



## **CALL FOR APPLICATIONS 2013**

### **Key Changes in 2013**

#### **Grant Budget Changes**

- The annual direct cost cap for the Research Project Award (RT), Full CARA (AT) and Full SARA (HT) mechanisms has been lowered to \$125,000. The total direct cost cap is now \$375,000 with a maximum duration of 3 years.
- The California Department of Education (CDE) contribution to the Full SARA has increased; school partners are now eligible for up to \$100,000 annually.
- The annual direct cost cap for the Exploratory/Developmental Research Award (XT), Pilot CARA (BT) and Pilot SARA (GT) has been lowered to \$100,000. The maximum duration is 2 years for a total direct cost cap of \$200,000.
- The CDE contribution to the Pilot SARA has increased; school partners are now eligible for up to \$30,000 annually.
- Eligible new grants to UC institutions will be entitled to F&A costs of up to 25%.

#### **New funding source – The California Cancer Research Fund**

- TRDRP now administers the California Cancer Research Fund. This year we invite applications in the area of lung cancer early detection in disproportionately impacted California groups. This constitutes an expansion of Research Priority 2. See [Research Priority 2](#) for details.

#### **Research Priorities**

- [Research Priority 4](#) now includes the promotion of health equity and the area of nicotine dependence and neuroscience.
- The retail environment is highlighted as an area where research is needed in both [Research Priority 4](#) and [Research Priority 5](#).
- The impact of trade agreements on regulation is highlighted as an area where research is needed in both Research Priorities 1, 3 and 5.

- The California Department of Education’s research priorities for the School-Academic Research Awards have been updated.

### **XT/ Pilot CARA/Pilot SARA Application Requirements**

- Applicants for these award types are now required to explain a) why their proposed research is of an exploratory nature; and b) how they propose to leverage funds if their TRDRP XT or Pilot CARA/Pilot SARA proposal is funded.

### **ST – Research Infrastructure Awards**

- The Research Infrastructure Award is no longer offered. Instead applicants may include expenses in their proposed budget related to the use of electronic, biological, clinical, and informational support systems that are critical to the successful completion of their proposed research project; the infrastructure resource must be directly related to the specific aims in the Research Plan. Such resources may include, for example, document libraries or archives; human tissue repositories for the genetic analysis of tobacco addiction susceptibility; or unique analytical resources specifically targeted to new tobacco product evaluation. Infrastructure costs must be included within the allowable budget cap.

### **Re-submission Policy**

- In accordance with [NIH policy](#), beginning with new original applications that were submitted January 2012 TRDRP will accept only a single re-submission of the same or very similar project, regardless of change in application title. Under extraordinary circumstances a second re-submission *may* be allowed at the discretion of the program.

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## **PURPOSE**

The purpose of this TRDRP Call for Applications is to stimulate research on tobacco control and tobacco-related disease that is of highest priority and potential benefit to the State of California. The program anticipates that this will be achieved by supporting research that will inform and strengthen tobacco control efforts at the local, state and national levels; lead to the early detection and secondary prevention of tobacco-related diseases; and advance the prevention and cessation of nicotine and tobacco products, particularly among the most heavily affected of California's diverse populations.

## **BACKGROUND**

### *From Tobacco to Nicotine*

In our Call for Applications last year we stated that, "The science and practice of tobacco control is a dynamic, rapidly evolving, and radically different field from that of just a few years ago." This actively changing landscape has continued unabated, both in the science and the practice of tobacco control. With the announcement by [Philip Morris International at its shareholder meeting June of 2012 that they planned to introduce a low-risk cigarette by 2017](#), the vaporizing e-cigarette movement has gone mainstream with eyes on transforming the world. Louis Camilleri, PMI's Chief Executive Officer made this clear: "We are on the eve of what we all believe could be a paradigm shift for our industry, [these new products have] "the very real potential to not only be a game-changer, but also be the key to unlock several hitherto virgin territories, most notably the huge Chinese market." Indeed, tobacco may be an artifact of the 20<sup>th</sup> century; nicotine addiction in the 21<sup>st</sup> century will increasingly be through a host of new products, including orbs, sticks, lozenges, inhalers and e-cigarettes. All have crashed onto the market and there is little research on the immediate or long-term health effects of these products.

### *The Affordable Care Act*

Another new development on the tobacco research and control landscape is the Affordable Care Act (ACA). [The ACA new rules on preventative care](#) will add over 30 million new people to the health care roles and can provide counseling and smoking cessation services to most. However, people on Medicaid who are not pregnant are not guaranteed coverage of cessation treatments. Hence, it will fall to the States to guarantee this potential benefit. What will California do; will the ACA actually expand cessation services; will the ACA save Californian lives and health care cost? These questions among others are new and important research questions that we are confronting in the new tobacco control landscape.

## *The FDA*

The Food and Drug Administration's (FDA) authority to regulate tobacco products, while not new, is just a few years old and it (the FDA) is still determining its limits and extent of its authority. Following the [TPSAC Menthol Report](#), the FDA has spent the past year doing its own investigation of menthol; one might argue that no other substance has been scrutinized so widely. But, as the issue of menthol languishes, the FDA is taking the first tentative steps to regulate cigars, including small cigars and cigarillos. This latter move could have a tremendous impact on urban inner city smokers, many of whom use small cigars.

## *Tobacco Industry Influence*

One thing that hasn't changed in the tobacco control and tobacco research landscape is the influence of the tobacco industry. Case in point is the defeat of Proposition 29, which would have raised taxes on tobacco products by \$1 dollar. The tobacco industry poured over \$50 million dollars into the defeat of Proposition 29, the [California Cancer Research Act](#), in an attempt to ensure that California remains the largest consumer of tobacco products in the United States. Since 1988, California has dropped from 1<sup>st</sup> to 33<sup>rd</sup> in the U.S. in tobacco taxes per pack and ranks only 23<sup>rd</sup> in tobacco prevention spending.<sup>1</sup> As a result, key tobacco control indicators foreshadow significant slippage in both health and economic benefits to the State.<sup>2</sup> Tobacco interests continue to maintain a strong presence in California policymaking through spending millions of dollars on campaign contributions and lobbying expenditures.<sup>3</sup> The industry also continues to recruit and retain smokers through price manipulation, artificially lowering the price of cigarettes and particularly targeting price-sensitive groups like youth and low-income individuals. Once the nation's leader in protecting workers from the toxic effects of secondhand smoke, California has fallen behind the national standard set by the Centers for

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<sup>1</sup> Campaign for Tobacco Free Kids. *Key State-Specific Tobacco-Related Data & Rankings*. <http://www.tobaccofreekids.org/research/factsheets/pdf/0176.pdf>

<sup>2</sup> Max, W., Sung, H., & Lightwood, J., *The Impact of Changes in California Tobacco Control Expenditures on Healthcare Expenditures, 2012 – 2016, Final Report to the Tobacco-Related Disease Research Program*. 2011.

