Frequently Asked Questions and Answers
Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54)

RFA-OD-22-003
Updated March 17, 2022

NIH Guide FOA: Center for Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54 Clinical Trial Not Allowed)

NIH-FDA Tobacco Regulatory Science Program Website

1. Application Requirements

What are the required Components for a CASEL application?

The following are the required Component Types specified in Part 2 Section IV of the application:

- Leadership and Logistics Core
- Analysis and Rapid Response Core
- Career Enhancement Core
- Dissemination Core
- Optional: other center-named core(s) as needed and justified

What research programs will be coordinated and facilitated by CASEL?

CASEL will provide coordination and facilitation of tobacco regulatory science grants and programs funded by the FDA Center for Tobacco Products (CTP), including the National Institutes of Health (NIH) Tobacco Regulatory Science Program (TRSP), Tobacco Centers of Regulatory Science (TCORS, RFA-OD-22-004), Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (RFA-OD-22-002), and awardees of R- and K-grants. In addition, FDA CTP-funded research is supported through the Centers for Disease Control and Prevention, other FDA Centers, and research contract organizations. See CTP-Supported Tobacco Regulatory Research Projects.

What scope of research is covered in the FDA CTP-funded programs?

Research programs funded by the FDA CTP must fall within their regulatory authority. 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. Research funded to inform these authorities covers a broad range of scientific disciplines. For more information about research responsive to the FDA CTP's regulatory authorities, please see the TRSP Responsiveness FAQs.

What are the current research priorities of the FDA CTP?

CASEL will provide coordination and facilitation of tobacco regulatory science across the CTP-funded research program. The scope of the CTP-funded research program focuses on the following priority areas:

- Product composition and design – Understanding the chemical constituents in tobacco products and the methods for measuring them across products with diverse characteristics.
- Toxicity – Understanding how tobacco products and changes to tobacco product characteristics affect their potential to cause morbidity and mortality in users and nonusers through secondary exposure; including animal (in vivo) and cell culture (in vitro) models, as well as novel alternative toxicology approaches that test the toxicity of tobacco smoke (other than cigarette), aerosols, or specific constituents in tobacco and the tobacco product.
- Addiction – Understanding the effect of tobacco product characteristics on addiction and abuse liability across populations.
- Health effects – Understanding the short- and long-term health effects of tobacco products (excluding conventional cigarettes) with priority on longitudinal data. Areas of interest include cardiovascular, cancer, neurological (e.g., seizures), oral, reproductive, and respiratory health effects (including inflammation and lung disorders (e.g., asthma, COPD).
- Behavior – Understanding the knowledge, attitudes, perceptions, and behaviors related to tobacco product use and the impact of tobacco product characteristics on behaviors across populations, as appropriate.
- Communications – Understanding how to effectively communicate to the public regarding nicotine and the health effects of tobacco products through media campaigns and digital media.
- Marketing influences – Understanding the impact of marketing on susceptibility to and initiation of using tobacco products (both classes of products and products within classes) and transitions between experimentation, initiation, regular use, product switching, dual use, and cessation-related behaviors among different populations. Topics may include marketing such as advertising, digital media, and promotions.
- Impact analysis – Understanding the potential or actual impact of FDA regulatory actions.

If the applicant proposes to collaborate with one or more organizations in carrying out the work of the proposed CASEL, 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 have a substantive role in CASEL 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 cooperative agreement. In short, there is no cap on subcontracts.

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

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.

What are the application page limits?

All page limitations are described in the Request for Applications (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
- Administration Core (use for Leadership and Logistics Core): 6 pages
- Analysis Core (use for Analysis and Rapid Response Core): 6 pages
- Career Enhancement Core: 6 pages
- Dissemination Core: 6 pages
- Optional Center-Proposed Core: 6 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, and downloading forms and application packages, please contact Grants.gov Customer Support 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.

2. Rapid Response Projects

What's the role of CASEL in the planning and conduct of Rapid Response Projects (RRPs)?

RRPs are managed under the Analysis and Rapid Response Core. This core will serve as the organizational hub for an Opportunity Fund (OF) that will support time-sensitive, rapid response projects to which extramural investigators may apply. The OF will be made available each year to support projects that address the high priority, time-sensitive research needs of the FDA CTP. CASEL will set aside $1,500,000 of its direct costs per year to award subcontracts for this purpose.

3. 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.

Are institutions and investigators that are currently receiving FDA CTP or related NIH grants or contracts eligible to apply to this RFA?

Yes, institutions and individuals currently receiving CTP-funded or related NIH grants or contracts are eligible to apply. However, applicants may not request funding for activities that are already supported by active grants or contracts (regardless of funding source).

