UNC LINEBERGER COMPREHENSIVE CANCER CENTER

REQUEST FOR PILOT RESEARCH GRANT APPLICATIONS FOR 2024-2025

UNC's Tobacco Center of Regulatory Science (TCORS), titled Advancing Tobacco Regulatory Science to Reduce Health Disparities, requests applications for innovative pilot research projects that are responsive to FDA and Tobacco Regulatory Science priorities and our TCORS goals. We seek to fund small, interdisciplinary research projects that include researchers with expertise in public health, medicine, psychology, communication, media studies, and/or other relevant disciplines. We are particularly interested in supporting pre- and post-doctoral, new, and early-stage investigators.

Pilot research projects must address one or more of the <u>FDA Center for Tobacco Products' research</u> <u>priorities</u> and should also relate to the overall theme of the UNC TCORS program to build the science for effective regulation of and communication about tobacco products disproportionately used by priority populations, especially flavored tobacco products and e-cigarettes. Priority is also given to projects focusing on health disparities or advancing health equity. Pilot study proposals will be vetted through the FDA for approval prior to funding.

The total annual budget for pilot proposals is up to \$20,000 for primary data collection and up to \$8,000 for second data analysis. We anticipate funding 2-4 projects in the 2024-2025 period of funding.

Eligibility

<u>Eligible Individuals/Teams</u>: The principal investigator (PI) for each pilot project must be a student, postdoctoral fellow, staff, or faculty member at UNC Chapel Hill. For pre- and post-doctoral trainees, proposals must have a faculty co-PI affiliated with the UNC TCORS. Affiliates from other universities and institutions participating with TCORS may collaborate with UNC TCORS PIs and participate in pilot research as co-investigators.

Key Deadlines

- Application due date: Friday, June 14, 2024 (Midnight EST)
- Award notification: Monday, August 19, 2024
- Complete IRB application for the pilot study, Friday, August 30, 2024
- Anticipated grant start: Monday, September 2, 2025 (Pending IRB approval)
- Progress reports: Friday, February 7, 2025, and Monday, June 9, 2025

Budget and Timeline

- 1. The duration of the pilot project is up to 12 months.
- 2. The maximum pilot proposal budget is \$20,000 if primary data collection is proposed and \$8,000 if second data analysis is proposed.
- 3. Faculty support must be in-kind; pilot funds cannot replace current pre and post-doctoral student TCORS salary support.
- 4. The funding period will begin on Monday, September 2, 2024, and end on August 31, 2024.
- 5. Research should be planned for the allotted time period, as no-cost extensions are not permitted except in individual cases of extenuating circumstances.

Proposal Instructions

The proposal should have ½" margins on all sides and 11pt Times Roman or Arial fonts only. The body of the proposal should not exceed 6 pages (the Title page *and 5 pages that include specific aims, significance, approach, collaboration, and grant funding*).

- A. **Title Page.** Include the title of the pilot study, the date, your name, and the name(s) of a faculty advisor if the applicant is a student or postdoc.
- B. **Specific Aims. (1 page).** Please include the research gap, primary goal of the research, and the central hypothesis. The study aims should briefly include how each study aim will be evaluated/measured.
- C. **Significance.** Briefly summarize the literature that motivates the study and the significance of the anticipated findings. How does the research address FDA priorities and the UNC TCORS theme? How does the research advance health equity? How is the research innovative?
- D. **Approach.** Describe the overall strategy, methods, and analyses. These should be well-reasoned and appropriate for accomplishing each of the specific aims proposed within 12 months. Also, present potential problems, alternate strategies, and benchmarks for success. Your team should use state-of-the-science methods and approaches.
- E. **Collaboration.** Briefly describe your team and any interdisciplinary or multi-site collaboration. Explain how the proposed research involves a team science approach. If PI is a student or Postdoctoral Fellow, please identify your faculty advisor in this section and describe how they will support the project.
- F. **Grant Funding.** Briefly describe how the proposed pilot study's results could inform the development of a full-scale research grant proposal.

Appendices (not included in the 6-page limit)

- A. **Timeline:** Must include a timeline with 3 or 6-month goals/targets achievements.
- B. **Ethics/Human Subjects Protection** Prior to receiving funds, projects must obtain approval from the relevant IRB. All investigators and other people named on the budget page must have certification of training in the protection of human subjects (and HIPAA, if relevant).
- C. Budget and Budget Justification: The Budget should be in a spreadsheet with appropriate salary fringe and benefit rate calculations. Salary support is recommended for students, should be well justified if requested by staff, and is not permitted by faculty. Budget justification should be sufficiently detailed (e.g., look up actual cost online) for reviewers to assess whether the request is for appropriate resources. Inadequate justification may result in a less favorable score or lower funding. If the investigator has received other grant support for the proposed research or similar research in the past, include this information. Indirect costs are not allowable for these pilot grants; please include only direct costs in your budget.
- D. Biosketches. Include NIH-format biosketches for all key collaborators using the new format.
- E. References. Numbered references are preferred.

*The appendices should not include any other materials.

Review Criteria

We will not review proposals that are not responsive to FDA research priorities (e.g., we will reject proposals that have cessation-only aims with no policy or regulatory focus or that address aims related to bench science). Dr. Leah Ranney and one of the Career Core PIs will lead the review committee for the pilot proposals. Additionally, we will invite two other reviewers not associated with pilot research applications. As specified by NIH, research proposals selected for awards will need FDA approval before notifying awardees.

Evaluation of Proposals:

In addition to the NIH evaluation rubric: <u>Review Framework for NIH Research Project Grant Applications</u>, we will also evaluate each proposal on the following criterion:

- 1. responsiveness to FDA TRS priorities;
- 2. focus on messaging to priority populations or regulatory impacts on tobacco use disparities;
- 3. potential for using the pilot data or results for future grants; and
- 4. feasibility of completing the project in 12 months.

Additional Expectations

<u>Progress Reports:</u> Awardees must complete two brief progress reports by Friday, February 7, 2025, and Monday, June 9, 2025, and submit them to the Career Core (<u>Leah_ranney@unc.edu</u>). The career core will contact award recipients who report minimal progress for an in-person meeting to discuss how to facilitate pilot study progress. The one-page report describes:

- 1. progress to date and any unanticipated barriers by grant aim,
- 2. any study findings, and
- 3. any completed or planned dissemination activities (e.g., talks or peer-reviewed publications).

<u>Presentation</u>: Pilot study awardees will be required to share their research (in progress or results) in a trainee or an executive committee meeting.

Proposal Submission

Send the completed proposal application **IN PDF FORMAT** to Leah Ranney at <u>Leah ranney@unc.edu</u>. Applications are due **Friday**, **June 14**, **2024** (midnight pm EST). Leah will acknowledge receipt of all applications via email.

If you have questions about the proposal application process, contact Leah Ranney at Leah ranney@unc.edu.