Lightwood, J. & Glantz, S., *Predicted Effect of California Tobacco Control Educational Funding on Smoking Prevalence, Cigarette Consumption, and Healthcare Costs, 2012-2016. Final Report to the Tobacco-Related Disease Research Program, 2011*.

Pierce, J. et al. 2010. Forty years of faster decline in cigarette smoking in California explains current lower lung cancer rates. *Cancer, Epidemiology, Biomarkers, and Prevention* 19(11):2801-10.

<sup>3</sup> California's Center for Tobacco Policy & Organizing. *Campaign Contributions and Lobbying of Tobacco Interests in California: January 2009-June 2010*. <http://www.center4tobaccopolicy.org/tobacomoney>

Disease Control and Prevention (CDC). California is not considered a 100% smoke-free state by the CDC. Meanwhile, 24 other states and the District of Columbia provide greater secondhand smoke protection in the workplace than California.<sup>4</sup> The current status of tobacco control within the State challenges TRDRP to focus its limited resources in areas that will result in the evidence to develop, implement, and enforce the public policies and programs necessary to halt and reverse such trends. It calls for an intensified effort across a range of scientific disciplines focused on informing a new generation of California public policies and tobacco control initiatives.

### *Early Disease Diagnosis*

As with the science and practice of tobacco control, the science of tobacco-related disease is also undergoing fundamental changes. Biomedical research has been and will continue to be a cornerstone of TRDRP's mission and portfolio. The program has strategically shifted its focus to the early detection and secondary prevention of tobacco-related disease.

One example is lung cancer which, given its strong association with smoking and high mortality when diagnosed in its later stages, remains an area of particular interest to the TRDRP. Over 160,000 people in the US will die of lung cancer in 2012.<sup>5</sup> Most are still diagnosed late in disease progression – as a result the current 5-year overall survival rate is only 16%.<sup>6</sup> Computerized tomography (CT) screening offers hope for detecting lung cancer early enough to improve lung cancer prognosis at least in high-risk patients. After years of uncertainty and controversy the results are in: low-dose computerized tomography (CT) screening saves lives. A 20% reduction in mortality has been observed when smokers at high risk of lung cancer were diagnosed using CT as compared to those who underwent chest X-ray.<sup>7</sup> Medical professionals now recommend that current or former smokers at high risk of lung cancer undergo routine CT screening. The American College of Chest Physicians, and the American Society of Clinical Oncology for

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<sup>4</sup> Centers for Disease Control and Prevention. *Press Release, New CDC Report Says Increased Efforts, High-Impact Strategies Needed to Reduce Smoking and Save Lives*. April 23, 2010. : <http://www.cdc.gov/media/pressrel/2010/r100423.htm>

<sup>5</sup> American Cancer Society. *Cancer Facts & Figures 2012*. Atlanta: American Cancer Society; 2012.

<sup>6</sup> Howlader N. et al. (eds) *SEER Cancer Statistics Review, 1975-2009 (Vintage 2009 Populations)*, National Cancer Institute. Bethesda, MD, [http://seer.cancer.gov/csr/1975\\_2009\\_pops09/](http://seer.cancer.gov/csr/1975_2009_pops09/), based on November 2011 SEER data submission, posted to the SEER web site, 2012.

<sup>7</sup> The National Lung Screening Trial Research Team. 2011. Reduced lung cancer mortality with low-dose computed tomographic screening. *N. Engl. J. Med.* 365: 395-409

example recommend that CT screening be offered to current and former smokers aged 55 to 74 who have smoked for 30 pack years or more and either are still smoking or have quit in the past 15 years. The American Association for Thoracic Surgery guidelines extend that age range to 79 years and furthermore recommend that long-term lung cancer survivors be screened to detect second primary lung cancer<sup>8</sup> while the National Comprehensive Cancer Network recommends screening starting at age 50 with no upper limit to the age range.<sup>9</sup>

These recommendations, while a tremendous diagnostic advance, beg the question of how to diagnose lung cancer in never smokers, those who stopped smoking more than 15 years prior to diagnosis or smokers who have not accumulated more than 30 pack years. Furthermore, as with any medical procedure, CT carries its own risks including a high probability of a false positive diagnosis which in turn may lead to unnecessary and potentially injurious follow-up.<sup>10</sup> Damage from repeated radiation exposure is also a concern. Given the risks associated with CT screening, a non-invasive test or imaging technology using molecular biomarkers to either selectively target those patients most at risk or to confirm CT screening results and reduce the number of false positives is one area of interest to the TRDRP.

#### Disproportionately Affected Populations

While significant advances in the science and practice of tobacco control have been evident over the past 20 years, it is also clear that certain populations, including military personnel, specific ethnic and racial groups, lesbian, gay, bisexual, and transgender (LGBT) individuals, and those in the lowest socioeconomic strata, continue to bear a disproportionate burden of tobacco-related illness and death.<sup>11 12</sup> California is composed of a sizable majority of these populations, including the

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<sup>8</sup> Jacobson F.L. et al. 2012 Development of The American Association for Thoracic Surgery guidelines for low-dose computed tomography scans to screen for lung cancer in North America: Recommendations of The American Association for Thoracic Surgery Task Force for Lung Cancer Screening and Surveillance. *J Thorac Cardiovasc Surg.* 144:25-32.

<sup>9</sup> NCCN Guidelines for Detection, Prevention, and Risk Reduction. Lung Cancer Screening - Version 1.2013 [https://subscriptions.nccn.org/gi\\_login.aspx?ReturnURL=http://www.nccn.org/professionals/physician\\_gls/pdf/lung\\_screening.pdf](https://subscriptions.nccn.org/gi_login.aspx?ReturnURL=http://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf)

<sup>10</sup> Bach, P.B. et al., 2012. Benefits and harms of CT screening for lung cancer A Systematic Review . *JAMA* 307: 2418-2429.

<sup>11</sup> Fagan P. et al. Eliminating tobacco-related health disparities: directions for future research. *Am J Public Health* 2004; 94: 211–17.

