page count towards the page limitations specified in [Section IV of the RFA](#)?

- A. Applicants have the opportunity to upload a Specific Aims Page to summarize their specific aims. This Specific Aims document is **separate** from the allowed page limitations listed in [Section IV of the RFA](#). This applies to all components of the application.

36. Where can the applicant find additional information regarding application submission?

- A. For questions regarding Grants.gov registration and submission, as well as downloading forms and application packages, please contact [Grants.gov Customer Support at support@grants.gov](#).
- B. For questions regarding application instructions, process, and finding additional NIH grant resources, please contact GrantsInfo at GrantsInfo@nih.gov.
- C. For scientific and responsiveness questions, please contact the appropriate scientific contact listed in [Section VII of the RFA](#).

37. 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.

38. May applicants provide a list of acronyms for the different sections of the application?
- A. **(CORRECTED ANSWER):** Yes. Applicants are welcome to include a list of acronyms in the Research Strategy for the different Cores, but such a list will be included in the page limit for that attachment.

Responsiveness

39. 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.

40. 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 polices
 - Regulating tobacco growing

41. Will applications that propose to study products not yet available in the United States be considered responsive?
- A. Yes, if the product(s) meets the statutory definition of a "tobacco product" under the Tobacco Control Act (i.e., any product made or derived from tobacco and intended for human consumption, including any component, part, or accessory of a tobacco product), then studies examining these products could be considered responsive to the RFA. However, the application must demonstrate that the proposed research can directly contribute to the FDA's regulatory authority over the manufacture, marketing, and distribution of tobacco products within the United States. As the relevance may be dependent on not only the product, but also the types of research being conducted, we recommend that you discuss any particular proposed research with one or more of the [Scientific/Research Contacts listed](#) in the RFA.

42. Would an application that proposed to study a heat-not-burn product that is already included in a modified-risk tobacco product (MRTP) application be considered responsive?
- A. Potentially, yes. While heat-not-burn products would be considered a “tobacco product” under the Tobacco Control Act and would fall under the regulatory authority of the FDA CTP as a result of the [deeming rule](#), both the responsiveness of a research proposal investigating this product and its relevance to the FDA CTP priorities would depend upon the type of research being proposed. As such, we recommend that you discuss any particular proposed research with one or more of the [Scientific/Research Contacts](#) listed in the RFA.
43. Are studies of acute topography effects of second-generation ENDS responsive to this RFA (as early-generation ENDS acute topography studies are non-responsive)?
- A. Yes. For this RFA, the FDA is not interested in studies of short-term health effects and/or acute topography/clinical pharmacology testing of early-generation ENDS products.
44. The RFA states that “short-term studies of the acute effects of reduced nicotine content cigarettes” would be deemed non-responsive to the RFA. What does this RFA consider “short- term”?
- A. There is not a specific timeframe that defines “short term” or acute outcomes. However, the appropriate length for any study is dependent upon the research question. Applicants are encouraged to familiarize themselves with the funded research and published literature in this area through the [NIH](#), the [TRSP program, and other CTP-supported tobacco regulatory research](#) and see how their proposed research could expand on the current understanding of reduced nicotine cigarette use.
45. 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.**
46. What topics are considered responsive within the Scientific Domain “Impact Analysis”?
- A. The following types of analyses are examples* of topics that would be considered responsive under “Impact Analysis”:
- Computational/mathematical modeling and simulation and/or statistical modeling of the public health impact of potential FDA/CTP action
 - Health and economic impact of tobacco use and/or tobacco regulatory policies on vulnerable populations
 - Economic burden (e.g., health care cost, productivity loss) of tobacco-related diseases on users and non-users (e.g., secondhand and thirdhand exposure)

- Studies evaluating the impact of tobacco regulatory actions (e.g., mandated changes in product characteristics) on consumer behavior or behavioral intentions

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

47. 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.

48. 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.

49. 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.**

50. 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.**

51. 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

52. 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.

