End Nicotine Addiction in Children and Teens (ENACT)

- **Each applicant must be an AHA Professional Member.**
- Join or renew when preparing an application in ProposalCentral, online, or by phone at 301-223-2307 or 800-787-8984. Processing for your partner account takes 3-5 days; ***do not wait until the application deadline to renew or join.***
- Supported Web Browsers (PDF)
- View the detailed Applications Instructions (PDF).

Timeline

November 17, 2019 - Program announcement and funding opportunity published.

December 9, 2019 - ProposalCentral is open for application submissions
If you anticipate submitting an application for this opportunity, please send an email to SFRN@heart.org. This will help us anticipate application volume for proposal reviews. No details are necessary with this email.

January 7, 2020 - Application submission deadline
Applications must be received no later than 5 p.m. CST on the deadline date. The system will shut down at 5 p.m. CST. Early submission is encouraged. Your institutional Grants Officer (GO) has the final responsibility of submitting your completed application to the American Heart Association. It is important that you check with your GO for his/her internal deadline.

- February 11, 2020 - Notification of finalists
- February 27, 2020 - Invited finalists interviews
- February/March 2020 - Announcement of award(s)

Statement of Purpose

The AHA is committing up to $20 million to fund two or three (2-3) bold, ground-breaking research projects focused on the health impacts of nicotine and nicotine delivery products in children and youth. The AHA seeks to accelerate desperately needed answers about the health effects of e-cigarettes and other novel nicotine delivery devices (ENNDs) and how to prevent and/or reverse the developing epidemic of nicotine addiction, among children and youth (defined as 15-24 years of age).

The Urgent Need

As rates of combustible cigarette use fell to historic lows, the tobacco industry devised a novel way to addict a new generation of customers to their nicotine products. E-cigarettes have been falsely marketed as safer for users, less intrusive to others, and an

effective means for quitting combustible tobacco. The reality is the biological impacts of the myriad chemicals delivered via the various types of available e-cigarettes and other novel nicotine delivery devices (ENNDs) on multiple organ systems (heart, brain, lungs, vasculature, etc.) are largely unknown, especially among vulnerable children and youth - who are still growing. The difficulty in defining the etiology of the recent outbreak of vaping-related lung disease and deaths is an additional tragic validation of this urgent gap in knowledge.

There is also insufficient data on behavioral factors, specific social influencers, and policies on initiation, dual-use, addiction, and/or cessation across or between diverse populations. Policymakers, regulators, medical professionals and parents are seeking strategies, policies, and solutions, but the scientific evidence to inform these efforts is in many cases inadequate as understanding of the long-term effects of nicotine addiction in children and youth have been inadequately researched.

The Opportunity

The rapid pace of e-cigarette products entering the market without provision of essential safety information requires an equally rapid, ambitious, comprehensive response on the part of the research/scientific community. The AHA seeks to accelerate desperately needed answers about the health effects of ENNDs and how to prevent and/or reverse the developing epidemic of nicotine addiction, among children and youth (defined as 15-24 years of age). **To that end, the AHA is committing up to $20 million to fund two or three (2-3) bold, ground-breaking research projects focused on the health impacts of nicotine and nicotine delivery products in children and youth.**

Science Focus

The AHA is uniquely positioned to launch a bold research initiative addressing key gaps in basic, clinical, and behavioral science related to e-cigarette use and nicotine addiction in children and& youth. Based on the latest available and emerging evidence, the AHA has identified a number of topics of priority interest; however, they ***should not be considered exclusive***. Innovative, original research proposals leading to rapid discovery will be of the highest interest.

- Nicotine's impact on adolescent brain development, intelligence and learning;
- The physiological impact of nicotine and other e-cigarette chemicals;
- The role and influence of device type, flavors and other e-cigarette chemicals and byproducts on addiction;
- How to reverse nicotine addiction in youth using behavioral, pharmacological and/or mobile health technology solutions;
- Natural history and progression of ENNDs use, including dual-use, transitions to/from combustible tobacco, and cessation effectiveness, with a focus on equity and variations among populations;
- The impact of policies eliminating flavors, imposing sales age restrictions and restricting marketing practices on youth e-cigarette use

It is recognized that the gap in research on children and youth is due to appropriately stringent legal and ethical standards that have made conducting these studies difficult. Nevertheless, major advances in understanding nicotine and e-cigarette use in children and youth are dependent on studies in these populations. **Thus, studies must be in children and/or youth, or have direct applicability to addressing use in these populations**. Proposals with animal studies will be considered if they demonstrate clear applicability to the problem in human populations.

The AHA will grant **competitive research awards of up to $10 million over two years** to two or three (2-3) highly inspiring and innovative integrated team(s).

Research Leader and Team

Applicants are expected to select a domestic or international Principal Investigator (PI) and an **integrative team** that will leverage diverse skills and perspectives to address a compelling **selection or combination** of the above or equally compelling relevant topics. The members, and thus the perspectives of the integrative team, might include researchers and clinicians as well as biomedical specialists, sociologists, psychologists, business, fiscal, lay adult and/or children stakeholders or other experts as required. Fellowships and training within the projects are welcome, but not required.

Target/Eligibility

Research Leaders are expected to demonstrate the following or equivalent attributes:

- Ph.D. and/or M.D. or strong research experience and success
- Ability to develop new tools and methods that support creative, experimental approaches, utilizing techniques from other disciplines, if needed/appropriate
- Creativity in scientific ideas and commitment to take risks on forward-looking concepts of major scientific impact
- U.S. government employees are not eligible

We seek and strongly encourage applications from women and members of racial and/or ethnic groups that are under-represented in biomedical sciences.

