Pilot Research Grants Program Objective

The American Heart Association (AHA) Tobacco Regulation and Addiction Center (A-TRAC) is committed to utilizing interactive programs of multidisciplinary research to add to the existing information base on tobacco regulatory science as it relates to the effects of tobacco products on cardiovascular health. The Center is focused on providing data that will help inform regulations of the manufacture, distribution, and marketing of tobacco products, as well as to facilitate effective communications of FDA-CTP regulatory policies among different population groups.

The Development and pilot research component of A-TRAC (Pilot Core) was envisioned as a foundation for funding short term innovative pilot projects with well-defined aims that could be accomplished in their entirety within the funded period. They should be closely aligned with A-TRAC’s scientific direction and FDA/NIH priorities, while having an ability to integrate the pilot projects into a larger research framework. Short term pilot projects with well-defined aims that can be accomplished in their entirety within the funded period will be considered for funding. Studies focused on assessing the mechanisms related to the adverse health outcomes of tobacco product use are not considered responsive to the FDA specified aims of TCORS.

Regulatory science research

Tobacco regulatory science research translates general scientific knowledge into specific findings which can serve as a guide for regulatory decisions and actions. The project should have a high probability of leading to new policies related to tobacco use and cardiovascular health and add to the existing scientific body of knowledge. Applicants are encouraged to highlight the specific rule or other regulatory decision that could potentially be made based on their proposed research. Submissions are encouraged from the entire spectrum of scientific disciplines including basic, translational, behavioral, population and epidemiological, community, and clinical investigations, relevant to research on effects of tobacco use on stroke, cardiovascular health and disease. The main purpose of this Core is to fund rapid response projects focusing on time sensitive topics required to meet the knowledge gaps in regulatory science.

The Pilot Research Grant program aims to promote new and bold scientific ideas. Proposed work may be an extension of a currently funded project, but should not have any budgetary overlap or overlap in aims with the parent projects being funded; it could also be an entirely new project.

Submissions are encouraged from the entire spectrum of scientific disciplines including basic, translational, behavioral, population and epidemiological, community, and clinical investigations, relevant to research on effects of tobacco use on stroke and cardiovascular health and disease, as well as the application of the best available science to specific regulatory questions pertaining to tobacco use.
Science focus of applications
- **Product diversity** – understanding the types of tobacco products and how their specific characteristics affect people's attitudes, beliefs, perceptions, and use of these products
- **Addiction** – understanding what effect different levels of nicotine and other factors have on addiction
- **Toxicity** – understanding how changes in tobacco products affect their potential for harm and ways to reduce that harm
- **Health consequences** – understanding the risks of different tobacco products
- **Communication** – finding ways to effectively convey information about the risks of using tobacco and about CTP's role in regulating tobacco products
- **Marketing** – understanding the impact of tobacco product marketing and public education on people's attitudes, beliefs, perceptions, and use
- **Economics and policy** – estimating the economic impact of CTP's regulations; also understanding how CTP's actions change tobacco use and illness and death from tobacco use

Focus of pilot projects
1. To identify and evaluate the cardiovascular toxicity of harmful and potentially harmful substances in emerging tobacco products such as e-cigarettes, hookah and smokeless tobacco, with special emphasis on flavorings in animal models
2. Identify biomarkers of exposure and long-term cardiovascular injury due to tobacco product use in prospective cohorts and determine how these vary between different ethnic groups, with special emphasis on rare exposures (pipes, cigars and cigarellos)
3. Examine acute effects of nicotine and reactive carbonyls on cardiovascular function.
4. Evaluate the association between attitudes and perceptions, tobacco use and cardiovascular disease risk in populations of different ethnicity
5. Develop effective messaging targeted to different ethnic populations using AHA programs (Go Red for Women, Heart Walk and Hoops for Heart)

Eligibility Requirements
At the *time of application* the applicant must fulfill the eligibility requirements below
- The applicant/PI should be an employee of one of the TCORS member institutions (listed under “Location of Work”) or other CTP-funded institutions.
- Investigators from TCORS member institutions other than A-TRAC affiliated institutions must have a collaborating A-TRAC investigator.
- The project must not have any overlap with any on-going A-TRAC supported project.
- These grants are open to investigators of any rank, including but not limited to the following: Post-doctoral students and fellows, early career faculty and Assistant, Associate, or Full Professors.
- The A-TRAC investigators are committed to the career development of early career investigators. Hence, we encourage early career investigators and TCORS trainees to apply for pilot funds.
- Applicant should have a Masters or post-baccalaureate doctoral degree, including MPH, RN, PharmD., MD., DO., or PhD.
• Interdisciplinary research teams are eligible, but a contact PI must be identified who will take responsibility for scientific and administrative oversight of the project.
• Previous projects that were not funded are eligible for reapplication, but the project will be reviewed as a de novo submission.
• Applicants with an existing A-TRAC pilot project can apply for an additional year of funding, however, they should clearly describe the progress made during the previous funding cycle. Applications for continuation of a project will be evaluated as a competitive renewal grant application and will be scored relative to all other applications.
• An investigator may hold another AHA award (affiliate or national) in concurrence with an A-TRAC pilot project as long as there is no budgetary or scientific overlap in the specific aims of the projects.

Percent Effort
While no minimum percent effort is specified, the PI must demonstrate that adequate time will be devoted to ensure successful completion of the proposed project.