<sup>12</sup> Conway T.L. 1998 Tobacco use and the United States military: a longstanding problem. *Tobacco Control*, 7: 219 - 221.

largest “minority” population in the United States (57% of the state population) and an estimated 1,079,000 lesbian, gay, and bisexual individuals (2.96% of the population).<sup>13</sup> Despite the significance of health disparities within tobacco control and tobacco-related disease, a greater understanding of societal, cultural and behavioral factors driving these differences is still needed.<sup>14</sup> TRDRP is committed to prioritizing and supporting the scientific investigation needed to identify optimal strategies to address health inequities and to understand how to interrupt increasing disparities among certain populations. With this Call for Applications, TRDRP encourages a concerted effort by scientists, health professionals, policymakers, and community activists across the state towards eliminating tobacco-related health disparities.

## **PRIORITY RESEARCH OBJECTIVES**

Our research priorities for 2013 are an elaboration and particularization of our first strategic goal, “to fund high priority areas of research.” Consequently all research applications submitted in response to this Call must be responsive to at least one of the following 5 research priorities:

**Research Priority 1: Advance policies to reduce environmental exposure to the toxic effects of tobacco smoke, tobacco smoke residue, cigarette butts, and other tobacco products.**

*Cigarette Butt Pollution-* Cigarettes and butts are the leading littered item on US roadways. 360 billion cigarettes were consumed in the US alone in 2007. Over 1 million cigarettes and filters, 16,000 lighters, 73,000 cigar tips and almost 37,000 tobacco packages or wrappers were removed from US waterways in 2010. Ingested cigarettes are poisonous to children and adults as well as animals and butt leachates are toxic to marine life. Over \$5.6 million is spent annually to clean up tobacco litter in San Francisco. The impact on the environment and the risks to human health of this material are unknown and largely unexplored.

For example, research is needed on:

- Exposure and toxicity of cigarette butt waste
- Environmental and economic impact of cigarette production and tobacco product waste
- Potential novel policy approaches to reduce or mitigate waste at the municipal, county, or state level
- Bioaccumulation as a result of cigarette butt waste pollution in marine and fresh water environments

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<sup>13</sup> Minority population growing in the United States, census estimates show. Los Angeles Times, June 20, 2010 Available at: <http://articles.latimes.com/2010/jun/10/nation/la-na-census-20100611>

<sup>14</sup> Fagan P. et al. 2007 Identifying health disparities across the tobacco continuum. *Addiction* 102 (Suppl. 2), 5–29.

*Third hand Smoke* - "THS consists of residual tobacco smoke pollutants that remain on surfaces and in dust after tobacco has been smoked; or are re-emitted back into the gas phase; or react with oxidants and other compounds in the environment to yield secondary pollutants".<sup>15</sup> Toxic compounds so far identified in THS include many that are also present in SHS and mainstream smoke, as well as novel tobacco-specific nitrosamines. If and how involuntary inhalation or dermal uptake of THS affects human health is unknown. Research on third hand smoke has just begun; there are still many unknowns and numerous research opportunities.

For example, research is needed on:

- The identity of THS constituents
- Toxicology of potentially dangerous THS constituents
- Biomarkers of THS exposure
- Risk assessment under normal conditions in the field

*Indoor Air* - Since the inception of the TRDRP much of its funding has been devoted to secondhand smoke (SHS) measurement, exposure and health effects. SHS causes premature death and disease in children including SIDS, acute respiratory infections, ear problems, asthma exacerbations and slowed lung growth and causes immediate adverse cardiovascular effects. As a result of these efforts and others across the country, SHS was classified by the US EPA as a Class A carcinogen and the 2006 Surgeon General's Report on the health consequences of involuntary SHS exposure concluded that there is no risk-free exposure to SHS. The only way to fully protect non-smokers from exposure to SHS is to eliminate smoking in indoor spaces. As a result laws have been passed in many states banning smoking in restaurants, bars and certain outdoor areas. However many municipalities and local businesses have been resistant to such measures. Research is needed to understand SHS exposure and health risks in multi-unit housing, health risks associated with SHS exposure in casinos and the social-behavioral, economic and legal barriers to adoption of smoking bans in these areas.

For example, research is needed on:

- Indoor SHS measurement in multi-unit housing
- Health effects of smoke exposure in multi-unit housing
- The potential economic, social, and health care cost impacts of controlling tobacco use in American Indian gaming casinos, California card rooms, and the US gaming industry
- Public perception of SHS exposure and public response to existing and proposed policies to control SHS in buildings and.
- The pragmatic and ethical implications of policies banning the smoking of addictive products in indoor public spaces

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<sup>15</sup> Matt G.E. et al. 2011 When smokers move out and non-smokers move in: residential thirdhand smoke pollution and exposure. *Tobacco Control* 2011;20:e1 doi:10.1136/tc.2010.037382

- The effects of different current local policy approaches to controlling smoking in multi-unit housing
- Countermeasures by the tobacco industry aimed at weakening public support for minimizing SHS exposure in multi-unit housing and indoor public spaces.

*Outdoor Air* - Air pollution consists of natural and manmade (anthropogenic) gaseous and particulate components that have adverse effects on cardiovascular and respiratory health.<sup>16</sup> One of these manmade toxic air contaminants is tobacco smoke. Exposures to tobacco smoke in outdoor environments can be significant. Nicotine concentrations in several outdoor environments such as schools, amusement parks and airports, outside of office buildings can reach levels comparable to those found in smokers' homes.<sup>17</sup> Air pollution is often concentrated in areas where the most vulnerable populations live – near refineries, freeways and industrial areas and tobacco smoke is no exception: retail tobacco outlets, targeted and intense tobacco advertising and under-priced tobacco products are concentrated in under-served communities and communities of color.<sup>18,19</sup> Recent evidence has shown that secondhand smoke can react with other common airborne pollutants to form carcinogenic nitrosamines not present in freshly emitted tobacco smoke. The health impact of thirdhand smoke exposure in enclosed environments is an area of active investigation. The interaction of tobacco smoke with outdoor air pollutants and its health effects, if any, is largely unexplored.

Research is needed, for example on:

- The effect of secondhand smoke on outdoor air quality.
- Whether significant levels of new carcinogenic compounds formed in outdoor environments when tobacco smoke and other air-borne pollutants interact.
- The impact of the greater concentration of tobacco outlets in poor communities on outdoor air quality compared to communities where there are fewer tobacco outlets. And if so, whether it contributes to disease outcomes.

