Request for Applications
Mentored Pilot Research Projects to Inform FDA Regulation of Tobacco Products
Center for Research on Flavored Tobacco (CRoFT)
University of Rochester/Roswell Park Comprehensive Cancer Center
Application Deadline: 3 May 2020
Project Start Date: 1 September 2020

Description: The aim of this RFA is to support new and innovative mentored pilot research relevant to the regulation of tobacco products by the Food and Drug Administration (FDA) Center for Tobacco Products (CTP). One goal of the pilot grants program is to foster careers in tobacco regulatory science-relevant research. Funded projects should lead to development of an application for externally funded research, for example, through the Tobacco Regulatory Science Program at the NIH and FDA (https://prevention.nih.gov/tobacco-regulatory-research), or through other NIH Institutes or Centers.

Projects will be required to identify a clear tobacco regulatory science (TRS) goal aligned with one or more FDA CTP priorities. Priority areas are: Toxicity, Addiction, Health Effects, Behavior, Communications, Marketing Influences, and Impact Analysis, all related to tobacco products including electronic nicotine delivery systems (ENDS). Additional detail on these priority areas can be found at https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm311860.htm. The NIH and FDA encourage use of the PhenX Toolkit (www.phenxtoolkit.org) and other common data elements (https://www.nlm.nih.gov/cde/), as appropriate. Priority will be given to projects that include collaborators from both Roswell Park and the University of Rochester and that engage with CRoFT research projects and cores as appropriate (https://www.flavoredtobacco.org/). For questions about specific CRoFT projects and cores, please click on "Contact" at the bottom of each page on this CRoFT flavored tobacco website, or email croft@roswellpark.org.

Following Notifications of Award, Postdoctoral Fellows and New/Early Stage and TRS transitioning applicants will identify a mentoring team to include at least one CRoFT investigator; will consult with the Biostatistics & Informatics Core to ensure appropriate study design, power calculation, and analysis plan; and will create a TRS career enhancement plan. This plan will use existing resources at both institutions, such as coursework from existing certificate programs; elective coursework including audits; an internship/rotation; TRS seminars and colloquia; Un-Meetings; participation in synergy manuscripts, and/or other team science experiences. Pilot awardees will present their work at the annual CROFT conference, held alternately at Roswell Park and the University of Rochester.

Eligibility: Mentored pilot projects are open to those with primary appointments at Roswell Park or the University of Rochester in any of the following categories: Postdoctoral Fellows with at least 1.5 years remaining on their funded training period at the time of award, New/Early Stage investigators, investigators transitioning to TRS, and current TRS investigators exploring new areas of TRS research. No funding from tobacco or e-cigarette industries in past 5 years is allowed (see https://www.drugabuse.gov/research/clinical-research/regulations-policies-guidance/points-to-consider-regarding-tobacco-industry-funding-nida-applicants). Each applicant may submit only one proposal as PI or MPI, though they may be listed as co-investigators on other submissions.

Funding: This RFA will fund up to 2 meritorious mentored pilot projects. A maximum of $13,600 each will be awarded for a 12-month period. Funding will include project costs, travel to a scientific meeting for presentation of project results, and travel to other TCORS or related sites for a rotation and/or collaboration.

Deadlines:

- 3 May 2020 – Full proposals must be received. Proposals received after 11:59 PM will be rejected.
- 1 July 2020 – Notifications of Award will be made.
- 1 September 2020 – Anticipated start date.

Application Guidelines: The application should be submitted through the REDCap portal at http://j.mp/39bC1WF. We encourage you to contact a CRoFT investigator prior to submitting to discuss your idea. A 3-page research plan, including all tables and figures (but not including references, budget, budget justification, and biosketches), should be uploaded and include the following components:

- Single-spaced, 11-point font minimum, at least 0.5-inch wide margins.
- The following Research Plan sections: specific aims, background and significance, innovation, research design and methods, future research plans.
    - Clearly identify how the proposed pilot addresses one or more of the FDA TRS priority areas: https://www.fda.gov/TobaccoProducts/PublicHealthScienceResearch/Research/ucm311860.htm
    - Clearly identify plans for development of an externally funded research proposal.
    - Clearly identify any collaborations between Roswell Park and the University of Rochester, and/or with other TCORS investigators.
- Include an NIH biosketch for yourself and other key investigators.
- For postdoctoral fellows, include a letter of support from your current fellowship mentor, who should also agree to serve on your mentoring team, *and* from a proposed primary mentor for your proposed project if that person is different from your current fellowship mentor.

Budget and Justification: Include a budget (in NIH format) and budget justification. Funds can only be used for direct costs associated with project research activities, staff or student support to implement project, project-related travel for conference travel and travel to other TCORS or related sites for rotations and/or collaborations to enhance TRS research experience, and purchase of research materials including data sets. Investigator salary is not allowed.

If Funded - Requirements Prior to Release of Funds:

- Proof of IRB or IACUC approval, as appropriate. For projects with an MPI at Roswell Park and U of Rochester, a central IRB through Roswell will be used in lieu of the local IRB.
- Proof of Delayed Onset approval from NIH: The NIH requires that CRoFT obtain explicit approval from the NIH for any pilot-funded research involving human subjects. Accordingly, the IRB-approved protocol and other materials must be submitted to the NIH at least 30 days prior to the project start date. CRoFT personnel will work with awardees to meet these requirements.
- Proof of Prior Approval of Vertebrate Animals Research: The NIH requires that CRoFT obtains explicit approval from the NIH for any pilot-funded research involving vertebrate animals. IACUC approval documentation and other materials must be submitted to the NIH at least 30 days prior to the project start date. CRoFT personnel will work with awardees to meet these requirements.

Reporting Requirements: Awardees will submit a mid-year report at the 6-month point following funding. Within 60 days after the end of the project, awardees will submit a final written report. Applicants will present their research at the annual CRoFT conference in Buffalo or Rochester,

depending on year, as described above. Applicants will agree to participate in brief follow-up surveys of TRS activities in the years following funding.

Publications: All publications that benefit in whole or in part from support provided by CRoFT must:

- Comply with the NIH Public Access Policy: Information regarding the Public Access Policy is located on the University of Rochester Miner Library website at http://www.urmc.rochester.edu/libraries/miner/publishing/NIHPublicAccessPolicyMinerLibrary.cfm.
- Acknowledge CRoFT grant funding as follows:
    - "Research reported in this [publication/press release/etc.] was supported by the National Cancer Institute of the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) Center for Tobacco Products under Award Number U54CA228110. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH or the FDA."
- Prior to issuing a press release concerning the outcome of this research, please coordinate with your department's communication contact person and notify Craig Steger, MA, Craig.Steger@RoswellPark.org, who will then notify the National Cancer Institute in advance to allow for coordination.

Review Priorities: Priorities for awarding pilot funding include:

1) Responsiveness to the RFA and FDA priorities.
2) Quality of the proposed science.
3) Potential to stimulate subsequent independent funding.
4) Collaborations. Proposals that include collaboration between U of Rochester and Roswell Park and/or with collaborators from another TCORS are preferred.

Review Process: Proposals will be reviewed by the CRoFT Pilot Review Committee, consisting of investigators from Roswell Park and the University of Rochester, and other selected *ad hoc* experts as needed to allow for rigorous scientific review. Decisions will be made following review, and a formal study section-style discussion and scoring meeting. Trainee proposals will be reviewed separately from the other categories.

Contacts: If you have questions regarding this RFA, please contact one of the following:

Application Contact:
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Scientific/Research Contact:
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