Pilot Research Projects in Tobacco Regulatory Science
Request for Applications for Early Career Researchers

Application Due Date: July 27, 2020
Project Duration: 12-18 months

The Pilot Projects Program of the USC Tobacco Center of Regulatory Science (TCORS) is requesting applications that propose high impact research that informs federal regulation of tobacco products by the U.S. Food and Drug Administration (FDA) Center for Tobacco Products (CTP). This mechanism is dedicated to early career researchers who can use the pilot project to advance research on tobacco regulatory science. All early career researchers from predoctoral level through early associate professor level are eligible and it is hoped that the pilot projects will increases the pool of talented tobacco regulatory scientists.

Due to COVID-19 Pandemic, this call focuses only on research projects that do not require new in-person face-to-face data collection. Studies can involve:

1. New questions addressed in longitudinal analyses of existing data sets, including publicly available resources (e.g., PATH Study, NYTS, NHIS, MTF) or other data sources with data relevant to tobacco regulatory science (e.g., social media, Nielsen sales), or comparisons of tobacco product use outcomes from multiple types of data (e.g., comparison of TCORS cohort data with a national data set, analyses of pooled data from multiple TCORS).
2. New studies involving remote data collection from research participants (e.g., web-based)
3. Econometric or other modeling studies of health impact of tobacco product use.
4. Moderator effects of vulnerable population group characteristics on tobacco product use.
5. Covariation of environmental exposures and/or local or state policy changes with effects of FDA regulatory policy on tobacco product use.

Science Focus
To be eligible, proposed studies must be responsive generally to one or more of the following research interest areas established by the FDA CTP:
(https://www.fda.gov/tobaccoproducts/publichealthscienceresearch/research/ucm311860.htm)
1. Toxicity- understanding how tobacco products and changes to tobacco product characteristics affect their potential to cause morbidity and mortality
2. Addiction- understanding the effect of tobacco product characteristics on addiction and abuse liability
3. Health effects- understanding the short- and long-term health effects of tobacco product use
4. Behavior- understanding the knowledge, attitudes, and behaviors related to tobacco product use and changes in tobacco product characteristics
5. Communications- understanding how to effectively communicate to the public and vulnerable populations regarding nicotine and the health effects of tobacco products, including media campaigns and digital media
6. Marketing influences- understanding how industry marketing strategies increase susceptibility to using tobacco products among never users and transitions to regular use and dual use
7. Impact analysis- understanding the impact of potential FDA regulatory actions

Project that do not address one of these areas or address topics fall outside of the purview of the FDA CTP will be considered non-responsive.

Application Deadlines and Key Dates
- **July 27th, 2020** – Full application due
- **August 17th, 2020** – Anticipated award notification
- **Project Period: 12-18 months from project start date** (project start date dependent on IRB approval and disbursement of funds).

Eligibility and Restrictions
Early career researchers at faculty, postdoctoral, and pre-doctoral levels are eligible to apply. Prior to submitting their application, applicants that are not members of USC TCORS must reach out to one of the USC TCORS faculty investigators to include them as a co-investigator on the newly proposed pilot project (see [Appendix USC TCORS Investigator Roster](#)). The reason for this requirement is to ensure that the project is designed and conducted in a fashion that meets FDA CTP priorities. Consult the [TCORS website](#) for additional information about relevant TCORS investigator collaborators to include on your project.

Award funds are intended for study-related activities (e.g., supplies, participant incentives, staff salaries) and are NOT intended to serve as primary support of awardees’ salaries. Investigator support will be limited up to 30% of salary for the applicant PI and Co-Is. All regulatory and IRB approvals for study activities must be obtained prior to the disbursement of funds.

Expectations and Requirements of Selected Studies
Leverage preliminary findings and data to support larger projects appropriate for independent investigator-initiated studies from NIH or other government agencies or private foundations, and to facilitate career development.

Review Criteria
Proposals will be reviewed by the USC TCORS Pilot Programs Review Committee, as well as by selected external reviewers. Scoring of proposals will be based on the standard NIH 9-point scoring system. Each proposal will be evaluated based on the following criteria:

- **Significance** (i.e., does the project address an important problem or critical barrier to progress in the field? Does the study have potential to generate new knowledge relevant to TCORS themes from a regulatory perspective?)
- **Investigator(s)** (i.e., if applicant is an early stage or new investigator, does he or she have appropriate experience and training? Is there evidence of productivity and/or potential to become an independent investigator in the area of tobacco regulatory science research?) Is there evidence that project timelines are likely to be met?
- **Innovation** (i.e., does the proposal utilize novel theoretical concepts, approaches or methodologies, instrumentation?)
- **Approach** (i.e., are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are study limitations acknowledged and addressed?)
- **Communication Plan** (i.e., proposed communication and decision-making process, how any disputes will be resolved).
- **Research Products** (i.e., planned publications, potential for a future grant application involving multiple TCORS, dissemination of findings and methods.)
- **Responsiveness to FDA CTP Priorities**
The review committee will also consider whether the proposed budget and timeline are appropriate for the scope and pilot nature of the project and whether human subject issues are likely to pose problems for study implementation.

**Application Procedures**

Please send full application to [krowshan@usc.edu](mailto:krowshan@usc.edu) and [tcors@usc.edu](mailto:tcors@usc.edu).

For any assistance, please contact Kiana Rowshan at [krowshan@usc.edu](mailto:krowshan@usc.edu).
Instructions for Submission of the Full Proposal

Please create one single PDF file that includes the sections listed below.

Format Requirements
- Arial font, 11 pt.
- Margins: minimum 0.5 inch.
- No appendices.
- Include page numbers and Table of Contents.