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<sup>16</sup> <http://www.atmosphere.mpg.de/enid/3or.html>

<sup>17</sup> "Environmental Tobacco Smoke: A Toxic Air Contaminant." California Air Resources Board California Environmental Protection Agency. October 18, 2006. <http://www.arb.ca.gov/toxics/ets/factsheetets.pdf>

<sup>18</sup> Lipton R et al. 2008. The spatial distribution of underage tobacco sales in Los Angeles *Substance Use and Misuse*. 43(11): 1597-1617.

<sup>19</sup> Hendriksen L. et al. 2012. Targeted advertising, promotion, and price for menthol cigarettes in California high school neighborhoods. *Nicotine Tob. Res.* 14:116-121.

- The magnitude of pollutant intake in non-smokers and smokers who live or work in environments where both tobacco smoke and other environmental pollutants such as ozone are present.
- Whether poor air quality and tobacco smoke result in increased risk to human health and if so the mechanisms by which this occurs.
- The public perception of SHS exposure and public response to existing and proposed policies to control SHS in outdoor public spaces.
- The pragmatic and ethical implications of policies banning the smoking of addictive products in outdoor public spaces.
- The countermeasures by the tobacco industry aimed at weakening public support for environmental impact policies related to smoking and outdoor air?

**Research Priority 2: Advance innovative research in the early diagnosis of tobacco-related diseases.**

*Cancer and Pulmonary Disease* - Substantial resources are spent by the federal government and the commercial sector on tobacco-related disease therapeutics. Many advances have been made and TRDRP has played a key role in supporting the efforts of California researchers in this and related endeavors since its inception. The next generation of TRDRP disease research support will focus solely on early diagnosis and secondary prevention of tobacco-related cancers and COPD.

For example, research is needed on:

- The role of inflammation and oxidative stress in tobacco-related disease pathogenesis.
- Identification of early detection biomarkers of carcinoma in situ and pre-metastatic malignancy.
- Clinical validation of known diagnostic biomarkers of disease.
- Development of precision analytical techniques to reliably and economically measure trace levels of biomarkers in non-invasive tissue samples such as blood, serum, expired air, saliva and urine.
- Identification of genetic signatures that can be reliably associated with variations in disease susceptibility among users of tobacco products.
- Development of chemoprevention approaches.

*Early detection of lung cancer in California's disproportionately impacted populations* - TRDRP administers contributions to the California Cancer Research Fund (CCRF), box number 413 on California state income taxes. CCRF contributions are to be allocated as grant awards to support research on the causes and treatments for cancer, expanding community-based education on cancer, and providing culturally sensitive and appropriate prevention and awareness activities targeted toward communities that are disproportionately at risk or afflicted by cancer.

Based on recommendations by a TRDRP-convened Strategic Visioning Committee, CCRF funds have been allocated to support a limited number of pilot or exploratory study proposals into the early detection of lung cancer and the early detection of lung cancer in disproportionately impacted California groups that will be submitted in response to this Call for Applications.

### **Groups Disproportionately Impacted by Lung Cancer**

Lung cancer incidence is higher for Vietnamese men in California than the incidence of other cancers.<sup>20</sup> Lung cancer is the second leading cancer for African Americans, American Indians, and Caucasian men and women and Chinese, Filipino, Pacific Islander, and Laotian men in California.<sup>21</sup> Lung cancer continues to be the leading cause of cancer deaths for African Americans.<sup>22,23</sup> Individuals living in low socioeconomic status (SES) communities in California are at particularly high risk of death from lung cancer.<sup>24</sup>

### **Barriers to Lung Cancer Early Detection and Cancer Prevention**

Barriers to lung cancer screening and cancer prevention in underserved communities include fatalistic thinking and fear, fears about radiation exposure, screening cost, low access to and availability of health care services, competing priorities, lack of knowledge of cancer prevention and screening recommendations, culturally inappropriate or insensitive cancer control measures, low health literacy, and mistrust of the health care system.<sup>25</sup>

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<sup>20</sup> American Cancer Society. 2009. Cancer disparities: A chart book.

<http://action.acscan.org/site/DocServer/cancer-disparities-chartbook.pdf?docID=15341>

<sup>21</sup> American Cancer Society. Sept. 2011. California Cancer Facts and Figures 2012. California Department of Public Health. California Cancer Registry. Oakland, CA: American Cancer Society, California Division.

[http://www.ccrca.org/pdf/Reports/ACS\\_2012.pdf](http://www.ccrca.org/pdf/Reports/ACS_2012.pdf)

<sup>22</sup> American Cancer Society. Cancer Facts & Figures for African Americans 2011-2012. Atlanta: American Cancer Society, 2011.

<sup>23</sup> U.S. National Institutes of Health. National Cancer Institute: Seer Cancer Statistics Review, 1975-2009.

[http://seer.cancer.gov/csr/1975\\_2009\\_pops09/](http://seer.cancer.gov/csr/1975_2009_pops09/).

<sup>24</sup> Ou, S.H. et al. 2008. "Low socioeconomic status is a poor prognostic factor for survival in stage I nonsmall cell lung cancer and is independent of surgical treatment, race, and marital status." *Cancer* **112**(9): 2011-2020.

<sup>25</sup> Jonnalagadda S. et al. 2012. "Beliefs and attitudes about lung cancer screening among smokers." *Lung Cancer*. Jun 6. [Epub ahead of print]

Wolff, M. et al. 2003. Cancer prevention in underserved African American communities: Barriers and effective strategies-A review of the literature. *Wisconsin Medical Journal* 102: 36-40.

**Factors associated with delayed diagnosis of lung cancer include** health professionals' lack of or inadequate awareness of the nature and variation of lung cancer symptoms, quality of health services, health professionals' knowledge of patient referral criteria, social and cultural factors.<sup>26</sup> African Americans are less likely than Caucasians to receive treatment after a lung cancer diagnosis, making early detection particularly important in this group.<sup>14</sup>

Disparities in cancer screening are also associated with social, behavioral, and economic factors such as unequal access to care, language barriers, unhealthy environments, and racial discrimination.<sup>14</sup> Innovative interventions are needed to overcome financial, cultural, geographic and educational barriers to screening.

Healthcare related-research is needed to address the following barriers and issues<sup>27</sup>: Synchronization of CT technique and scan interpretations; value of the diagnostic work-up techniques for positive screening findings and establishing standards for follow-up; optimal surgical management of detected nodules in patients; and optimal screening interval for both screen-negative and screen-positive patients.

