

**Questions and Answers for Center for Evaluation and Coordination of Training and Research (CECTR)
in Tobacco Regulatory Science (U54)**

[RFA-OD-13-117](#)

Updated November 26, 2013

Check back for updates

APPLICATION STRUCTURE & ORGANIZATION

1. What are the required components of a responsive application?
 - A. There are five required components:
 - i. Overview of the proposed Center;
 - ii. Leadership and Administrative Core;
 - iii. Evaluation Core;
 - iv. Education and Training Core;
 - v. Analytics and Synthesis Core.

2. What is expected for the overall organization and order of sections in the application?
 - A. As indicated, the overall application and each individual section must follow the instructions in the PHS398 Application Guide, <http://grants.nih.gov/grants/funding/phs398/phs398.html>, and will use the page limits as indicated in the Table of Page Limits, http://grants.nih.gov/grants/forms_page_limits.htm. The organization for the CECTR application is as follows (indicated page limits may not be exceeded):
 1. Overall Component (*this section provides an "Overview of the Proposed Center," including all cores*)
 - a. Face Page (Overall, *please list PI of overall center in PI fields.*)
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Overall)
 - c. Table of Contents (Overall)
 - d. Detailed Budget for Initial Budget Period (Overall)
 - e. Budget for Entire Proposed Project Period (Overall)
 - f. Biosketches (for the overall center, all cores, 4 page max per person)
 - g. Resources (Overall)
 - h. Research Plan (Overall), 12-page limit
 - i. Resource Sharing Plan
 - j. Checklist
 2. Leadership and Administrative Core
 - a. Face Page (Leadership and Administrative Core, *please list Core Lead in PI field.*)
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Leadership and Administrative Core)
 - c. Table of Contents (Leadership and Administrative Core)
 - d. Detailed Budget for Initial Budget Period (Leadership and Administrative Core)
 - e. Budget for Entire Proposed Project Period (Leadership and Administrative Core I)

- f. Biosketches (Leadership and Administrative Core)
 - g. Resources (Leadership and Administrative Core)
 - h. Research Plan (Leadership and Administrative Core), 6-page limit
3. Evaluation Core
 - a. Face Page (Evaluation Core, *please list Core Lead in PI field.*)
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Evaluation Core)
 - c. Table of Contents (Evaluation Core)
 - d. Detailed Budget for Initial Budget Period (Evaluation Core)
 - e. Budget for Entire Proposed Project Period (Evaluation Core I)
 - f. Biosketches (Evaluation Core)
 - g. Resources (Evaluation Core)
 - h. Research Plan (Evaluation Core), 6-page limit
 4. Education and Training Core
 - a. Face Page (Education and Training Core, *please list Core Lead in PI field.*)
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Education and Training Core)
 - c. Table of Contents (Education and Training Core)
 - d. Detailed Budget for Initial Budget Period (Education and Training Core)
 - e. Budget for Entire Proposed Project Period (Education and Training Core)
 - f. Biosketches (Education and Training Core)
 - g. Resources (Education and Training Core)
 - h. Research Plan (Education and Training), 6-page limit
 5. Analytics and Synthesis Core
 - a. Face Page (Analytics and Synthesis Core, *please list Core Lead in PI field.*)
 - b. Summary, Relevance, Project/Performance Sites, Senior/Key Personnel (Analytics and Synthesis Core)
 - c. Table of Contents (Analytics and Synthesis Core)
 - d. Detailed Budget for Initial Budget Period (Analytics and Synthesis Core)
 - e. Budget for Entire Proposed Project Period (Analytics and Synthesis Core)
 - f. Biosketches (Analytics and Synthesis Core)
 - g. Resources (Analytics and Synthesis Core)
 - h. Research Plan (Analytics and Synthesis), 6-page limit

The order of sections should be as presented above.

