CALL FOR AppalTRUST Tobacco Regulatory Science Pilot Funding

Click here to apply

INTRODUCTION

The University of Kentucky Appalachian Tobacco Regulatory Science Team (AppalTRUST) Tobacco Center of Regulatory Science (TCORS) is pleased to announce a call for proposals for **Tobacco Regulatory Science (TRS) Pilot Funding**. The goal is to support projects that align with the mission of AppalTRUST and inform tobacco regulatory policy in the US. The overall mission of AppalTRUST is to investigate the impact of US Food and Drug Administration Center for Tobacco Products (FDA CTP) regulatory policies in rural communities, a priority and understudied population, through collaboration, education and pioneering regulatory scientific research. **Applications must be within the scope of current NIH Tobacco Regulatory Science Program (TRSP) and FDA CTP research priorities , and fall within the FDA CTP's regulatory authority over the manufacture, marketing, and distribution of tobacco products**.

Pilot study proposals will be vetted through the AppalTRUST Center, NIH, and FDA CTP for approval prior to funding. The results from each funded project should provide preliminary data to support a grant application for external funding in tobacco regulatory science to be submitted within 12 months from the project pilot funding conclusion. In the pilot application, applicants are required to detail external funding opportunities, the funding announcement numbers, and the funding application deadlines they intend to pursue. We are particularly interested in supporting post-doctoral, new, and early-stage investigators, as well as those new to tobacco regulatory science. The number of awards will depend on the availability of funds, total budget requests, and application merit.

The goal is to support projects that align with the mission of AppalTRUST and inform tobacco regulatory policy. The overall mission of AppalTRUST is to investigate the impact of US Food and Drug Administration Center for Tobacco Products (FDA CTP) regulatory policies in rural communities through collaboration, education and pioneering regulatory scientific research. Applications must be within the scope of current NIH Tobacco Regulatory Science Program (TRSP) and FDA CTP research priorities and fall within the FDA CTP's regulatory authority over the manufacture, marketing, and distribution of tobacco products.

TIMELINE

Release Date: 04/15/2026

Application Deadline: 06/01/2026

Anticipated Funding Start Date: 09/01/2026

Project Duration: 12 months (ending August 31, 2027) unless described as needing less time.

ELIGIBILITY

The principal investigator (PI) for each pilot project must be a full-time postdoctoral fellow or faculty member at the University of Kentucky. This program is open to full-time faculty members (all title series including regular, research, extension, lecturer, clinical, and special) and postdoctoral researchers at the University of Kentucky. To be eligible to apply for funding, applicants must apply to be an AppalTRUST Affiliate (link here).

For post-doctoral trainees, proposals must have a faculty co-I affiliated with the UK AppalTRUST. Post-doctoral mentors can apply to be an AppalTRUST Affiliate (link here).

Collaboration with existing AppalTRUST investigators is permitted but is not required. Affiliates from other universities and institutions participating with TCORS or conducting TRS research may collaborate with UK AppalTRUST investigators and participate in pilot research as co-investigators.

As this grant is funded by NIDA. NIDA provides researchers with additional considerations regarding applicants who also receive tobacco-industry funding. Based on your COI disclosures, AppalTRUST TCORS may ask for additional information regarding potential conflicts of interest.

RESEARCH PRIORITIES

Proposals should address current National Institutes of Health (NIH) Tobacco Regulatory Science Program (TRSP) and US Food and Drug Administration Center for Tobacco Products (CTP) research priorities, with a specific focus on regulatory policies in rural communities, a priority and understudied population.

Responsiveness to FDA's Center for Tobacco Products Regulatory Authority.

These FAQs (PDF) clarify research that is and is not within scope of the FDA's Center for Tobacco Products (CTP) regulatory authority (see #3). Only research that is within the regulatory authority of the FDA CTP will be considered for funding. Note: For this mechanism you do not need to contact NIH staff to determine if pilot grant ideas are responsive to FDA CTP authority. If you have questions about whether your idea is responsive, please contact melinda.ickes@uky.edu to discuss your idea prior to submission.