Research is needed for African Americans, Hispanic, and Asian American ethnic groups on:

- Best practices for early lung cancer detection, especially in resource-limited treatment settings
- Overcoming barriers to lung cancer screening such as
  - healthcare access issues
  - fatalistic beliefs about screening and a positive diagnosis
- Appropriate follow up procedures following a positive screen
- Culturally sensitive health communications on discussing detection and lung cancer
- Overcoming financial and other barriers to lung cancer screening and follow up care
- Identification of psychosocial and biological correlates of lung cancer detection

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<sup>26</sup> Tod A.M. & Craven, J. 2006. Diagnostic delay in lung cancer: Barriers and facilitators in delay. [http://info.cancerresearchuk.org/prod\\_consump/groups/cr\\_common//@nre/@hea/documents/generalcontent/cr\\_043178.pdf](http://info.cancerresearchuk.org/prod_consump/groups/cr_common//@nre/@hea/documents/generalcontent/cr_043178.pdf)

<sup>27</sup> Lok B. 2012. What are the barriers to using low dose CT screen for lung cancer? *Clinical Correlations*: The NYU Langone Internal Medicine Blog-A Daily Dose of Medicine. <http://www.clinicalcorrelations.org/?p=5238>

- Cost/benefit analysis of lung cancer screening in disproportionately impacted communities.

**NOTE: Funds accruing to the California Cancer Research Fund must be used to support research on cancer and TRDRP must adhere to the intent of the legislation regarding allocation of these funds. While TRDRP is soliciting applications for lung cancer screening in disproportionately impacted California groups in 2013, any application proposing research on cancer early detection is eligible to receive California Cancer Research funds, contingent upon a scientific merit score that falls within the funding range.**

*Cardiovascular Disease* - Tobacco smoking and SHS exposure have long been recognized as prominent risk factors for cardiovascular disease. The mechanism by which known and as-yet-unidentified toxicants in smoked and smokeless tobacco products increase the risk of CVD is still a promising area of research particularly in light of the FDA's new responsibility to evaluate and regulate existing and emerging tobacco products<sup>28</sup>.

For example, research is needed on:

- The effects and mechanism of action of tobacco toxicants and oxidative stress on endothelial function
- The identification of toxicants responsible for platelet activation
- The mechanism by which tobacco toxicants contribute to the development of insulin resistance.

**Research Priority 3: Expand the scientific basis to inform the regulation of nicotine and tobacco products at the local, state and national level.**

Since the [Family Smoking Prevention and Tobacco Control Act of 2009](#) granted the FDA the power to require appropriate testing of and evaluation of tobacco products, many new challenges have arisen and old questions persist. Increasingly nicotine delivery systems are produced in non-tobacco forms. Whether oral nicotine delivery devices (orbs and lozenges) or vaporized nicotine (e-cigarettes), all these products require scientific scrutiny to determine both their short and long-term health impact. The FDA has asserted that these nicotine containing products can be regulated like other tobacco products under the [Federal Food, Drug, and Cosmetic Act](#). Studies and findings about the toxicity and health effects of these products is not only essential at the federal regulatory level but will also be very useful to state and local tobacco control programs to educate consumers and inform regulatory policy.

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<sup>28</sup> U.S. Department of Health and Human Services. *How Tobacco Smoke Causes Disease: The Biology and Behavioral Basis for Smoking-Attributable Disease: A Report of the Surgeon General*. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2010.

These new research challenges take their place alongside old questions still confronting the FDA, foremost among them is what to do with menthol in tobacco products. There has been ample research linking menthol to youth initiation, especially among African Americans, Native Hawaiians, Filipinos and Puerto Ricans among others. Simply, candy flavorings promote tobacco initiation. The Tobacco Products Scientific Advisory Committee of the FDA agrees and states in their report of 2011 that “removal of menthol cigarettes from the market place would benefit the public health.” [TPSAC Menthol Report](#). Research in this area should be focused on the consequences of removing mentholated cigarettes from the market place.

Research is needed on all putative modified risk products; products used to treat tobacco addiction; and e-cigarettes. Research is also needed to inform the creation of tobacco product standards and to assess consumer perceptions of tobacco product labeling and advertising. FDA’s scientific framework for regulation of tobacco products includes 1) Toxicity: constituents, formulation and product design including in vitro, in vivo and human laboratory and clinical trial analyses; 2) Pharmacological addiction potential; 3) Abuse liability, i.e., use intensity and factors affecting use intensity in humans including product appeal, consumer perception, marketing and social influences; 4) After-market prevalence of use and health outcomes; and 5) Price and availability.

For example, research is needed on:

- How consumers may smoke de-nicotinized cigarettes differently
- The regulation of cigars, especially small cigars and cigarillos
- Cigarette design features other than nicotine that may contribute to its reinforcing effect
- FDA graphic and 1-800-Quit-Now warning labels
- The risk/benefit of low nitrosamine tobacco products
- The results of targeted marketing of putative modified risk products, e.g., e-cigarettes, etc.
- Whether de-nicotinized cigarettes are an effective cessation tool
- How information regarding tobacco product constituents are best tailored to various sub-populations such as low SES, ethnic/cultural groups, youth, LGBT, and others
- The impact of trade agreements on regulation

We encourage all applicants interested in tobacco regulatory sciences to visit the [Center for Tobacco Products, Food and Drug Administration Research Priorities](#); many of their areas of interest and concern, mirror those of the TRDRP.

**[Research Priority 4](#): Prevent and treat tobacco use and promote equity among disproportionately impacted groups. Studies on the basic neuroscience of nicotine addiction.**

Tobacco related diseases are not proportionately distributed, with the greatest incidence and mortality falling on communities of color and other specific sub-populations throughout the state. African Americans have the highest lung cancer rates in the state; Latino's have the greatest exposure to secondhand smoke while at work; Vietnamese, Koreans and American Indians have some of the highest smoking rates in the state; 40% of cigarettes are purchased by persons with mental illness; LGBT smoking rates are significantly higher than the general population; and women and girls of low socioeconomic status (SES) are at increased risk for lung cancer. Understanding how and why different sub-populations of Californians use tobacco products and whether there are discernible differences in the health consequences of their use are critical steps towards reducing tobacco-related health disparities.

With the constant migration of people from the Pacific Basin and Rim, South and Central America and Mexico, coupled with in-migration from other states, California presents tobacco control researchers with an extremely rich and heterogeneous population. The TRDRP encourages all investigators to capitalize on this population diversity to craft research proposals that seek to understand and mitigate tobacco related health disparities. Geography, occupation, ethnicity, race, gender, sexual or gender orientation, culture, military background, age, SES, and/or disability can define populations experiencing tobacco-related health disparities. Consistent with this priority, all investigators should focus their studies on one or more specific disproportionately impacted group or sub-population rather than on generally diverse samples of participants.

