RFA for Pilot Research Projects in Tobacco Regulatory Science

Release Date: October 28, 2019
LOI Deadline: December 2, 2019
Project Duration: 12-18 months

The Developmental/Pilot Projects Program of the USC Tobacco Center of Regulatory Science (TCORS) aims to support new and innovative research relevant to the regulation of tobacco products by the Food and Drug Administration. We are prioritizing funding support for junior researchers who can use the pilot project process as a capacity building and career enhancing opportunity in tobacco regulatory science (TRS). It is expected that TCORS trainees will submit competitive proposals to this call, as well as other emerging researchers not associated or supported by TCORS. It is expected that up to 3 proposals will be funded in this round depending on number and type of applicants received. Pilot research projects focused on one or more of the following areas are welcome in response to this RFA.

1. Studies focused on FDA’s regulatory priories as outlined in their Advanced Notices for Proposed Rulemaking and Other Notices (e.g. flavors, nicotine standards in combustible cigarettes)
2. Studies that utilize the resources available through USC TCORS (adolescent and young adult longitudinal cohort(s) data and methods, vape shop customer intercept interview data and methods, human laboratory product appeal and abuse liability testing data and methods, social media data and methods)
3. Effects of changes in local, state, federal policies on tobacco product use that may inform federal regulations within the FDA purview (e.g., local sales restrictions on flavored products)
4. Research on the use, marketing, appeal, purchasing behavior, or addiction of newly emerging products and product characteristics (e.g. IQoS, Snus and other oral nicotine products, nicotine salt formulations in e-cigarettes)

Science Focus
To be eligible, proposed studies must be responsive generally to one or more of the following research interest areas established by the Food and Drug Administration’s Center for Tobacco Products: (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 as well as novel alternative toxicology approaches that test the toxicity of smoke, aerosols, or specific constituents
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 products
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 why people become susceptible to using tobacco products (both classes of products and products within classes) and to transitions between experimentation and initiation to regular use and dual use
7. Impact analysis- understanding the impact of potential FDA regulatory actions

Application Deadlines and Key Dates
- Monday, December 2, 2019 – Letter of intent due
- Monday, December 16, 2019 – Selected applicants are invited to submit a full proposal
- Monday, January 27, 2020 – Full application due
- Monday, March 9, 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
Applicants at faculty, postdoctoral, and pre-doctoral levels are eligible to apply. Early-career investigators are especially encouraged to apply. A multiple PI structure is encouraged for projects that require equal and complementary research contributions by other TCORS.

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 investigator salary for faculty and none for pre-doctoral and postdoctoral fellows. 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 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?)
- **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 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**

Applications will only be accepted if submitted via the USC TCORS online Grant Application Processing System (GAPS), available at [http://gaps.usc.edu/](http://gaps.usc.edu/). For first-time applicants, please use this link to register and set up an account. For returning applicants wishing to establish a new user account, please contact Andrew Zaw at andrewz@usc.edu. All required application materials (including LOI and budget templates) are accessible via GAPS.

For technical assistance with GAPS, please contact Andrew Zaw at andrewz@usc.edu. For program-specific or administrative questions, please email the USC TCORS at t cors@usc.edu.

**Instructions for Submission of the LOI**

Before uploading the Letter of Intent:

1. Read the list of “CTP Interest Areas” that appears on pages 1-2 of this announcement.

2. Complete the LOI form that appears in this document or complete the fillable LOI form available directly on GAPS. Do not exceed 1 page total. *Please note that a letter of intent is required before a full application can be considered.*
Letter of Intent Form

Please complete per the above instructions and attach to application site (gaps.usc.edu) or complete the fillable LOI form available directly on gaps.usc.edu.

1. Proposed project title:

2. PI names, titles, phone, and email contact information:________________________

3. Which CTP interest areas does your proposal address (please refer to the CTP Interest Areas listed on pages 1-2 of this RFA):__________________________________________

4. Brief description of project aims, design, sample, sites, measures, analysis plan, and goals (1 page):
   a. Aim(s):
   b. Design:
   c. Sample:
   d. Site(s):
   e. Measure(s):
   f. Analysis Plan:
   g. Overall Goal:

5. Significance to tobacco regulatory science (1 sentence):

6. Innovation (1 sentence):

7. Environment that you feel enables timely IRB project approval and project completion within 12-18 months (1 sentence):

8. Estimated direct cost budget (2 sentence summary of cost breakdown):

9. How this project will enhance your career development (1 sentence):
Instructions for Submission of the Full Proposal

If you are invited to submit a full application, 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** – (Template can be found on GAPS)

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 (4 pages 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. **Collaboration** – 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 an R01 (or equivalent) submission.

6. **Project Timeline (1 page)** – a proposed timelines 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 $15,000 direct costs for pre docs, $30,000 for post docs and $100,000 for junior faculty with up to 30% salary support total; indirect (F&A) costs are included). A sample budget template can be found on GAPS. Final amounts subject to committee approval.

9. **Budget Justification** – a detailed explanation and justification of the funding request.

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 Pilot Projects Core.
If applicable, additional letters of support from consultants may be necessary and should include consulting charges/rates, quotes, and core facilities. If collaborators from non-TCORS institutions are part of key personnel, a letter of commitment that clearly states their roles and commitment to the project is strongly encouraged.

**Reporting Requirements and Timeline**

Written progress reports are due on the following:

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

4. Final report due at project completion with enrollment table