Pilot Research Grants Program Objective
To fund innovative ideas and meritorious pilot research projects related to tobacco use and cardiovascular health that are focused on target areas consistent with the American Heart Association (AHA) Tobacco Regulation and Addiction Center (A-TRAC) mission of aiding in the development and evaluation of tobacco product regulation by the Food and Drug Administration (FDA) and thereby contributing towards the protection of public health and reduction of tobacco-related disease, disability and death. A-TRAC is part of the larger Tobacco Center of Regulatory Science (TCORS) funded through the National Institutes of Health (NIH) and the U.S. FDA.

The Pilot Research Grant program aims to promote new and bold scientific ideas; hence, proposals need not include preliminary data. Proposed work may be an extension of a currently funded project without a budgetary overlap or an overlap in aims with the parent project. It could also be an entirely new project. The project should have a high probability of leading to new avenues of investigation related to tobacco and cardiovascular health and adding to the scientific body of knowledge. Funding by this program may provide pilot or seed funding that could potentially lead to competitive future proposals for additional funding beyond the pilot period. Shorter term projects with well-defined aims that could be accomplished in their entirety within the funded period will be given equal consideration for funding. Studies focused on assessing the mechanisms related to the adverse health outcomes of tobacco product use will not be considered responsive to the FDA specified aims of TCORS. However, studies assessing the varied pathophysiologic effects across the spectrum of tobacco products will be considered for funding.

Science Focus
Research broadly related to assess the effects of tobacco products on cardiovascular health and disease, as well as communication and marketing approaches related to the use, distribution and sale of tobacco products and intervention strategies suitable for cessation of tobacco product use in both general and minority populations.

Disciplines
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 the effects of tobacco use on stroke and cardiovascular health and disease, as well as proposals in the area of tobacco regulatory science research.

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 A-TRAC member institutions (listed under “Location of Work”).
- These grants are open to investigators at any rank, including but not limited to the following: Post-Docs, early career faculty and Associate or Assistant or Full Professors.
- 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.
- 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*, 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 A-TRAC institutions may apply in this first round of pilot project funding:

- University of Louisville
- University of Mississippi Medical Center
- Northwestern University
- Boston University Medical Center
- Johns Hopkins University
- Wake Forest University
- New York University

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 per year
- Indirect - 10 percent of direct costs ($7,500 per year)
- Total - $82,500 over one year (within September 1, 2014 - August 31, 2015)

Four projects will be selected for funding for this application cycle.

Salary stipends and fringe for principal investigators and mentors will be allowed up to a maximum of $15,000 per year.

Subcontracts to other institutions are not allowable.

Peer Review Criteria
The A-TRAC Pilot Project Executive Committee will pre-screen all proposals for relevance to the A-TRAC mission before submitting the applications for the final peer-review process. The Executive Committee will also make the final funding decision based on relevance to A-TRAC mission 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 proposal.

1. **Significance:** Does this study address an important problem broadly related to effects of tobacco on cardiovascular health and disease? Does the proposal focus on tobacco regulatory science that can contribute to the science base that FDA can use to develop necessary product regulation, which will in turn reduce the toll of tobacco-related disease, disability, and death?
2. **Approach:** Are the conceptual framework, design, methods and analyses adequately developed, well integrated, well-reasoned, feasible, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative strategies?

3. **Innovation:** Is the project original and innovative? Does the project challenge existing paradigms and address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?

4. **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

5. **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

6. **Impact:** How does this project relate to the mission of A-TRAC to build healthier lives, free of cardiovascular disease and stroke and provide scientific evidence related to tobacco use, and to inform and evaluate FDA’s prior, existing and prospective tobacco regulatory activities?

**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 already-funded 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 of the current project.
- If unfunded, an applicant will be allowed to resubmit the same or similar application during subsequent A-TRAC pilot project funding cycles.

**Proposal Components and Format**

- Please refer to the Application Guidelines for the components of the research plan and format requirements.
- A final progress report detailing study achievements and progress towards the goals is required at the end of the grant year.
- All applicants are expected to either present their research findings to the entire A-TRAC group in person at the annual A-TRAC meeting scheduled from 10-12 March, 2015, at the
University of Louisville campus, or in the form of a Webinar to the entire A-TRAC investigator panel.