For example, research is needed on:

- The prevalence of smoking among the homeless
- Culturally appropriate smoking cessation interventions for Koreans
- Migrant workers and smoking
- How the gay bar scene promotes smoking behavior
- Targeted marketing aimed toward girls and young women
- How much tobacco use in the American Indian community is ceremonial versus commercial
- How local multi-unit smoking regulations are perceived and implemented in low SES and communities of color
- Smoking in the military (on and off military-owned land) and the subsidization of tobacco products on military bases
- The retail environment; point of sale promotions are where the tobacco industry spends 90% of its advertising dollars.

*Focus on African American Health Disparities* - One compelling example of an area in which tobacco-related health disparities research is needed is that of smoking in

the African-American community. To meet this need TRDRP launched a research initiative aimed at understanding and mitigating the health disparities faced by African Americans in California.

African American men and women have the highest adult smoking prevalence in California, 21 percent and 17 percent, respectively (California Tobacco Control Program, 2010). There is anecdotal evidence that the prevalence is even higher. An innovative and rigorous methodological approach is needed to accurately assess the smoking prevalence of African Americans in California.

In California, deaths from lung cancer among African American women are 41 per 100,000 compared to 35 per 100,000 among white women. In California, 92 out of every 100,000 African American men were diagnosed with lung cancer compared to 62 out of every 100,000 white men. African American men are 37 percent more likely to develop lung cancer than white men, even though their overall exposure to cigarette smoke – the primary risk factor for lung cancer – is lower. African Americans are more likely to be diagnosed later, when cancer is more advanced. African Americans are more likely to wait longer after diagnosis to receive treatment, more likely to refuse treatment, and more likely to die in the hospital after surgery.<sup>[1]</sup>

Moreover, while African Americans comprise only 6.2 percent of the population of California, they account for 7.6% of the smoking attributable deaths in the state. African Americans lose more years of life per death (16.3 years) than all other groups (12.0 years) due to smoking attributable causes.<sup>[2]</sup>

Given these sobering statistics and with the input from numerous stakeholders and advisors, the TRDRP is prioritizing the following research questions/areas for support as part of this initiative.

- The prevalence of smoking and tobacco use in California's African American community.
- The impact of banning menthol tobacco products and identification and prevalence of menthol analogues.
- Best practices for African American cessation. The practice of African American health care providers and smoking cessation advice.
- The economic impact of tobacco use and tobacco product availability in African American communities. The impact of tobacco taxes and whether they are regressive in the African American community.

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<sup>[1]</sup> African Americans and Lung Cancer, American Lung Association available at: <http://www.lungusa.org/about-us/our-impact/top-stories/african-americans-and-lung-cancer.html>

<sup>[2]</sup> Max W. et al. 2010. The disproportionate cost of smoking for African Americans in California. *Am J Public Health* 100: 152-158.

- The relationship between stress and tobacco use for African Americans.

*Social and Behavioral Interventions to Treat Tobacco Dependence* – Evidence based tobacco dependence treatments do not reach some groups of smokers. There has been discussion in the field as to whether tailored smoking cessation interventions are more useful for priority groups than treatments developed for the general population. For example, research is needed on the pros and cons of tailored vs. non-tailored tobacco interventions in priority groups. Tobacco use has shifted over the years to light and non-daily smoking yet the evidence supporting tobacco treatments came from pack-a-day smokers. Research is needed on appropriate interventions for light and nondaily smokers. Provider-initiated cessation and relapse prevention advice is on the decline. Research is needed on addressing the barriers to provider-initiated tobacco interventions.

*Basic Neuroscience of Nicotine Addiction* - Understanding and blunting nicotine addiction remains critical to tobacco cessation efforts. Over 30 million people remain addicted to tobacco products generally and nicotine in particular. While advances in understanding how nicotine affects the brain and subsequently leads to dependence have been made, the key mechanisms and pathways that can blunt nicotine's addictive properties are still to be identified. Moreover, focused research on what therapeutic agents and processes can be identified to stem the tide of nicotine addiction is needed.

For example, research is needed on:

- Identifying vaccines that can prevent the uptake of nicotine
- Improving the efficacy of varenicline and/or developing more efficacious partial agonists
- Testing the efficacy and side effects of varenicline in racial/ethnic minority, LGBT and low socioeconomic status groups
- The addictive potential and abuse liability of different tobacco products
- Long-term use of low dose nicotine products (patch, gum, etc.)
- Desensitization of nicotine's effects on smokers by interrupting the causal chain in nicotine addiction thereby leading to more effective smoking cessation treatments

**Research Priority 5: Advance the ability of communities throughout California to assess and limit the influence of the tobacco industry.**

The tobacco industry invested over \$50 million dollars into the defeat of Proposition 29, the [California Cancer Research Act](#) to ensure that California remains the largest consumer of tobacco products in the United States. Research pinpointing and documenting what part of the industry's message resonated with voters will be very important to understanding the nature of the influence of the tobacco industry on the California public in such matters. Indeed, the tobacco industry remains a fixture in Sacramento, where just in the first six months of 2012, [The Center for Tobacco Policy & Organizing of the American Lung Association in California](#)

documented that the industry spent more than \$4 million on lobbying and campaign contributions to influence legislative policy and elections in California. Research that documents how and when the tobacco industry affects state and local policies can be very helpful to tobacco control advocates. Policy research that demonstrates the health impact of smoke free policies and regulation can give local tobacco control advocates the necessary evidence for establishing smoke free multi-unit housing.

For example, research is needed on:

- The role of the tobacco industry in affecting local policies and ordinances
- The tobacco industry's contributions to non-profit organizations and their effect on organizational policies and programs
- The tobacco industry's presence or influence in our public schools, civic, cultural, advocacy organizations, and the hospitality industry
- The tobacco industry's role in maintaining smoking in Indian Gaming Casinos
- Evaluation of community efforts to blunt the activities of the tobacco industry
- The retail environment; point of sale promotions are where the tobacco industry spends 90% of its advertising dollars
- Policy research that documents lives and money saved by tobacco control ordinances
- The impact of trade agreements on regulation

**MECHANISMS OF SUPPORT**

The following types of grants are available to pursue the above 5 research priorities.

