Pre-Application Webinar

Tobacco Centers of Regulatory Science for Research (TCORS) Relevant to the Family Smoking Prevention and Tobacco Control Act (U54)

Monday, March 21, 2022
Questions or Technical difficulties?

Please use the Chat Option to send a message to “Technical Support” for direct assistance.
Closed Captions

- You can view live closed-captions by clicking the Closed Caption icon found at the bottom of the screen.
Using the Chat for Webinar Questions

- **Questions for the panelists** should be sent directly to “TRSP – Send Questions Here” during the event for consideration.
Post Webinar

• A recording of today’s webinar and presenter slides will be available on the TRSP website in approximately two weeks.
Pre-Application Webinar
Tobacco Centers of Regulatory Science (TCORS)

March 21, 2022

RFA-OD-22-004 (U54)

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Office of Disease Prevention
Tobacco Regulatory Science Program (TRSP) 

Background

- TRSP coordinates the partnership between FDA’s Center for Tobacco Products (CTP) and the NIH
- TRSP has NIH oversight responsibility for the trans-NIH grant activities with CTP (FOAs, grantee mtgs., etc.)
- All TRSP-supported research must be responsive to CTP regulatory authorities
- TRSP represents an addition to the NIH tobacco research program and does not replace or diminish any existing tobacco research activities at any of the Institutes or Centers.

More information available at:  
http://prevention.nih.gov/tobacco
The Tobacco Regulatory Science Program (TRSP) is an interagency partnership between the NIH and the FDA. The program is designed to foster tobacco regulatory research.

With the passage of the 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), the FDA acquired the authority to regulate the manufacture, marketing, and distribution of tobacco products in order to protect public health. Within the framework of the Tobacco Control Act, the NIH and FDA formed this partnership to establish a comprehensive research agenda in tobacco regulatory science.

**New Funding Opportunities**
- RFA-GM-22-002: Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (U01 Clinical Trial Not Allowed) — Pre-application webinar

**Research Priorities**

**FAQs: Responsiveness to FDA's Center for Tobacco Products Regulatory Authority (PDF)**

These FAQs clarify research that is and is not within scope of the FDA’s Center for Tobacco Products (CTP) regulatory authority. Only research that is within the regulatory authority of the FDA CTP will be

**FDA Makes Progress in Application Review**

The FDA has taken action on over 90% of more than 6.5 million deemed new tobacco product applications that were submitted by September 9, 2020, including issuing Marketing Denial Orders for more than $46 million flavored E-cigarette products because their applications
Companion Funding Opportunities

RFA-OD-22-003 - Coordination of Analysis, Science, Enhancement, and Logistics (CASEL) in Tobacco Regulatory Science (U54)

RFA-OD-22-001 - Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace (U01)

NOT-OD-22-094 - Notice of Change to RFA-OD-22-004, Tobacco Centers of Regulatory Science (TCORS) for Research Relevant to the Family Smoking Prevention and Tobacco Control Act (U54 Clinical Trial Optional)

Note the following regarding personnel for center grants:

- A TCORS PD/PI cannot serve as PD/PI of CRST grant
- A TCORS PD/PI or other key personnel cannot serve as a member of a CASEL awardee team

TCORS WEBINAR AGENDA

- FDA Center for Tobacco Products and the Tobacco Control Act – Dana van Bemmel (CTP, FDA)
- Application – Mary Garcia-Cazarin (TRSP)
- Review – Lauren Fordyce (CSR)
- Grants Management – Amy Bucheimer (NIDA)
- Questions and Answers

Webinar and FAQs will be posted to website http://prevention.nih.gov/tobacco