Citizenship
At the time of application, the applicant must have one of the following designations:
• U.S. citizen or noncitizen national
• Permanent resident
• Pending permanent resident. Applicants must have applied for permanent residency and have filed form I-485 with the U.S. Citizenship and Immigration Services and have received authorization to legally remain in the United States (having filed an Application for Employment Form I-765)
• E-3 - specialty occupation worker
• F1 - student visa
• H1-B Visa - temporary worker in a specialty occupation
• J-1 Visa - exchange visitor
• O-1 Visa - temporary worker with extraordinary abilities in the sciences
• TN Visa - NAFTA Professional
• G-4 Visa - family member of employee of international organizations and NATO

Awardee must meet the American Heart Association citizenship criteria throughout the duration of the award.

Location of Work
Only applicants from the following TCORS may apply in this round of pilot project funding:
- American Heart Association TCORS
- University of California San Francisco TCORS
- University of Vermont TCORS
- University of North Carolina TCORS
- Georgia State University TCORS
- Pennsylvania State University TCORS
- University of Pennsylvania TCORS
- Ohio State University TCORS
- University of Maryland TCORS
- University of Southern California TCORS
- University of Texas TCORS
- Virginia Commonwealth University TCORS
- Yale University TCORS &
- Other Institutions conducting CTP-funded research

Budget Guidelines

Project Support: Project-related expenses, such as salaries and fringe of technical personnel, consultant services, supplies, equipment, travel, subject costs, publication costs, within the following limits:
- Direct - $75,000-$1,50,000 per year
- Indirect - 10 percent of direct costs ($7,500-$15,000 per year)
- Total - $82,500-$1,65,000 over one year (within July 1, 2017 – June 30, 2018)

Investigators from TCORS member institutions other than A-TRAC affiliated institutions, should have a subaward agreement with the collaborating A-TRAC investigator’s institution.

Peer Review Criteria
The A-TRAC Pilot Project Executive Committee will pre-screen all proposals in Phase I of application cycle to assess the responsivenss of the project to FDA’s research guidelines and the competitiveness of the application. Only projects selected in this phase will be invited to submit full research proposals for the final peer-review process. The Executive Committee will also make the final funding decision based on relevance to A-TRAC mission, FDA/ NIH research priorities and scientific merit. To judge the merit of the application, reviewers will comment on the following criteria. Please ensure that you fully address each of these in your full proposal in Phase II.

1. Significance: Does the project address an important issue or a critical barrier in regulatory authority over tobacco products? If the aims of the project are achieved, how will regulatory science research be informed or regulation affected? How will successful completion of the aims have affect on the concepts, methods, technologies, or regulation of tobacco products? How does the project relate to the thematic focus of ATRAC?

2. Investigator(s): Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience, training to carry out the proposed study aims? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD(s)/PI(s), do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
3. **Innovation:** Does the application challenge and seek to shift current research in the field of tobacco science as it relates to the manufacture, distribution, and marketing of tobacco products? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, or instrumentation proposed? Will the outcomes of the project provide new information to further develop the knowledge base that informs the manufacture, distribution, and marketing of tobacco products in order to protect public health?

4. **Approach:** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

5. **Environment:** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

6. **Impact:** How does this project relate to the mission of the FDA to generate science that can inform and evaluate FDA’s prior, existing and prospective tobacco regulatory activities? What is the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved?

**Restrictions**
- While this proposed project can include a new hypothesis and aims, or describe an outcome or natural progression of an already-existing project, this proposal should not have overlap with any projects (budgets or specific aims). Awards are not intended to duplicate currently funded work. Pilot projects may be extensions of currently funded projects but must demonstrate lack of duplication with the funded project.

**PROPOSAL COMPONENTS AND REQUIREMENTS:**

- This is a **single phase application cycle** with the following requirements: Applicants are required to submit a full proposal listing the significance of the proposed research and how it relates to the FDA tobacco regulatory research priorities. The application should list the specific aims, regulatory policy impact, significance of project, detailed research plan, human subject protection plan, budget, budget justification, letters of support, institutional assurances (IRB & IACUC), biosketch, collaborating investigator’s biosketch and research support documentation and consultants’ letter. The proposals will be reviewed based on the peer-review criteria section of this document and award notifications will be sent out after all review and approval steps have been completed.
Please include the following documents in the order specified below:

- Title of project, abstract, specific aims and regulatory implications *(no more than 2 pages)*
- Research plan *(no more than 6 pages)*
- Literature cited *(not included in the 6 page limit of the res. plan)*
- Human subject protection plan and planned enrollment, if applicable *(Instructions can be found on the NIH human subject research policy page)*
- Research environment *(no more than 1 page)*
- Vertebrate Animal Subjects section *(if applicable)*
- IRB/ IACUC approvals or a brief statement if the approval does not include your name or project title. If this is an independent project and you have not applied for IRB approval yet, please mention so in this section with a note to send in the approval documents before the project starts.
- NIH Biosketch and Other support pages for all investigators
- Letter of support from collaborator/s *(if applicable)*
- Detailed budget in PHS 398 template
- Detailed budget justification

All documents should be submitted using NIH forms and these form templates are available on the A-TRAC website. Please use the continuation page template for all sections except the budget, biosketch, planned enrollment table and other support pages.

**In addition to the proposal, please also submit:**

- A Statement of Intent (SOI) showing the Institutional Financial Conflict of Interest (FCOI) policy from the main applicant institution’s Sponsored Programs Office. If you will have other institutions working with you, those institutions will need to be subrecipients and we will need SOI’s from each.
- A completed face page (attached template) with your full application during submission.

Please email these documents as a single PDF file to Anshula Kesh by **April 28, 2017**.

- A final progress report detailing study achievements and progress towards the goals is required at the end of the grant year. A scientific progress report will also be required for inclusion in the Center’s interim progress report.

- All applicants are expected to either present their research findings to the entire A-TRAC group in person at the **2018 annual A-TRAC meeting**, or in the form of a webinar to the entire A-TRAC investigator panel.

**In case of any questions about the application, please contact:**

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