**Overview of Current 2013-2014 Mechanisms:**

2013-2014 Grant Mechanisms	Purpose	Max Amount	Max Duration (Yrs)	LOI Due	Application Due	Award Start
<b>Research Project (RT)</b>	Research Projects	Up to \$375,000	Up to 3			
<b>Exploratory &amp; Developmental (XT)</b>	Pilot and Exploratory Research Studies	\$200,000	Up to 2			
<b>Participatory Research - (Pilot CARA/SARA)</b>	Preliminary Studies for Participatory Projects	\$200,000	2	Nov 13, 2012	Jan 24, 2013	Aug 1 2013

<b>Participatory Research - (Full CARA/SARA)</b>	Community or School and Academic Collaborative Research Projects	\$375,000	3			
<b>Postdoctoral (FT)</b>	Postdoctoral Career Development	\$135,000	3			
<b>Dissertation (DT)</b>	Pre-doctoral Research Training	\$60,000	2			
<b>Special Projects (ST) – Conference</b>	Research Dissemination	Variable	1	Not Required	Continuous	Variable
<b>Cornelius Hopper Diversity Supplement (CHDAS)</b>	Research Training	\$30,000	2	Not Required	April 16 2013	Aug 1 2013

**NOTE:** Principal Investigators may submit more than one proposal per funding cycle; however only one grant in a given award mechanism will be awarded to any one individual.

### RESEARCH PROJECT AWARD (RT)

**Purpose:** Investigator-initiated research. Proposals should be fully developed, scientifically rigorous, and include sound background information, hypotheses, and promising preliminary studies or supporting data.

**Maximum Award:** Average annual direct costs cannot exceed \$125,000. Allowable expenses include salaries, fringe benefits, supplies, equipment, and travel. Travel to scientific meetings is restricted to \$2,000 per year (excluding travel to the TRDRP Conference). All applicants must budget a maximum of \$500 for mandatory travel to the TRDRP Conference in the first year. Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25%.

**Maximum Duration:** Up to 3 years

### Review Criteria:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field of tobacco-related diseases, tobacco control, social & participatory research, nicotine addiction, prevention or policy?
- **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and

appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

- **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms, interventions, clinical practice, or policy issues; 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?
- **Investigator:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **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?

## **EXPLORATORY/DEVELOPMENTAL RESEARCH AWARD (XT)**

**Purpose:** The purpose of these grants is to gather preliminary data or demonstrate proof-of-principle. The ultimate goal of these awards is to provide the foundation for proposals for fully-developed research project awards from other funding programs or TRDRP.

**Maximum Award:** Average annual direct costs cannot exceed \$100,000. Allowable expenses include salaries, fringe benefits, supplies, equipment, and travel. Travel to scientific meetings is restricted to \$2,000 per year (excluding travel to the TRDRP Conference). All applicants must budget a maximum of \$500 for mandatory travel to the TRDRP Conference in the first year. Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25%.

**Maximum Duration:** 2 years.

### **Review Criteria:**

- **Responsiveness to Intent of the Award Type:** Is the study pilot or exploratory in nature? Does the study represent a new research trajectory that is not currently funded from other sources? Does the applicant describe how the pilot study will lead to an expanded research effort in the future including specific funding sources and award types?
- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts,

methods, technologies, treatments, services, or preventative interventions that drive this field of tobacco-related diseases, tobacco control, social & participatory research, nicotine addiction, prevention or policy?

- **Approach:** Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project and the pilot nature of the grant type? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- **Innovation:** Is the project original and innovative? For example: Does the project challenge existing paradigms, interventions, clinical practice, or policy issues; 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?
- **Near Term Cost Leveraging Opportunities:** When the TRDRP-funded studies under an Exploratory/Development Research Award are completed, is there compelling promise and high likelihood that their results will constitute a larger RO1 or PO1 study with high probability of funding from another agency such as the NIH or from another TRDRP mechanism? In other words, with TRDRP funding of the proposal, can the applicant leverage funding from other sources to further develop this area of research, within 2-3 years after initial funding?
- **Investigators:** Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **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?

## **PARTICIPATORY RESEARCH AWARDS (CARA/SARA)**

**Purpose:** The purpose of the Community Academic Research Awards (CARA) and the School Academic Research Awards (SARA) is to stimulate and support collaborations between community-based organizations/schools with academic investigators. These awards support a collaborative partnership to perform scientific research into tobacco control issues that are identified as important and meaningful to specific communities/schools in California.

The roles and responsibilities for each of the partners must be clearly described. The applicant partners must demonstrate the use of methods that are relevant, culturally sensitive, and appropriate in terms defined and accepted by the participating community members/schools. Establishing a high level of contact and communication between community or school staff and the researchers is imperative and must be described. Efforts to mitigate power differences in decision making and control at all stages of the research process should be described. All partners must be involved in each stage of the project, i.e., identifying the problem, formulating the research questions, designing the intervention, writing the grant application, carrying out the research, and interpreting project outcomes.

TRDRP encourages applications that represent the breadth of community participatory research approaches. For example, one project may focus on developing new research methods for a particular community/school while another project could focus on tailoring scientifically-based methods to an underserved group or community not included in the literature.

The process of building trust and a working relationship among partners is part of the spirit of participatory research and should be described in the application. Applicants should include a plan to provide information related to the project back to the target community/school.

**Community** is broadly defined as any group of individuals sharing a common characteristic, such as culture, language, race, ethnicity, gender, age, sexual orientation, or other attribute that might impact the effectiveness of tobacco control programs.

**Schools** can be any public elementary, middle and high schools, continuation high schools, alternative, juvenile court, community schools or direct-funded charter schools.

**Supplemental Funding** to defray school-site costs related to participating in a SARA is available for schools that are operated by a local educational agency. Local educational agencies are school districts, county offices of education or direct-funded charter schools that have a valid County-District-School Code in the California Public School Directory. Additionally, to be eligible for these contracted supplemental funds, the participating local educational agency must be certified by CDE as having met tobacco-free school district criteria on or before July 1, 2012. A list, by county, of certified local educational agencies that meet the California Health and Safety Code Tobacco Free Schools requirements can be found at: <http://www.cde.ca.gov/ls/he/at/tobaccofreecert.asp>. Beginning with this Call for Applications, the budget for these costs is submitted as part of the application to TRDRP.

## **CDE Research Priority Areas for Pilot/Full SARA Awards**

The CDE has identified the following research questions/topic areas as responsive to their current school-based tobacco control priorities. However, applicants may also submit applications addressing other school-based research gaps and research questions/topics identified as important and meaningful by schools in California.