In general, what areas of research are within the FDA CTP's regulatory authority?

Research is encouraged in the following scientific domains:

- Chemistry and Engineering
- Toxicity
- Addiction
- Health effects
- Behavior
- Communications
- Marketing influences
- Impact analysis

In general, what areas of research are not within the FDA CTP's regulatory authority?

The Family Smoking Prevention and Tobacco Control Act gives the FDA the authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by youth.

In general, the FDA CTP's regulatory authorities do NOT extend to the following:

- 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
- Mechanistic studies (i.e., basic science of disease development) unless biomarkers of harm with predictive value for disease development associated with tobacco product use is an outcome

APPLICATION PROCESS

Applications must be submitted through the application portal (link). Please use the following format: single-spaced, at least 11-point Arial font, and adhere to 1/2-inch margins. The proposal documents should be compiled into one PDF to upload to the application portal. Please note grant applications at UK normally require a Proposal Initiation Form and Internal Approval Form (eIAF), but these steps are not required at the proposal stage. Upon the time an application is selected for funding by UK and NIDA, an eIAF will be required.

Required Application Materials

Pilot Grant application form (link)

Lay abstract (300-word max) – provide a succinct overview of the proposal, including how the proposal is relevant to FDA's tobacco regulatory authority, relevant to the overall theme of the UK AppalTRUST TCORS, or other TCORS sites or centers.

Specific Aims Page (maximum of 1 page)

a. Briefly describe the research question(s) and significance of the proposed study
b. Brief statement on how the project aligns with AppalTRUST's mission and research priorities
c. Brief statement on the relevance of the project to FDA/CTP's tobacco regulatory authorities and research priorities

Research Plan (maximum of 2 pages)

a. Significance/Innovation: Describe how addressing the study aims will promote the translation of scientific knowledge that will impact tobacco regulatory science. Describe how the aims, methods, etc. are innovative.
b. Approach/Scientific Rigor and Reproducibility: Describe the activities that will be undertaken to address the study aims. Include a description of how scientific rigor and reproducibility will be ensured.
c. Investigators and Environment: Describe the qualifications of the investigative team, the role each team member will perform, and resources in the environment that will support the conduct of the study. Describe collaborations with UK AppalTRUST TCORS; and other TCORS sites or centers, as applicable.

Dissemination and External Funding (½ page, does not count towards the 2-page limit for the Research Plan.)
Describe plans for specific deliverables and outcomes beyond the pilot project. This should include dissemination activities such as submission of at least one peer-reviewed manuscript based on pilot findings and presentations at scientific conferences or TRS events.

Additionally, outline plans for extramural funding, including the specific funding mechanisms to be targeted (e.g., NIH R03, R21, or R01) and the anticipated timeline for submission of external grant applications.

Timeline (does not count towards the 2-page limit for the Research Plan)

Must include a timeline with goals/targets achievements.

References (no page limit)

NIH style biosketch for each investigator (5-page limit per investigator)
Clearly outline each investigator's role on the project. Please check here for instructions on formatting an NIH biosketch. Combine all biosketches into one PDF.

Budget and budget justification (Maximum of 2 pages)
Provide a detailed justification for each budget item or category.

a. Allowable expenses include: faculty, staff, student, post-doc effort/salary; travel costs associated with data collection or recruitment; participant payments; supplies or materials to support the research; conference travel for dissemination.
b. The PI must indicate effort on the proposed budget. Awarded projects will be subject to the currently applicable NIH Salary Cap if applicable for salary supported personnel.
c. No-cost extensions are not permitted
d. Please note indirect costs do not need to be included as part of the application but will be set up as is required upon the time the project is awarded and setup with a WBS element account number.

Note: The review committee will make budgetary recommendations that may impact the final award amount. Budgets are recommended for development and/or review by CGS for validation of appropriate and allowable costs.

Post-docs are required to include a letter of support from their mentor.