53. 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 impact score for the entire application, which will reflect that independent review of the individual project plus the reviews of all other sections. 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).

54. 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.

55. Will there be reviewers reviewing individual projects who will not have access to the overarching description?

- A. Reviewers will either be assigned specific sections of each application to review or be assigned to the entire application. Though they all will have access to the entire application, please do not expect that reviewers will refer to sections outside of their assignment to review the part they are assigned. Applicants are encouraged to construct each Research Project and Core as separate and self-contained.

56. For existing TCORS, how should progress be reported? How will it be used in the review process?

- A. If the existing TCORS is submitting as a renewal application, the applicant should incorporate progress of current TCORS and preliminary results, but must stay within

specified page limits. Renewals also are allowed to submit a progress report publications list.

57. Do all current TCORS have to go in as a renewal? If the TCORS is submitted as a renewal, do the title and aims have to be the same from the original submission?
- A. It is up to the applicant to decide whether or not to submit as a type 1 (new application) or type 2 (renewal). Type 2 applicants are permitted to submit a progress report publication list, but should also be aware that reviewers will have access to the summary statement from the original type 1 application. Please keep in mind that if you are submitting as a New application (type 1), you may not include the progress report publication list, and you would not include a progress report in the Research Strategy section. The type 1 applicant may include preliminary data, but should prepare the application with no references to the funded application. If submitted as a renewal, changes in title and aims are up to the applicant.
58. If an additional statistical core is included in the proposal, are the additional cores evaluated separately or as a whole?
- A. It will be evaluated individually and incorporated in the overall evaluation.
59. Our manuscript was accepted for publication after the application due date. Can I send it to the Scientific Review Officer (SRO) to be included with my application?
- A. Yes, you can send the SRO a note of acceptance that **only** includes the list of authors and institutional affiliations, title, and journal/citation. Do **not** send comments, abstract, manuscript, or links--just a note that the manuscript has been accepted. Such a note must be submitted or approved by the Grant Signing Official and not later than one month before the date of the review meeting. Please note that this option is to indicate *acceptance* of the manuscript, not for final publication. For post-submission guidelines, see the *supplemental materials policy* here: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-130.html>

Post-Award Management & Reporting

60. 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.
61. 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.

62. 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.
63. 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.
64. 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

65. 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).
66. 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

67. 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](#).

68. Will NIDA research cigarettes (e.g., SPECTRUM) be available for TCORS research funded through this RFA on a similar basis as currently?

A. Yes. NRC Spectrum Cigarettes will be available for this round of TCORS awards. However, please contact Ms. Phylcia Porter (Phylcia.porter@nih.gov) in the NIDA Drug Supply Program with a grant number and a Letter of Authorization (LOA). LOAs are specifically based on grant numbers. Please visit <https://www.drugabuse.gov/nicotine-research-cigarette-drug-supply-program> for updated information on the NIDA Drug Supply Program.

69. Might it be possible to obtain other research tobacco products (e.g., cigars, roll-your-own tobacco or e-cigarettes) with known nicotine concentrations for use in TCORS research projects funded through this RFA?

A. At this time, we are aware of one additional research tobacco product, the standardized research e-cigarette (SREC) developed by the National Institute on Drug Abuse (NIDA), NIH. Unlike the SPECTRUM combustible cigarette provided by NIDA to researchers at no cost, the SREC was developed under a small business contract issued by NIDA to NJOY, LLC. Consequently, researchers will purchase the SREC directly from NJOY. The SREC is anticipated to be available for purchase by the second half of CY2017. Researchers with NIH funding to use the SREC are guaranteed to be able to purchase the devices; however, there is no expectation that NJOY will be limiting access to the SREC.

70. 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.

71. 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).

NIH Guide FOA:

<http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-006.html>

NIH-FDA Tobacco Regulatory Science Program Website:

<https://prevention.nih.gov/tobacco-regulatory-science-program>