3. 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.
4. What are the 12 pages titled, "Research Plan (Overall)" expected to address?
 - A. "Research Plan," though a misnomer, is required terminology for NIH Requests for Applications (RFAs). In this section, provide a concise description of the vision and proposed plan for the Center. You should include a concise description of the structure of the Center, including a brief management plan and organization chart with the role of the Administrative Core defined. Explain how the CECTR cores, including key personnel, will interact; how their activities will contribute to the accomplishment of the overall Center goals; and how the organization of the components into a Center will create an

entity that will result in a resource useful and important for the greater tobacco regulatory research community.

5. What are the 6 pages for each Core, titled “Research Plan,” expected to address? Should each Core be conducting original research?
 - A. In this section, provide a description of the vision and proposed plan for each Core. Describe how you plan to address the “Specific Research Objectives and Requirements for the CECTR” outlined in Part 2, Sections I and IV, of the RFA that are relevant to each Core. Note that the “Research Plan” section of the application should address the specific activities and outcomes of each Core, regardless of whether the Cores will conduct research. The work of the Cores will serve to advance research through evaluation, coordination, training, and analytic support rather than through the conduct of original research.

While research will be conducted in the Evaluation Core, by the training awardees in the Training and Education Core, and by the Analytics and Synthesis Core, the focus of the “Research Plan” should be on the structure, function, and operational plan for the Core, rather than on the proposals for specific research projects. As such the “Specific Aims” should describe the goals of the Core rather than research hypotheses.

6. Does every core need a data sharing plan or can we prepare one data sharing plan for the overall application?
 - A. A data sharing plan should be provided for every core where applicable, as well as for the entire application. (Question added 10/28/2013)
7. If the applicant proposes to collaborate with one or more organizations in carrying out the work of the proposed CECTR, is there a ratio or percentage of work that can be subcontracted from the applicant organization?
 - A. No, there is no set percentage or 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 the coordinating center 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.

ELIGIBLE APPLICANT ORGANIZATIONS

8. Are foreign institutions eligible to apply?
 - A. No, foreign institutions are ineligible to apply for this RFA.
9. Are tobacco companies eligible to apply to this funding opportunity?
 - A. Yes. As stated in the funding opportunity announcement, for-profit organizations are eligible to apply. It is the responsibility of the NIH peer review and council recommendations to identify the merit and quality of applications, as well as the Food and Drug Administration’s (FDA) consideration of the relevance of the application to program priorities, to determine the entity’s success in securing funding for research.

10. Are institutions and investigators that are currently receiving FDA Center for Tobacco Products (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). (Question updated 10/28/2013)

BUDGET

11. What is the budget cap? Will applications that exceed the budget cap be considered?
- A. The budget cap is \$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 nonresponsive.
12. How should applicants prepare budgets for future years of the CECTR?
- A. Applicants should follow the budget instructions in the [PHS 398](#) application guide, which states that actual institutional-based compensation should be requested and justified at the time of application and that these requested amounts may be adjusted at the time of the award. Please see the PHS 398 application guide, page I-36, for the discussion on institutional base salary, and the [NIH Grants Policy Statement Glossary](#) for the definition of institutional base salary. The RFA states, a *U54 center may not exceed \$2 million in total costs per year*. Therefore, applicants should not request significant program expansion beyond that amount.
13. Is a certain amount of the TCORS budget set aside for their travel to two meetings per year?
- A. Yes, TCORS investigators are expected to provide funds to support travel of key investigators and training appointees to attend up to two investigator meetings per year. The CECTR is not responsible for travel costs of TCORS investigators to these meetings. (Question added 10/28/2013)
14. 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 80 investigators and 50 federal staff to attend the TCORS investigators meeting and 400 investigators and 100 federal staff 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 best judgment in anticipating how much meeting/logistical support a large research program may require. (Question added 11/26/2013)

TIMELINE

15. What are the upcoming dates to keep in mind?
- A. Letters of Intent must be RECEIVED by November 10, 2013. CECTR Center applications must be RECEIVED by December 10, 2013.
16. When will awards be made?
- A. We anticipate that awards will be made by July 2014.

