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-22-004
Updated June 13, 2022

NIH Guide FOA: Tobacco Centers of Regulatory Science (TCORS) for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (U54 Clinical Trial Optional)

NIH-FDA Tobacco Regulatory Science Program website

1. Application Requirements

What are the Research Objective requirements for a Tobacco Centers of Regulatory Science (TCORS) application?

Applicants are required to: 1) identify an overall Integrative Theme for their proposed TCORS, and 2) propose a program of research that identifies no fewer than two of the Scientific Domains listed in the Request for Applications (RFA).

What type of Integrative Theme would be appropriate for a TCORS application?

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).

What are the Scientific Domains relevant for this application?

Applications must propose a program of research that includes no fewer than two of the following eight Scientific Domains across all projects: Composition and Design of tobacco products, Toxicity, Addiction, Health Effects, Behaviors, Communications, Marketing Influences, and Impact Analysis. Please see description of each Domain in the RFA.

Does each Research Project need to address two or more Scientific Domains?

No. Each research project must address one or more of the eight Scientific Domains. The Research Projects in an application must collectively address two or more Scientific Domains.

Would it be beneficial to propose a TCORS covering all Scientific Domains?

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.

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?

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.

What are the required Components for a TCORS Administrative Structure?

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
- A Career Enhancement Core
- Optional: other Center-named core(s) as needed and justified.

Do principal investigators (PIs) for the overall TCORS and individual projects need to have R01s in order to apply to this RFA?

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 assess whether the PD(s)/PI(s), collaborators, and other researchers are well suited to the project. Generally, the overall PI of a U54 would be expected to have extensive experience as a lead investigator.

Should the individual projects be considered as R01-like?

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.

2. Pilot Projects

What are pilot projects?

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 the 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.

Are pilot projects limited to postdoctoral scholars/fellows only?

No. Pilot 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.

3. Career Enhancement Core

What are the requirements of the Career Enhancement Core?

The Career Enhancement Core will provide exposure to and experience in 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.

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 Center for Tobacco Products (CTP) to assess responsiveness to FDA CTP Tobacco Regulatory Authorities before any expenditure of funds and/or work on the pilot project is initiated.

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 the development of TRS expertise, including existing curricula/courses, research opportunities, and the expertise of established investigators.

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.

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 funds for career enhancement conference participation. However, conference costs associated with career enhancement must be managed through the center's Career Enhancement Core.

Can funds be requested to support pre-doctoral and/or post-doctoral candidates at NIH stipend levels and including tuition remission?

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.

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.

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)?

Given the description of the Career Enhancement Core that was included in the Funding Opportunity Announcement (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.

4. Eligible Applicants

Are foreign institutions eligible to apply?

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.

May applicants include NIH intramural researchers as part of the transdisciplinary/multidisciplinary team?

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.

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?

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.

Can a single scientist serve as an investigator on the TCORS application and CASEL and/or CRST?

While an investigator may participate in more than one center application, note the following restrictions for participating on these grants once they are funded: the overall TCORS PD/PI awardee cannot serve as overall PD/PI of a CRST awardee nor as key personnel of a CASEL awardee. However, a TCORS project lead/key personnel could serve as overall PD/PI of a CRST awardee. Key personnel of a TCORS awardee cannot include key personnel from the research team of a CASEL awardee.

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?

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.

5. Budget

What is the budget cap? Will applications that exceed the budget cap be considered?

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.

Will there be administrative cuts to any funded applications?

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.

How should applicants prepare budgets for future years of a TCORS?

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.

Can institutional funds be used to support work in a TCORS?

TCORS award funds can only be used for research activities (projects, cores, aims) outlined in the grant application that fall within CTP's regulatory authority. Non-CTP funds (e.g., NIH, institutional, or other funds) cannot be combined with TCORS funds to support work on approved primary research project aims. However, non-TCORS funds can be used to support work outside the proposed research aims, such as additional support for center core activities. Use of funds outside the TCORS award must be tracked separately from TCORS funds. This responsibility is solely on the grantee. Non-TCORS funds should not be the only support for required TCORS components such as the administrative or career enhancement cores. Planned use of additional funds or resources should be referenced in the application (e.g., letter of support or brief narrative description).

6. Timeline

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.

What are the upcoming dates to keep in mind?

Letters of Intent must be RECEIVED by May 14, 2022. TCORS Center applications must be RECEIVED by July 14, 2022.

Am I required to submit a Letter of Intent?

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 fewer 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 a 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

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?

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.

Where do I send the letter of intent?

The letter may be sent by email to: TRSP@mail.nih.gov

When will awards be made?

Awards will be made in FY2023.

7. Other Application Guidelines

What are the application page limits?

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
- Administrative Core: 6 pages
- Career Enhancement Core: 6 pages

- Other Core(s): 6 pages
- Research Projects: 12 pages

Does the specific aims page count towards the page limitations specified in Section IV of the RFA?

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.

Where can the applicant find additional information regarding application submission?

- For questions regarding Grants.gov registration and submission, as well as downloading forms and application packages, please contact Grants.govCustomerSupport at support@grants.gov.
- For questions regarding application instructions, process, and finding additional NIH grant resources, please contact GrantsInfo at GrantsInfo@nih.gov.
- For scientific and responsiveness questions, please contact the appropriate scientific contact listed in Section VII of the RFA.

Should descriptions of affiliated Centers be included in the appendix?

No, DO NOT use the appendix to circumvent the page limits.

May applicants provide a list of acronyms for the different sections of the application?

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.

8. Responsiveness

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

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 fewer than two of the eight Scientific Domains listed in the RFA
- All Specific Aims across Application Component Types (Overall, Cores, and Research Projects) must fall within the regulatory authority of the FDA Center for Tobacco Products and the RFA's Research Objectives
- 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.

