Pre-Application Webinar
Center for Rapid Surveillance of Tobacco (CRST) to Assess Changes in Use Behaviors, Product Marketing, and the Marketplace

Jan 13, 2022

RFA-OD-22-002 (U01)

National Institutes of Health
Office of Disease Prevention

Purpose of the Center for Rapid Surveillance of Tobacco (CRST)

- Assess changes in use behaviors, product marketing, and the marketplace to better understand the rapidly evolving tobacco landscape in the U.S.
- Support time-sensitive data acquisition strategies, data harmonization, data synthesis and analysis, and reporting activities on emerging and current tobacco use trends
- Work collaboratively with NIH and FDA CTP to implement a model that utilizes multiple data sources to identify emerging tobacco use issues, and to track tobacco use trends through regular monitoring of key data from sentinel sites
- Research results from the CRST are expected to generate findings and data that are directly relevant in informing the FDA's regulation of the manufacture, distribution, and marketing of tobacco products to protect public health

CRST Topic Areas

The CRST must address the following:

Rapid surveillance of changes in tobacco product use behaviors

- Changes in tobacco use behaviors among youth, young adults, and other populations with tobacco-related disparities
- Changes in how these groups access or obtain these products
- Emerging trends

Rapid surveillance of tobacco product marketing

- Recent changes in mechanisms/platforms of current tobacco product marketing in traditional and non-traditional channels
- Recent changes in industry tobacco product marketing strategies

Rapid surveillance of tobacco product marketplace

- Recent changes in the tobacco retail environment
- Recent changes and/or trends in tobacco product sales

CRST Responsibilities

The CRST must also:

- Establish and convene meetings of a CRST Steering Committee
- Establish one or more CRST-led surveillance and/or data analysis initiatives to serve as a core set of indicators
- Develop and maintain a sentinel site network composed of experts on tobacco control data from selected priority communities to assist in the ongoing monitoring and interpretation of data

CRST Responsibilities Continued

- Conduct cross-site data analyses from harmonized CRST data
- Report to NIH and FDA on a regular basis
- Identify approaches for translating, reporting, and publishing CRST findings for the scientific community and other stakeholders
- Provide operational, administrative, and logistical support

Additional Considerations: Non-responsive Topics

- Human laboratory studies, e.g., topography, fMRI
- Laboratory analysis of tobacco products, e.g., smoking machine, device analysis
- Biospecimen collection or analysis
- Environmental scan of policies
- Please also note that clinical trials are not allowed. The NIH definition for clinical trial is “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. ”

Additional Considerations: U01 Mechanism

- The funding mechanism for CRST is a U01. This is a cooperative agreement with substantial Federal scientific or programmatic involvement
- Applications to the U01 mechanism require Specific Aims and does not require Projects or Cores
- Applicants may consider organizing their application by specifying how they will address the required topic areas in separate Specific Aims. The organizational structure and associated activities may be described in additional specific aims and/or in a graphical representation included within the application

Additional Considerations: CRST Budget

- NIH, via support from the FDA Center for Tobacco Products (CTP), intends to fund one award, corresponding to up to $2.8 million total costs for fiscal year 2023 and up to $3.8 million total costs per year for subsequent years

- Year 1 funding is capped at $2.8 million total cost to account for lead time needed for project start-up. Budget needs to reflect actual needs of the proposed project and future year funds after Year 1 will depend on availability of funds

Additional Considerations: TCORS and CASEL

- The CRST PD/PI cannot serve as PD/PI of a TCORS grant
  - However, a PD/PI on CRST can be project co-investigator or core lead on a TCORS
- Key personnel of the CASEL awardee team cannot include key personnel from the CRST awardee team
- In addition, applicants are encouraged to carefully consider the level of effort they will have on these large grants as level of effort will be taken into consideration

Critical: Ensuring your application is responsive

Multiple aspects of the application contribute to a determination of responsiveness, including the following requirements:

- A program of research that comprehensively addresses the required topic areas and CRST responsibilities
- All Specific Aims 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 Contacts
    - **Kay Wanke, PhD, MPH** (TRSP) Kay.Wanke@nih.gov
    - **Maria Roditis, PhD, MPH** (NCI) Maria.Roditis@nih.gov
  - Submit a letter of intent early to allow time for feedback

Letter of Intent

- Not required, but strongly recommended
- Submit no later than March 20, 2022
- Suggested content of LOI:
  - Descriptive title of proposed activity
  - Name(s), address(es), and telephone number(s) of the Program Director(s) (PD(s))/PI(s)
  - Names of other key personnel
  - Participating institution(s)
  - Number and title of this funding opportunity
  - Specific aims
- Send to TRSP@mail.nih.gov

Scientific Research Contacts

- **Kay Wanke, PhD, MPH** (TRSP) Kay.Wanke@nih.gov
- **Maria Roditis, PhD, MPH** (NCI) Maria.Roditis@nih.gov

Contact us early in the process!