PAGE LIMITS

17. What are the application page limits?
- A. All page limitations described in the PHS 398 Application Guide and 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:
- Overview of the proposed Center: 12 pages
 - Leadership and Administrative Core: 6 pages
 - Evaluation Core: 6 pages
 - Education and Training Core: 6 pages
 - Analytics and Synthesis Core: 6 pages

REVIEW

18. Are decisions appealable?
- A. No, the FOA is not being reissued. Review and funding decisions are not appealable.
19. Will individual cores receive scores and 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).
20. Will these applications be reviewed by a standing study section?
- A. These applications will be reviewed by a single, special-emphasis panel convened specifically to address the science proposed in the applications.
21. 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 contained.

POST AWARD MANAGEMENT & REPORTING

22. What does A-110 (Shelby Amendment) mean and how does it relate to this RFA?
- A. The Shelby Amendment tasks the Office of Management and Budget (OMB) to change OMB Circular A-110 so that all federally-funded research data can be accessed through the mechanisms set forth in the Freedom of Information Act (FOIA). With regard to this FOA, the research findings generated from the CECTR funding may be used to provide

scientific evidence informing the regulation of the manufacture, distribution, and marketing of tobacco products to protect public health. If research data are cited publicly in support of regulation, institutions of higher education, hospitals, and other non-profit organizations are subject to the Freedom of Information Act (FOIA) as outlined in Revised Circular A-110 (http://www.whitehouse.gov/omb/circulars_a110/).

23. Are the reporting requirements for CECTR the same as other NIH grants?
- A. No. Interim Reports will be due midway between regular annual reports.
24. 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, 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 statute, Congress must actually appropriate the funds before FDA can obligate them. The tobacco industry has no control over CTP funding decisions. FDA uses some of these funds to award research grants.

RESEARCH RESOURCES

25. The FOA mentions “CTP-funded research.” What is considered “CTP-funded research”?
- A. CTP funds scientific programs at NIH, the Centers for Disease Control (CDC), FDA, and research contract organizations to inform its regulatory authority. CTP-funded research at NIH consists of the [PATH Study](#) and the [Tobacco Regulatory Science Program’s research and training portfolio](#). CTP also supports research at CDC and FDA’s National Center for Toxicological Research (NCTR). The objective of the overarching CTP-funded research program is to conduct research programs that will aid the development and evaluation of tobacco product regulations and address the research priorities related to the regulatory authority of the FDA CTP.
26. What are “TCORS”? Where are they located? Where can we find information about the funded TCORS?
- A. TCORS are the P50 Tobacco Centers of Regulatory Science, funded in FY13 by CTP to demonstrate research excellence and leadership in tobacco regulatory science that will contribute to the science base that FDA will use to develop meaningful product regulation. Essential elements of the TCORS include at least three theoretically grounded, strong research projects with an integrative theme; an Administrative Core and other cores as needed; the ability to conduct developmental/pilot and time-sensitive research; and a program for career development and training. Fourteen TCORS, made up of scientists with a broad range of expertise (e.g., epidemiology, economics, toxicology, addictions, and marketing) have been funded. More information about each of these fourteen TCORS can be found at <http://prevention.nih.gov/tobacco/tcors.aspx> and in the [NIH RePORTER](#) by entering RFA-DA-13-003 into the “FOA” field. (Question updated 10/28/2013)
27. What is the PATH Study and what are its aims?