1. Cover Sheet with project title – (If template needed, email krowshan@usc.edu)

2. Project Abstract (300 words or less) – a brief summary of the project.

3. Specific Aims (1 page) – concise goals of the proposal research and a summary of expected outcomes, including specific objectives. NOTE: This section should include the targeted CTP priority research area (by number).

4. Research Strategy (6 MAXIMUM)
   a. Significance – describe the importance of the problem or critical barrier that the project addresses, and explain how the project will improve scientific knowledge, technical capability, or clinical practice if the proposed aims are achieved. List the Center for Tobacco Products (CTP) research priorities addressed in the project (1/2 page).
   b. Innovation – describe how the proposed research seeks to shift research practice paradigms and how any methodologies or theoretical concepts that are being developed or used in the project may have an advantage over existing practices (1/2 page).
   c. Approach – describe specific research and measurement designs, samples, measures, and analytic plan. If the proposed study involves collaboration, describe the collaboration between the USC TCORS and the other TCORS or organization and the scientific advantages of the collaboration. Address mechanisms for the collaboration and potential problems and how they will be resolved.

5. Grant Potential (1 page) – clear description of how a successful pilot project and/or expansion of the project will lead to a subsequent grant submission (e.g., F31/F32/K99/K01 for pre-doc, F32/K99/K01/R21/R01 for post-doc, R01 for faculty).

6. Project Timeline (1 page) – a proposed timeline of study performance should be included, identifying specific tasks and milestones in project progress for the project funding period. Show how the study will be completed in 12-18 months.

7. Planned Enrollment Table – (NIH Template)

8. Budget – an NIH-style budget table of labor, equipment, supplies, travel and other estimated costs to perform the proposed project (applicants may budget up to $35,000 direct costs for pre-doctoral trainees over the entire 12-18 month period, $65,000 for post docs over the entire 12-18 month period, and up to $125,000 for months 1-12 and $50,000 for months 13-18 for early career faculty). Up to 30% of funds can be spent on salary support for the trainee; indirect (F&A) costs are included. Final amounts subject to committee approval.

9. Budget Justification and Personnel – a detailed explanation and justification of the funding request, including description of the investigators and personnel and their roles on the project.

10. NIH-Format Biosketches – required for all PI’s and Co-Investigators (4 page limit per investigator, including Other Support pages).

11. Letter(s) of Support – for junior investigators, department chairs/unit heads should comment on the independence of the applicant and availability of research space and other resources for the proposed research. Include the letter(s) of support at the end of your PDF proposal and address it to TCORS Career Enhancement Core.
If applicable, additional letters of support from consultants may be necessary and should include consulting charges/rates, quotes, and core facilities.

**Reporting Requirements and Timeline**

Written progress reports are due on the following:

1. **May 15, 2020** – One paragraph update with enrollment tables sent to t cors@usc.edu

2. **Oct 2020** – A 15-minute update in presentation format presented in-person or via zoom to the TCORS Team

3. **Feb 1, 2021** – One page progress update with enrollment tables sent to t cors@usc.edu

4. Final report due at project completion with enrollment table
Appendix: USC TCORS Investigator Roster

**Project 1: Effects of Social Media Marketing and Messages on Tobacco Transitions**  
**PIs:** Tess Cruz, Ph.D. and Jennifer Unger, Ph.D.

Project 1 incorporates two complementary studies to determine how pro-tobacco marketing and messages about e-cigarettes on social media will influence e-cigarette susceptibility, experimentation, and transitions in tobacco use among adolescents (under age 18) and young adults (ages 18-29). Results can guide FDA regulations affecting marketing on social media that may have differential effects on non-users and users, and FDA’s evaluation of the potential risk of messages outlined in new product marketing applications.

**Project 2: Influence of Tobacco Product Characteristics and Marketing on Diverse Populations of Vape Shop Customers**  
**PIs:** Steve Sussman, Ph.D. and Lourdes Baezconde-Garbanti, Ph.D.

Project 2 contrasts three groups of vape shop customers—e-cigarette-only users (who never smoked cigarettes extensively); switchers (who quit smoking and now only use e-cigarettes); and dual users (who currently use both e-cigarettes and cigarettes)—regarding anticipated purchase or use of e-cigarettes and combustible products currently and after hypothetical but plausible regulatory changes. Vape shops, which specialize in selling a variety of e-cigarette devices and liquids, are a key channel of exposure to these products. The goal of this project is to examine how different segments of the vape shop customer population would likely react to hypothetical (but plausible) e-cigarette regulations. Researchers will conduct interviews with customers (ages 21 and older) exiting vape shops in a racially/ethnically diverse set of neighborhoods. Findings hope to inform future regulatory activities related to e-cigarettes.

**Project 3: Product characteristics, marketing, and e-cigarette and cigarette use across adolescence and young adulthood**  
**PIs:** Rob McConnell and Jessica Barrington-Trimis

P3 will test hypotheses about e-cigarette product characteristics and marketing strategies that may attract never-smokers and put them at risk for tobacco product use. Researchers will survey participants in three cohorts of adolescents and young adults (ages 14-25) in southern California recruited as part of the TCORS Population Core.

**Project 4: E-Cigarette Flavors and Other Product Characteristics in the Human Laboratory**  
**PI:** Adam Leventhal, Ph.D.

Project 4 will determine effects of e-cigarette product diversity on 1) appeal and abuse liability in never-smoking young adults e-cigarettes users versus older adult smokers, 2) ability to resist smoking in older adult smokers, and 3) appeal, abuse liability, and resisting smoking by sex. Through the human laboratory paradigm, the investigators will experimentally manipulate the content of the e-liquid or the packaging to expose users to products and measure the effects of these exposures.