Awardees will be invited to and expected to attend symposia, conferences and other gatherings of American Heart Association researchers. These events offer time for cross-fertilization of leading-edge research ideas and new collaborative opportunities.

Application Submission

The application requires the following four documents. Formatting instructions are in the last section below.

A. Research Proposal (up to 12 pages). Please address the following points:
    1. **Concept (1-2 pages):** Your creative idea or hypothesis related to nicotine/e-cigarette (ENNDs) use and related effects in children and youth. Include:

    a. How your plan advances research into new areas and/or difficult problems not previously explored.
2. **Plan (8-10 pages):** Your research plan to produce compelling new knowledge prioritized in this call for proposals. Include a timeline of key milestones you would target in this 2-year study.
3. **Team (1-2 pages):** Who will be on your team and why you selected them. Include:
    a. The number of team members and their roles (e.g., Principal/Co-Investigator, technical research staff, biostatistician, clinicians, social scientists, lay adult/children stakeholders, etc.). Percent effort allocation is not required. If your proposal involves multiple institutions, please provide this information for each institution.
    b. Your (team's) capacity to develop new tools and methods that support creative experimental approaches.

B. Biosketch for PI and any co-PIs (up to 5 pages each)
C. A list of up to 10 relevant or important publications (1 page)
D. Budget request (1 page): Whereas a detailed budget will only be required for invited proposals, please provide the following information:
    - Total funds requested
    - If your proposal includes multiple institutions, provide the estimated budget for each institution

Applications to be Completed in ProposalCentral

- Applications must be submitted via ProposalCentral by the institution's Grants Officer. Submit the application your institution's Grants Officer in enough time to allow them to review and submit it to the AHA by the deadline.
- The required uploads must each be created as word-processed documents, converted to Portable Document Format (PDF) files, and uploaded within ProposalCentral. If ProposalCentral is not yet open to accept proposals, applicants can prepare the required documents. *Note: ProposalCentral will not accept a document that exceeds the page limit.*
- Internet Web site addresses (URLs) may not be used to provide information necessary to the review. Reviewers are under no obligation to view the Internet sites. Moreover, reviewers are cautioned not to directly access an Internet site, as it could compromise their anonymity.
- The only place a URL may be used is in the biographical sketch as described in the instructions for that form. Provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.

Format/Type Requirements

Applicants must comply exactly with the AHA's format/type requirements and page limits. Failure to comply will result in the administrative withdrawal (disqualification) of the application.

- Only Portable Document Format (PDF) files will be accepted.

- No more than 15 characters per inch (cpi) or an average of no more than 15 cpi (cpi includes symbols, punctuation and spaces).
- No less than ¾" margins allowed.
- Sixty lines per page are the maximum allowed. The average number of lines per page using the font and point size below will be approximately 50-55 lines.
    - Windows users: Arial Font style, 12 point font size
    - Macintosh users: Helvetica Font style, 12 point font size
    - Figures, charts, tables, graphics and legends may be smaller in size but must be clear and legible.

Award Amount & Duration

- **Duration**: Awards are for a two-year period.
- **Amount**: Applicants should propose a scope of research that could be completed at a target level of $7-10 million. A Selection Committee will determine finalists and provide budget guidance for invited second stage submissions.
- **Number of Awards**: Two or three* (2-3) Research Leaders and their investigative teams will be awarded. Awards will be selected based on scientific merit and how each group aligns with the mission and goals of AHA and any other partner may AHA bring to this project.
- **Budget**: Costs such as PI and any co-PI salary/fringe; salaries/fringe of technical personnel; other expenses such as laboratory supplies; equipment; marketing surveys; focus group costs; animal costs; human subject recruitment/reimbursement; travel; publication costs. Up to 10% may be used for institutional indirect costs. As noted, a skeleton budget is required in the application; however, a full budget will be requested from awarded teams.

*The AHA reserves the right to determine the final number of awardees.

Peer Review Criteria

Impact: Is the research described by the applicant likely to lead to the development of significant contributions in areas outlined in the RFA? Does the research challenge existing paradigms or critical barriers to progress in the field? Does the leader/team propose transformative approaches to understanding the adverse effects of nicotine?

Innovation: Are there new conceptual innovations in the proposed project? Does the applicant describe the development of new tools and methods that support creative experimental approaches to questions, encompassing concepts or techniques from other disciplines?

Investigator(s): Does the leader and/or team express creative ideas and a commitment to pursue pioneering work at the leading edge of science? Does his/her/their record of accomplishment and scientific choices suggest the ability to transform the field and leverage different domains of science and expertise?

Collaboration: Does the leader/team provide evidence of the proposed team's ability and commitment to collaborate effectively, particularly as it relates to integrated

strategies of the proposed topics of study? Does the applicant and/or team have a strong history and track record of collaborating with other experts in the field?

Synergy: Does the proposal provide a clear vision of scientific direction, with a compelling selection or combination of topics that complements and contributes to an integrating theme? Will the combined effect be greater than the sum of its parts?

Review Process

The first stage of review will evaluate the written proposal against the peer review criteria listed above.

A second stage review will be conducted from only the highest ranked candidates and will include a reverse site visit for project principals. Detailed requirements for the interview phase will be communicated when finalists are notified of their advancement.

Applicants are prohibited from discussing proposals with peer reviewers. This is a form of scientific misconduct and will result in removal of the application from funding consideration and institutional notification of misconduct.

Relevant Policies

Public Access: The AHA requires that all journal articles resulting from AHA funding be made freely available in PubMed Central within twelve (12) months of publication. It will be the responsibility of the author to ensure this occurs.

Open Data: Any research data that is needed for independent verification of research results must be made freely and publicly available in an AHA-approved repository within twelve (12) months of the end of the funding period (and any no-cost extension).

For more information on the above polices, see AHA's Open Science Policy.