- A. In October 2011, the FDA and the NIH announced a joint national, prospective, longitudinal cohort study of tobacco users and those at risk for tobacco-product use to monitor and assess their tobacco use and the resultant health impacts. The initiative, called the Population Assessment of Tobacco and Health (PATH) Study, represents the first large-scale NIH-FDA collaboration on tobacco regulatory research since Congress granted FDA the authority to regulate tobacco products under the Family Smoking Protection and Tobacco Control Act (FSPTCA). Scientific experts at the National Institute on Drug Abuse (NIDA) and FDA's Center for Tobacco Products will coordinate this effort via a research contract awarded to Westat in Rockville, MD. The PATH Study will prospectively follow almost 60,000 people who are users of tobacco products and those at risk for tobacco-product use ages 12 and older in the United States. The study will a) examine what makes people susceptible to tobacco-product use; b) evaluate initiation and use patterns including use of new products, dual use, poly use, and switching of tobacco products; c) study patterns of tobacco-product cessation and relapse ; d) evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes; and e) assess differences in attitudes, behaviors, and key health outcomes among racial/ethnic, gender, and age subgroups. The PATH Study will also collect biospecimens from adults to analyze biomarkers of tobacco use and disease processes.
28. What will be the availability of the PATH data in terms of timing and content?
- A. It is anticipated that the PATH baseline restricted-use file and codebook will be available by late summer 2015. Details, when available, will be posted to the PATH website, PATHstudyinfo.nih.gov, which is currently under construction.
29. When will PATH biospecimens and biospecimen data be available?
- A. It is anticipated that PATH biospecimens and biospecimen data will become available by late summer 2015. Details, when available, will be posted to the PATH website, PATHstudyinfo.nih.gov, which is currently under construction.
30. The RFA states that one of the strategic objectives of the CECTR is to “facilitate collaborative research...(to) include the identification, adoption, and support for the use of consensus measures for shared scientific topic areas...” How will the consensus measures be identified? (Question added 10/24/13)
- A. The TRSP and the FDA CTP recently teamed up with the NHGRI-funded, RTI-led initiative, PhenX (www.phenx.org) to develop a toolkit of consensus measures for tobacco regulatory researchers. The PhenX Toolkit (www.phenxtoolkit.org) provides standard measures-to help researchers compare and combine data from multiple studies. The process that will be used to develop Tobacco Regulatory Research collections of measures will be similar to the process that was used to identify Substance Abuse and Addiction (SAA) collections (<http://www.genome.gov/27547274>). Publications describing various aspects of PhenX, the consensus process, and the PhenX Toolkit can be found at <https://www.phenxtoolkit.org/index.php?pageLink=resources.publications>.

CECTR STRUCTURE AND ROLES

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

- A. The Steering Committee will work collaboratively across its membership, comprised of representatives of the CECTR, CTP-funded investigators, NIH and FDA CTP scientific, administrative, and program staff, and selected outside expert(s). (Question added 10/28/2013)
32. Are you expecting the TCORS and all the K and R grantees to attend two meetings in person per year?
- A. Appropriate TCORS investigators and personnel are expected to attend the grantee meetings. However, other CTP-funded investigators will be invited but not expected to attend. (Question added 10/28/2013)
33. As the CECTR won't be funded until July 2014 at the earliest, are there currently, or are there going to be, any evaluation efforts with the TCORS prior to that? For example, is there some type of baseline evaluation measurement planned?
- A. As stated in the RFA, the approach for the program evaluation will be determined in consultation with the CECTR Steering Committee, NIH and CTP staff, and evaluation and tobacco-control experts. No formal baseline evaluation measures are planned prior to the establishment of the CECTR. However, prior to the establishment of CECTR, NIH and CTP are compiling foundational information that could inform evaluation efforts, such as the development of common measures and a bibliometric analysis of tobacco regulatory science. (Question added 10/28/2013)
34. Have the TCORS been informed that CECTR is being established? To what degree will the TCORS be expected to heed the CECTR's leadership advice and guidance?
- A. Yes, the TCORS have been informed that the CECTR will be established. The cross-site collaboration and coordination will be catalyzed through the Steering Committee, and as the membership of the Steering Committee will include individuals from the CECTR, NIH, FDA-CTP, and the TCORS, this is envisioned as a collaborative process. The CECTR and the TCORS are seen as partners with the NIH and FDA-CTP and will be active participants in making major decision that affect the entire program. As such, our vision of the program is that the investigators will be participating because of their motivation to impact the science. It has been our experience with other programs and our early experience with CTP-funded investigators, that they are excited about the promise of having an impact on the science and on public health. Successful CECTR applicants will have an investment in capitalizing on this enthusiasm and positioning themselves as a resource for the TCORS and the tobacco regulatory science community and will provide effective scientific leadership, motivation, and inspiration to guide the process. (Question added 10/28/2013)

NIH Guide FOA: <http://grants.nih.gov/grants/guide/rfa-files/RFA-OD-13-117.html>
NIH-FDA Website: <http://prevention.nih.gov/tobacco/default.aspx>