TCORS | Center for the Assessment of Tobacco Regulations [CAsToR]

REQUEST FOR APPLICATIONS (RFA)
PILOT PROJECTS IN TOBACCO REGULATORY SCIENCE
Letter of Intent Deadline: Monday, November 20, 2023
Full Application Deadline: Monday, January 15, 2024

OVERVIEW: This RFA is being issued by the Center for the Assessment of Tobacco Regulations (CAsToR), a multi-institutional center headquartered at the University of Michigan. The purpose of this RFA is to support pilot tobacco regulatory science research activities that could inform the FDA's Center for Tobacco Products (CTP) in its execution of the Family Smoking Prevention and Tobacco Control Act (TCA). The Act gives the federal government authority to regulate the manufacturing, marketing, and distribution of tobacco products for the protection of the public's health.

A goal of this RFA is to foster careers in tobacco regulatory science. Funded projects are intended to be stepping stones for the development of an application for externally funded research, for example, through the Tobacco Regulatory Science Program (TRSP) at the NIH and FDA. Applicants are encouraged to seek out collaborators across the network of Tobacco Centers of Regulatory Science, including CAsToR.

The priority research areas for pilot funding include projects that:

- Develop new simulation models, or extend existing models, that incorporate tobacco-related behavioral and health outcomes and/or policies, especially for new and/or potentially modified-risk tobacco products (e.g., ENDS, heated tobacco products, such as IQOS, and oral nicotine products, such as pouches).
- Analyze tobacco use trends, trajectories, and transitions in populations that experience tobacco-related disparities such as members of racial and ethnic minorities (e.g., Alaska Natives, American Indians, African Americans), young people, members of sexual and gender minority groups, people with mental health issues, people with low socioeconomic status, veterans, rural populations, and pregnant women.
- Analyze population-based tobacco surveillance data from U.S. and international sources, including analysis of consumer market data and longitudinal data. Analysis of population-based local data are also of high interest. Data sources of interest include, but are not limited to, the National Survey of Drug Use and Health, Population Assessment of Tobacco and Health Study, Tobacco Use Supplement of the Current Population Survey, National Health Interview Survey, Behavioral Risk Factors Surveillance System, Youth Risk Behavior Surveillance System, National Youth Tobacco Survey, Monitoring the Future, including state or local surveys, and data from the International Tobacco Control Policy Evaluation Project, Nielsen, Bureau of Alcohol, Tobacco and Firearms, and tax boards.

The NIH and FDA recommend use of the PhenX Toolkit and other common data elements as appropriate.

Applicants are encouraged to propose research that will inform computational models of use modeling approaches.

Applications must be within the scope of current NIH TRSP and FDA CTP research priorities and FDA CTP's regulatory authority over the manufacture, marketing, and distribution of tobacco products. The CTP has authority to, for example:

- Restrict cigarettes and smokeless tobacco retail sales to youth.
- Restrict the sale and distribution of tobacco products, including advertising and promotion, as appropriate to protect public health.
- Review modified risk tobacco products, such as those marketed for use to reduce harm, prior to their introduction to the market.
- Adjust warning labels for cigarettes and smokeless tobacco products in order to promote greater public understanding of the risks of tobacco use.
- Establish standards for tobacco products—for example, setting limits on harmful and potentially harmful constituents and nicotine levels—as appropriate to protect the public health.
- Review new tobacco products prior to their introduction to the market.

The FDA CTP regulatory does not extend to things like:

- Setting tax rates for tobacco products.
- Regulating therapeutic products, such as those marketed to treat tobacco dependence (regulated by other parts of FDA).
- Setting clean indoor air policies.
- Regulating tobacco growing.
- Requiring the reduction of nicotine yields to zero.
- Providing cessation services.
- Banning all cigarettes, smokeless tobacco products, little cigars, other cigars, pipe tobacco, or roll-your-own tobacco products.
- Changing the minimum age to purchase tobacco products.

ELIGIBILITY INFORMATION: The funds are available for researchers at earlier stages of career development. Only doctoral students, post-doctoral fellows, assistant researchers, and assistant professors may apply. This RFA is unable to fund applications from individuals at federal governmental institutions.

FUNDING: Doctoral student applicants will be eligible for a maximum award of $20,000. All other applicants can request up to $40,000. The project period will be 12 months beginning September 1, 2024.

DUE DATES: A Letter of Intent (LOI) is required to apply. The letter should briefly (one page maximum) describe the research to be proposed and how it will be responsive to the RFA's goals, **including how the project will be useful for tobacco regulation under FDA CTP authority**. The due date for the LOI is 11:59 PM EST Monday, November 20, 2023. After reviewing the LOIs, selected applicants will be invited to submit a full application via an online application submission system. Invited applications will be due at 11:59 PM EST Monday, January 15, 2024.

HOW TO APPLY: Submit your LOI via this form, which should take you about 5 minutes to complete if you have your LOI prepared.

INVITED APPLICATION GUIDELINES: The full application will have a four-page limit, including all tables and figures (but not including references, budget, and budget justification). Applications from doctoral students and post-doctoral fellows will require a letter of support from a faculty mentor with a brief description of a mentoring plan. The proposal should include the following sections, which align with NIH guidelines: specific aims, background and significance, research design and methods, and future research plans. Invited applications will be sent detailed instructions with additional details.

BUDGET AND JUSTIFICATION: Invited application will be asked to include a brief budget and budget justification (one page maximum). Funds can be used only for direct costs associated with project research activities, including faculty time, staff or student support, project-related travel, and purchase of research materials including data sets, software, and computing time. **Indirect costs and tuition are not allowable budget items.** Funds will be released after proof of IRB approval is provided and required subcontracts are fully executed. Carryover of funds is not guaranteed and may be denied. Please plan to expense all funds during the one-year funding period.

REVIEW PROCESS: Applications will be peer-reviewed using the current NIH TRSP application review criteria and scoring methods. Reviewers will assess the responsiveness of applications to the RFA. Priority will be given to proposals that clearly demonstrate that they will result in pilot results for a future grant application (such as an R grant or a K grant at the NIH).

REPORTING REQUIREMENTS: Awardees will be required to provide a photo and project abstract for posting on the CAsToR website. Within two months after the end of the project, awardees will submit a final written report. Awardees may be asked to deliver an oral presentation about their research and career development.

QUESTIONS? Answers to FAQs and information about past pilot projects can be found on our website. If you have other questions, please contact Molly Coeling (mcoeling@umich.edu).