Where can I find examples of general types of research considered responsive versus non-responsive under FDA CTP's regulatory authorities?

We have developed a comprehensive document with examples. Please see FAQs: Responsiveness to the FDA's Center for Tobacco Products Regulatory Authority.

What areas of research are *not responsive to this RFA*?

Although the following research topics may be within FDA CTP's regulatory authorities to fund, they are not to be included in applications and will be deemed non-responsive:

- Studies of short-term health effects and/or acute topography/clinical pharmacology testing of early generation ENDS products
- Mechanistic studies (i.e., basic science of disease development), unless biomarkers of harm with predictive value for disease development associated with tobacco product use is an outcome
- Studies developing or testing graphic health warnings for cigarette packages and advertisements
- Communicating harmful and potentially harmful constituents to the public
- Impacts of marketing restrictions on adults, except for studies on newly authorized products
- Descriptive studies of demographics and/or risk perceptions that describe only exposure to advertising without linking exposure to tobacco use behaviors
- Studies of retailer compliance to the tobacco product regulations not associated with user behaviors or marketing strategies
- Studies of physician or other health professional knowledge, attitudes, perceptions, and behaviors toward the use of ENDS or other tobacco products.

9. Review

Are decisions appealable?

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.

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?

Yes, individual projects will be reviewed and scored. There will also be an overall impact score for the entire application, which will reflect the 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).

Will these applications be reviewed by a standing study section?

No. These applications will be reviewed by a single Special-Emphasis Panel convened specifically to address the science proposed in the applications.

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

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 and review the part they are not assigned. Applicants are encouraged to construct each Research Project and Core as separate and self-contained.

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

Note that the Progress Report falls within the Research Strategy and is therefore included in the page limits for the Research Strategy. For renewal applications, provide a Progress Report with the beginning and ending dates for the period covered since the last competitive review. In the Progress Report, you should:

- Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement.
- Explain any significant changes to the specific aims and any new directions, including changes resulting from significant budget reductions.
- Discuss previous participant enrollment (e.g., recruitment, retention, inclusion of women, minorities, children, etc.) for any studies meeting the NIH definition for clinical research. Use the Progress Report section to discuss, but not duplicate information collected elsewhere in the application.

Note: Do not include a list of publications, patents, or other printed materials in the Progress Report. That information will be included in the "Progress Report Publication List" attachment. This information should be attached as a PDF file. See NIH's Format Attachments page.

For more information, please refer to the How to Apply - Application Guide, multi-project instructions.

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?

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.

If an additional statistical Core is included in the proposal, are the additional Cores evaluated separately or as a whole?

It will be evaluated individually and incorporated in the overall evaluation.

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?

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-19-083.html.

10. Post-Award Management & Reporting

What does collaboration across all funded Centers and cross-site scientific working groups mean?

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.

Will you consider any administrative supplements or competitive revisions?

Administrative supplements and/or competitive revisions may be considered if the FDA identifies a need.

Which NIH Institute/Center will manage my award?

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.

Are the reporting requirements for TCORS the same as other NIH grants?

No. In addition to the standard NIH reporting requirements, grants awarded using CTP funds are required to also submit a Mid-Period Progress Report six (6) months after the start of each budget period.

Some researchers are under limitations with respect to accepting funds from the tobacco industry. How will these FDA research awards be funded?

As mandated in the Tobacco Control Act, 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.

11. Resubmission

Can any unfunded applications in response to the TCORS FOA be resubmitted?

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).

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?

Yes. You may submit applications to existent FOAs. However, note that if the TCORS is funded, the individual R application will be withdrawn.

12. Research Resources

What is the PhenX Toolkit, and why does the RFA encourage its use?

NIH and FDA encourage investigators involved in human-subjects studies to consider a common set of tools and resources that will promote the collection of comparable data across studies, and to do so by incorporating the measures available in PhenX Toolkit, including the Tobacco Regulatory Research Core and Specialty Collections. Please see NOT-OD-17-034 for further details.

What will be the availability of confidential information obtained by the FDA, for example, specific tobacco product(s) and constituent reporting?

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.

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 product (ITP) request is recommended by the FDA (Reference: Draft Guidance on Use of Investigational Tobacco Products). What information is required in the ITP request?

The information to be included in an ITP request may vary depending on the proposed ITP and the type of study. The ITP request should identify all products intended for use in the study. Before reviewing the study protocol, the FDA needs to determine whether the product is a tobacco product, whether the tobacco product is within FDA's current jurisdiction, whether the tobacco product is an ITP, and whether the study products will be provided to human subjects. The FDA will review any protocol submitted to the agency that involves administration of an ITP to human study participants.

In particular, the FDA recommends submission of an ITP request and the study protocol to the FDA for review if the study design is likely to raise concerns about human subject protection and/or public health. As discussed in the February 2019 guidance Use of Investigational Tobacco Products, factors to consider include: studies that plan to enroll vulnerable populations (particularly those < 21 years old), studies that may involve significant increases over the participants' usual exposure to nicotine, studies that modify the tobacco product in a manner different from that described by the manufacturer, or study of a novel product for which there is limited experience and knowledge.

Examples:

- If the study design involves a change in labeling of a commercially marketed tobacco product and the product will not actually be used by human subjects (e.g., a perception study), then no ITP request is recommended.
- If one makes a change in labeling of a commercially marketed tobacco product and actual use by human subjects will occur, then the FDA recommends that an ITP request and the study protocol be submitted to CTP for review. However, as this example study protocol proposes the use of a marketed tobacco product with which the FDA is familiar, additional chemistry, engineering, and manufacturing will likely not be needed.

Additional questions should be directed to the FDA CTP at: CTP-OS-ITP@fda.hhs.gov.

NIH Guide FOA: grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-004.html

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