

PRE-APPLICATION WEBINAR
**TOBACCO CENTERS OF REGULATORY SCIENCE FOR RESEARCH
RELEVANT TO THE FAMILY SMOKING PREVENTION AND
TOBACCO CONTROL ACT**

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National Institutes of Health
Office of Disease Prevention

TOBACCO CENTERS OF REGULATORY SCIENCE (TCORS)



Establish the scientific foundation for regulatory and policy issues relevant to the work of the FDA Center for Tobacco Products



Build research capacity and scientific expertise



Ensure both a stable ongoing research enterprise and a flexible, responsive, and collaborative resource

TCORS COMPONENTS

Overall Component
Integrative Theme

Minimum 3 Research
Projects

Administrative Core

Career Enhancement
Core
Pilot Projects

Optional Cores (as
justified)

OVERALL INTEGRATIVE THEME

- ▶ Integrative theme: unifying goal, targeted area of research, specialization
- ▶ Organized around a variety of topics
 - Research need or gap
 - Populations
 - Product or constituents
 - Scientific domains :
 - Product Composition and Design
 - Addiction
 - Toxicity
 - Behavior
 - Health Effects
 - Communication
 - Marketing Influences
 - Impact Analysis

RESEARCH PROJECTS: SCIENTIFIC DOMAINS

- ▶ Overall TCORS must address no fewer than **two** of the eight Scientific Domains
- ▶ Single project may address one or more Scientific Domains
- ▶ Addressing many/all Scientific Domains is not advantageous
- ▶ Make explicit the Scientific Domains that are addressed

RESEARCH PROJECTS

- ▶ Three or more multidisciplinary research projects required
 - multidisciplinary integration within projects
 - integrated with the overarching theme
- ▶ Fully-developed R01-level projects
- ▶ Each project and each specific aim within the projects must be responsive to the RFA and fall within the regulatory authority of the FDA CTP
- ▶ Articulate *how* research will inform RFA priorities and tobacco regulation

ADMINISTRATIVE CORE

- ▶ Required
- ▶ Objectives
 - ▶ monitor and facilitate Center objectives
 - ▶ provide oversight and quality control
 - ▶ promote an atmosphere of collaboration

CAREER ENHANCEMENT CORE

- ▶ Required
- ▶ Objectives
 - ▶ Enhance development of TRS research expertise of students, New and Early Stage Investigators, and investigators new to TRS
 - ▶ Career enhancement pilot projects (require NIH/FDA approval)

OTHER CORES

- ▶ TCORS may propose additional Cores as needed and justified

EXPECTED FEATURES OF TCORS

- ▶ Open to collaboration
 - ▶ within/across TCORS, including career enhancement activities
- ▶ Identify common measures and protocols where feasible
- ▶ Open to addressing the ongoing scientific issues of the FDA Center for Tobacco Products

CRITICAL: ENSURING YOUR APPLICATION IS RESPONSIVE

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 all Research Projects must fall within scope of the regulatory authority of the FDA CTP
- ▶ No aim(s) may address the non-responsive research topics outlined in the RFA

CRITICAL: ENSURING YOUR APPLICATION IS RESPONSIVE

▶ *Strongly Recommended:*

- ▶ Discuss your research and specific aims with the Scientific/Research Contact from the Institute relevant to your research
- ▶ Submit a letter of intent early to allow time for feedback
- ▶ Clearly explain Integrative Theme and Scientific Domains both within your letter of intent **and** within your application

LETTER OF INTENT (LOI)

- ▶ Not required, but strongly recommended
- ▶ Submit no later than May 15, 2022
- ▶ Include:
 - Descriptive title of proposed research
 - Names and institutions of key personnel
 - Specific Aims for Research Projects
 - Integrative Theme
 - Scientific Domains
- ▶ Send to TRSP@nih.gov

Eligible Applicants

- Foreign institutions **are not** eligible to apply, including Non-domestic (non-U.S.) Entities and Non-domestic (non-U.S.) components of U.S Organizations.
- However, Foreign components, as defined by the NIH Grants Policy Statement, **are allowed**.

MORE INFORMATION IN FAQs AND TRSP WEBSITE

FAQs for this FOA will be posted in the next few days

A separate comprehensive FAQ document focused solely on questions of responsiveness can be found under "Funding Priorities" on our website.

Accessing our website:

Google search: NIH TRSP
prevention.nih.gov/tobacco



SCIENTIFIC RESEARCH CONTACTS

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Contact us early in the process!