## Yale

### Tobacco Center of Regulatory Science

### 2016 Pilot Project Program Announcement

#### **Annual Pilot Awards**

The Yale Tobacco Center of Regulatory Science (TCORS) is offering funding for pilot projects to initiate <u>research relating to understanding tobacco additives and modified risk tobacco products</u> through behavioral, molecular, laboratory, pharmacological, epidemiological, and economic sciences that involves humans (both clinical & epidemiological research) and animals (basic research). We are particularly interested in studies of menthol, flavors, sweeteners, and e-cigarettes and studies using novel techniques.

Up to 3-5 pilot projects will be funded at the level of \$25,000 to \$75,000 (direct costs only). The project must be completed in 1 budget year. Collaborative studies between Yale TCORS and one or more other TCORS are encouraged. Prior permission for a cross-TCORS collaborative proposal is required.

#### Letters of Intent

Letters of intent must:

- Be typewritten, double spaced, 12-point Times New Roman font with one-inch margins
- Provide a descriptive title and the name and title of the PI and key personnel
- Include a 250-word summary of the proposed project, including specific aims, the time frame needed to achieve the stated aims, and a budget estimate
- Include a brief description of how the project will support the Yale TCORS goals or the 10 FDA Research Priorities for 2013
- Include the applicant's signature, address, telephone and fax numbers, and email address
- Include a NIH Biosketch (PHS 398-Rev. 08/12\_approved through 8/31/15) with a Personal Statement of the PI's experience and interest as it relates to the proposed project

Convert your signed Letter of Intent into a PDF file and save it as "lastname\_LOI\_FY2016." Send your letter as an email attachment to tcors@yale.edu.

All letters must be received via email by **December 7, 2015 by 4:00 pm**. Facsimiles will not be accepted.

The letters will be reviewed by our Steering Committee and a full application will be requested from investigators whose projects are particularly promising and consistent with the TCORS funding interests of <u>research relating to understanding tobacco additives and modified risk tobacco products</u>. We will also consider research relating to the 10 FDA Research Priorities for 2013 appended to this notice.

#### Eligible Candidates

- Yale TCORS-supported trainees
- Yale TCORS investigators
- Yale Postdoctoral associates/fellows, junior investigators, and established investigators interested in pursuing tobacco regulatory research

#### **Important Dates**

Letters of Intent Due: December 7, 2015
Full Applications Invited: January 8, 2016
Full Applications Due: March 21, 2016
Funding Start Date: September 1, 2016

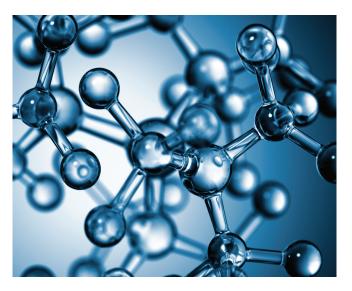
For questions or if you are interested in submitting a cross-TCORS collaborative proposal, please contact the Center's office via phone at 203-974-7591 or email <a href="mailto:tcors@yale.edu.">tcors@yale.edu.</a>

### Center for Tobacco Products

# Research Priorities 2013

Science will inform the FDA in regulation of the manufacture, marketing, and distribution of tobacco products in order to reduce the public health toll from tobacco product use in the United States. The following research priorities reflect an update of the 56 research questions released in January 2012.

- 1. Nicotine dependence threshold among youth and adults and impact of nicotine reduction on tobacco product use behavior (e.g., topography, compensation, switching, multiple use, initiation, cessation, relapse)
- 2. Cigar (small, large, cigarillos) initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity
- 3. Smokeless tobacco initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity
- 4. E-cigarettes initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity
- 5. Other tobacco product (e.g., hookah, pipes, dissolvables) initiation, use (including transitions to other tobacco products and multiple use), perceptions, dependence, and toxicity





- 6. The impact of tobacco product characteristics, (e.g., ingredients, constituents, components, additives such as flavors, and labeling and marketing) on initiation, especially among youth and other vulnerable populations
- 7. Toxicity thresholds for each of the 20 harmful and potentially harmful constituents identified in the March 2012 Guidance for Industry http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297752.htm
- 8. Statistical modeling of the public health impact of FDA/CTP regulation of potential modified risk tobacco products (e.g., product standards, communications regarding risks of tobacco products)
- 9. Consumer perceptions of tobacco products including the impact of labeling and marketing
- 10. Effective communication strategies regarding harmful and potentially harmful constituents and risks of tobacco products

Contact Us 1-877-CTP-1373 • AskCTP@fda.hhs.gov • www.fda.gov/tobacco FDA Center for Tobacco Products • 9200 Corporate Blvd • Rockville, MD 20850-3229