Institutional Review Board (IRB)
Should any component of the research require the use of human subjects, please indicate whether Institutional Review Board (IRB) approval is pending or approved.

a. New (or a modification of) human subjects approval from IRB is required before pilot project recruitment can commence. In addition, if a pilot project involves new activities with existing human subjects that are not covered under an existing IRB approval for studies currently in AppalTRUST/the UK TCORS, additional IRB approval will be needed before engaging in human subjects research. Studies not including human subjects research should obtain a non-human subjects research (NHR) designation from the IRB. link here
b. Additional details will be provided to those receiving funding.
c. Any other required regulatory approvals need to be indicated as necessary and its approval status (i.e. clinical trial registration).

AWARD REQUIREMENTS

1. ***Participation Requirements***

a. Awardees are expected to be responsive to ongoing contact from AppalTRUST to assess progress and outcomes from the award.
b. Awardees are required to attend regular progress "check-ins" each semester to review timelines and any budget questions.
c. Awardees are required to present their findings at an AppalTRUST sponsored event upon request (e.g. ELEVATE, TRS Seminar)
d. Awardees are expected to submit at least one peer reviewed manuscript during pilot period.

All publications, presentations, posters and other creative activities resulting from this award must include the following acknowledgment: *"Research reported in this publication was supported by grant number U54DA05825601 from the NIH and FDA Center for Tobacco Products (CTP). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the Food and Drug Administration."*

e. All pilot awardees will also receive an annual reporting survey to detail external grant submissions, citations from publications, presentations, patents, community dissemination activities as appropriate, and next steps.

2. ***Reporting Requirements***

a. Awardees will submit a one-page 6-month progress report describing project progress, barriers to progress, new feasibility concerns or major changes to the project, and any products from the project.
b. A final report that is one (1) page in length is due two weeks after project/funding completion. It must detail the tangible results, e.g., the status of related external grant submissions, citations from publications, presentations, patents, community dissemination activities as appropriate, and next steps.

REVIEW CRITERIA

All proposals will first be screened to ensure they are responsive to FDA CTP research priorities. Those that are not responsive will not be fully reviewed. The AppalTRUST Pilot Review Committee will review responsive proposals based on the criteria outlined below. The review committee will also assess whether the proposed budget and timeline are appropriate for the scope and nature of the project and whether any human subjects considerations may affect study implementation.

As specified by NIH, research proposals selected for awards will need NIH and FDA CTP approval before notifying awardees.

Each proposal will be evaluated based on the following criteria:

Overall Impact: Reviewers provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed). An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Factor 1. Importance of the Research

- *Significance*
    - Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.
    - Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.
- *Innovation*

- Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field.
- Evaluate whether the proposed work applies novel concepts, methods or technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

Factor 2. Rigor and Feasibility

- *Approach*: Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).
- *Rigor*:
  - Evaluate the potential to produce unbiased, reproducible, robust data.
  - Evaluate the rigor of experimental design and whether appropriate controls are in place.
  - Evaluate whether the sample size is sufficient and well-justified.
  - Assess the quality of the plans for analysis, interpretation, and reporting of results.
  - Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.
  - For applications involving human subjects or vertebrate animals, also evaluate:
    - the rigor of the intervention or study manipulation (if applicable to the study design).
    - whether outcome variables are justified.
    - whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup.
    - >whether the sample is appropriate and sufficiently diverse to address the proposed question(s).
  - For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.
- *Feasibility*:
  - Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances.
  - For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain an appropriately diverse population of participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment based on age, racial, ethnic, and sex categories.
  - For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

Factor 3. Expertise and Resources

- *Investigator(s)*: Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. For Multiple Principal Investigator (MPI) applications, assess the quality of the leadership plan to facilitate coordination and collaboration.
- *Environment: Evaluate* whether the institutional resources are appropriate to ensure the successful execution of the proposed work.

CONTACT

Please reach out to Dr. Melinda Ickes, Lead of the AppalTRUST Career Enhancement Core (melinda.ickes@uky.edu) with any questions.