

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

[RFA-OD-17-002](#)

Updated April 7, 2017

Application Requirements

1. What are the required Components for a CASEL application?
 - A. The following are the required Component Types specified in Part 2 Section IV of the application:
 - Leadership and logistics core
 - Analytics and synthesis core
 - Career enhancement core
 - Dissemination core
 - Optional: other center-named core(s) as needed and justified
2. What research programs will be coordinated and facilitated by CASEL?
 - A. CASEL will provide coordination and facilitation of tobacco regulatory science grants and programs funded by the FDA Center for Tobacco Products (CTP), including the NIH Tobacco Regulatory Science Program (TRSP <http://prevention.nih.gov/tobacco/funding.aspx>) (e.g., Tobacco Centers of Regulatory Science [TCORS] funded through [RFA-OD-17-006](#) and awardees of R-mechanism grants), as well as FDA CTP-funded research supported through the Centers for Disease Control and Prevention, other FDA Centers, and research contract organizations.
See <http://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm396257.htm> for CTP-supported Tobacco Regulatory Research Projects.
3. What scope of research is covered in the FDA CTP-funded programs?
 - A. 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 [TCORS FAQs](#).
4. What are the current research priorities of the FDA CTP?
 - A. 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 diversity – understanding the types of tobacco products and how their specific characteristics affect people's attitudes, beliefs, perceptions, and use of these products
 - Addiction – understanding what effect different levels of nicotine and other factors have on addiction

- Toxicity and carcinogenicity – understanding how changes in tobacco products affect their potential for harm and ways to reduce that harm
 - Health consequences – understanding the risks of different tobacco products
 - Communication – finding ways to effectively convey information about the risks of using tobacco and about CTP's role in regulating tobacco products
 - Marketing – understanding the impact of tobacco product marketing and public education on people's attitudes, beliefs, perceptions, and use
 - Economics and policy – estimating the economic impact of CTP's regulations; also understanding how CTP's actions change tobacco use and illness and death from tobacco use
5. 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?
- 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 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.
6. Can applicants provide a list of acronyms for the different sections of the application?
- A. Yes, it is recommended that a glossary of terms/acronyms for the different cores be included on the corresponding cover page for that section of the proposal.
7. 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
 - Leadership and Logistics Core: 6 pages
 - Analytics and Synthesis Core: 6 pages
 - Career Enhancement Core: 6 pages
 - Dissemination Core: 6 pages
 - Optional Center-Proposed Core: 6 pages
8. 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.
9. Where can the applicant find additional information regarding application submission?
- A. For questions regarding Grants.gov registration and submission, and 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](#).

Eligible Applicants

10. 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.

11. Are institutions and investigators that are currently receiving FDA CTP or related National Institutes of Health (NIH) grants or contracts eligible to apply to this RFA?

- A. Yes. Institutions and individuals currently receiving CTP 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](#) and [RFA-OD-17-006](#). Key personnel of the CASEL awardee team, however, cannot include key personnel from the research team of a TCORS awardee.

Budget

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

- A. The budget cap is up to \$2M 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.

13. Should salary increases due to escalation or inflation be included in the application's budget?

- 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](#).

14. Is a certain amount of the TCORS budget set aside for their travel to meetings per year?

- A. Yes, TCORS 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 investigators to these meetings.

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

- A. There will be at least two investigator meetings per year: (1) a TCORS investigators meeting and (2) an annual meeting for all TRSP-funded investigators. We anticipate about 150 people to attend the TCORS investigators meeting and 300 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.

Timeline

16. What are the upcoming dates to keep in mind?

- A. Letters of Intent must be RECEIVED by May 19, 2017. CASEL applications ARE DUE on July 19, 2017 by 5:00 p.m. ET

17. 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.

Suggested content for the 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

18. When will awards be made?

- A. We anticipate that awards will be made before September 30, 2018.

Review

19. Are decisions appealable?

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

20. 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?

- A. 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).

21. 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 evaluate the proposed applications.

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

- A. Reviewers will be assigned specific sections of each application to review. Though they will have access to the entire application, it should not be expected that reviewers will refer to sections outside of their assignment. Consequently, applicants are encouraged to construct each core as separate and self-contained.

Post-Award Management & Reporting

23. Are the reporting requirements for CASEL 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.

24. 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?
- A. 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.
25. How will CASEL interact with the Center for Evaluation and Coordination of Training and Research (CECTR), awarded under [RFA-OD-13-117](#), and the [first round of TCORS](#) awarded under [RFA-DA-13-003](#)?
- A. Both CECTR and the first-round TCORS may overlap with the initial project year(s) of CASEL. However, the coordination and facilitation of the final years of the first-round TCORS grants, including no-cost extension years, will remain the primary responsibility of CECTR. CASEL will have the primary responsibility for the coordination and facilitation of the TCORS funded through RFA-OD-17-006. CASEL personnel will also be expected to cooperate with CECTR personnel, NIH and FDA staff, and first-round TCORS investigators during the transition period.
26. What's the role of CASEL in the planning and conduct of Rapid Response Projects (RRPs) described in the [TCORS RFA](#)?
- A. CASEL will coordinate support for the TCORS Steering Committee and federal partners. As such, CASEL will help to establish and implement procedures for solicitation, review, and tracking of RRP. For example, this could include announcing a call for proposals and convening a review of the applications. As convener of the TCORS Steering Committee, CASEL leadership also may provide input regarding the research to be addressed.

NIH Guide FOA: <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-17-002.html>

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