Note: Applicant institutions may submit multiple applications in response to this FOA, RFA-OD-22-004 (TCORS), and RFA-OD-22-002 (CRST). Key personnel of the CASEL recipient team, however, **cannot** include key personnel from the research team of a TCORS nor CRST recipient.

4. Budget

Is there a cap on budget? Will applications that exceed a budget cap be considered?

The budget cap is up to **$3.8M** for fiscal year 2023. Future year amounts will depend on the availability of funds. Proposed budgets *cannot* exceed the budget cap, and applications exceeding the budget cap risk being returned as non-responsive.

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.

Is a certain amount of the TCORS and CRST budget set aside for travel to meetings per year?

Yes, TCORS and CRST investigators are expected to provide funds to support travel of investigators to attend up to two investigator meetings per year. CASEL is not responsible for travel costs of TCORS and CRST investigators to these meetings.

What is the estimated number of attendees for large meetings each year?

There will be at least one investigator meeting per year, alternating between: (1) a TCORS investigators meeting, and (2) an annual meeting for all TRSP-funded investigators. We anticipate about 300 people to attend the TCORS investigators meeting and 800 people to attend the annual TRSP investigators meeting. Please note that due to restrictions on federal employee travel, grantee meetings will be held at government facilities in Bethesda, MD for the foreseeable future. Consequently, potential applicants need not budget for space for these meetings. At this time, it is not possible to determine how many additional scientific and workgroup meetings may be needed. Applicants are advised to use their best judgment in anticipating how much meeting/logistical support a large research program may require.

5. Timeline

What are the upcoming dates to keep in mind?

Letters of Intent must be RECEIVED by May 14, 2022. CASEL applications ARE DUE on July 14, 2022 by 5:00 p.m. ET. Submit Letters of Intent to trsp@mail.nih.gov.

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.

Suggested content for the Letter of Intent:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the Program Director(s) (PD(s)) /Principal Investigators (PI(s))
- Names of other key personnel
- Participating institution(s)

- Number and title of this funding opportunity
- Specific aims

When will awards be made?

We anticipate that awards will be made before September 2023.

6. Review

Are decisions appealable?

No, the FOA is not being reissued. Review and funding **decisions are not appealable**.

Will individual cores receive scores? Is it possible for the overall application to receive funding even if one core does not receive a favorable review?

Individual cores will not be scored, but they will be evaluated while determining scientific and technical merit, and in providing an overall impact score. It is not possible for an award to be made at a partial level (e.g., by dropping one core).

Will these applications be reviewed by a standing study section?

No, these applications will be reviewed by a single Special-Emphasis Panel (SEP) convened specifically to evaluate the proposed applications.

Will there be reviewers reviewing individual projects who won't have access to the overarching description?

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 will refer to sections outside of their assignment. Consequently, applicants are encouraged to construct each core as separate and self-contained.

7. Post-Award Management & Reporting

Are the reporting requirements for CASEL 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 an Interim Progress Report 6 months after the start of each budget year.

What is the vision for the governing body/steering committee? Will it be self-governed with guidance as needed from the NIH/FDA, or will the NIH/FDA take a more direct role?

CASEL will be governed by a CASEL Steering Committee, to be established. The Steering Committee will advise the PD/PI and oversee the activities of CASEL, including the policies, procedures, and strategies that pertain to its work with the TCORS and other CTP-funded research programs. The CASEL Steering Committee will work

collaboratively across its membership, comprised of representatives of CASEL (PDs/PIs), CTP-funded PD(s)/PI(s), and NIH and FDA CTP scientific staff. The Steering Committee will also work collaboratively with any established sub-committees and working groups.

How will this CASEL RFA interact with the current CASEL RFA-OD-17-002, and the second round of TCORS awarded under RFA-OD-17-006?

Current CASEL RFA-OD-17-002 and the second-round TCORS may overlap with the initial project year(s) of this newly reissued CASEL under RFA-OD-22-003. However, the coordination and facilitation of the final years of the second-round TCORS grants, including no-cost extension years, will remain the primary responsibility of CASEL RFA-OD-17-002. CASEL will have the primary responsibility for the coordination and facilitation of the TCORS funded through RFA-OD-22-004. CASEL personnel will also be expected to cooperate with current CASEL personnel, NIH and FDA staff, and second-round TCORS investigators during the transition period.

NIH Guide FOA: grants.nih.gov/grants/guide/rfa-files/RFA-OD-22-003.html

NIH FDA TRSP Website: prevention.nih.gov/tobacco-regulatory-science-program