- What are the shared causes and risks associated with smoking uptake for both tobacco and marijuana? How does marijuana uptake influence tobacco use and is there a reciprocal cause or effect between tobacco and marijuana use?
- What are the unique risk and protective factors for tobacco use among priority population youth? What factors increase vulnerability to tobacco use in priority population youth in general? What factors increase vulnerability in specific priority groups? For example, what risk or protective factors increase or reduce tobacco vulnerability for LGBTQ youth?
- How does the tobacco industry adapt the availability and marketing of products to target youth to consume tobacco/nicotine and what practices best counter industry efforts?
- What are the best instructional content and strategies to help youth understand the environmental toxicity of tobacco litter and engage youth in anti-tobacco litter advocacy?
- What interventions work best for youth tobacco users with co-occurring risk behaviors? Early initiation of tobacco use among youth is a known predictor of other risk behaviors and problems, especially among 5th-7th graders. Will efforts to reduce student tobacco use be more successful if embedded in interventions that address a broad range of risk behaviors and problems? If so, what are the best practices for embedding tobacco prevention approaches in a multiple risk behavior intervention?

### **CARA/SARA Pilot Awards**

A pilot award supports the initial phases of a CARA or SARA project, including solidifying the collaborations, identifying research questions, negotiating roles and responsibilities, and detailing the research plan and methods. An expected outcome from these awards is the building of a strong working relationship between academic and community partners, the building of trust between partners and the community served and the sharing of power and decision making, which will establish a foundation and capacity for research.

### **Maximum Award**

**Pilot CARA:** \$100,000 total direct costs. Indirect costs are allowed in accordance with TRDRP policy.

**Pilot SARA:** \$100,000 total direct costs. Indirect costs are allowed for the TRDRP portion in accordance with TRDRP policy. An additional \$30,000 per year is provided by CDE to support the costs of participating local educational agencies. Indirect costs are not allowed for the CDE supplement.

**Maximum Duration:** 2 years

**Review Criteria:**

- **Responsive to the Intent of the Award Mechanism:** Is the project pilot in nature? Are the proposed activities focused on accomplishing the preliminary work necessary to provide a strong basis for continuing collaborative research?
- **Significance:** Does this study address an important problem? If the aims of the application are achieved, will the completion of the elements stated in the pilot allow investigators to compete for a full CARA/SARA? How will the community/school or community participants/students, staff, and faculty, the academic institutions, and their investigators benefit from the anticipated outcomes of the proposed research?
- **Approach:** Are the conceptual framework, design (including composition of study population), methods, and analyses appropriately developed for the pilot nature of the project? Are both the community/school and academic partner involved in the formation of the research question(s)? Does the proposed study methodology include the collection of preliminary data? Does the applicant clearly describe and/or define the community/school of interest? Do the research methods include perspectives and beliefs of community residents or school population of interest? Does the applicant describe procedures for community/school oversight during the implementation of the research? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the proposed work feasible?
- **Collaboration:** Are procedures identified to establish or strengthen the collaborative partnership? Do community/school members participate as equal partners in the research process (e.g., as core members of the research team or hired as research assistants)? Does the research process apply the knowledge of community participants/school members in the phases of planning, implementation, and evaluation? Are measures included

to assess the partnership? Are measures appropriately justified? Will the proposed study empower the community or school to address policy, economic, and social justice issues related to tobacco use? Are researchers and community or school members prepared to work together for an extended period of time?

- **Innovation:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigators:** Are the principal investigators and other key personnel listed in the grant proposal appropriately trained and well suited to carry out community- or school-based research? Are the roles and responsibilities of the partners clearly defined? Does the academic partner have a track record in the community, school or target school population? Has the community or school partner worked with researchers before? Has the academic partner placed the research question in its proper scientific context? How will the research process allow academic researchers to learn more about the community or school and how community/school members can learn more about the academic institution? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?
- **Environment:** Does the community or school environment in which the work will be done contribute to the probability of success? Does the proposed intervention take advantage of unique features of the target community/school and/or employ useful collaborative arrangements? Is there evidence of academic institutional support and community- or school-based organizational support?

### **CARA/SARA Full Awards**

These awards are to support fully developed CARA and SARA projects. These awards support a collaborative partnership to perform scientifically rigorous research into tobacco control issues that are identified as important and meaningful to specific communities/schools in the state. Ideas from community and academic partners should be integrated and recognizable in the application.

There must be a systematic plan developed by the partners for communicating the work and/or findings back to the community. A few examples include disseminating the relationship building process or study results to community/school programs engaged in similar work or to the target community. Although it is advantageous for the researcher to have a history of involvement with the specific community or school, lack of such experience is not a disqualifying factor.

**Full CARA:** \$125,000 average annual direct costs. Indirect costs are allowed in accordance with TRDRP policy.

**Full SARA:** \$125,000 average annual direct costs. Indirect costs are allowed for the TRDRP portion in accordance with TRDRP policy. An additional \$100,000 per year is provided by CDE to support the costs of participating local educational agencies. Indirect costs are not allowed for the CDE supplement.

**Maximum Duration:** 3 years

**Review Criteria:**

- **Significance:** Applicants should address important problems identified by the target community/school and demonstrate how scientific knowledge, community/school relations, and academic and community/school collaboration will be advanced. Applicants must describe how the community or school will benefit from the anticipated outcomes of the proposed research.
- **Approach:** The conceptual framework, experimental design, research methods and a description of the study population must be adequately developed, well-integrated, and appropriate to the aims of the project. CARA and SARA applicants must clearly describe and/or define the community/school of interest and maintain a balance between sufficiently rigorous research methods and integrating the perspectives and beliefs of community residents or school members. Applicants must delineate how the research findings will be disseminated within and to other communities and schools. Additionally, applicants must describe how research findings are disseminated within and to academic institutions. The applicant must describe procedures for community/school oversight during the implementation of the research. Applicants should acknowledge potential problem areas and consider alternative tactics in discussing the feasibility of their project.
- **Collaboration:** Community/school members and academic representatives should participate as equal partners in the research process. Specifically, both the community/school partner and the academic partner should be involved in all phases of planning, implementation, and evaluation of the proposed research. Both partners must be involved in analytic issues: interpretation, synthesis, and the verification of findings and conclusions. Applicants should discuss how the proposed research intervention will empower the community/school to address political, social and economic

issues related to tobacco use. Applicants must indicate that they are prepared to work together for an extended period of time.

- **Innovation:** When possible, the proposed research project should employ novel concepts, approaches or methods. Identifying original and innovative paradigms or developing new methodologies or technologies can be a plus for participatory research effort.
- **Investigators:** The principal investigators and other key personnel listed in the grant proposal should be appropriately trained and experienced to carry out community-based participatory research and/or school-based participatory research. Applicants should highlight the academic partner's track record in the community/school and the community/school partner's history of working with researchers and/or research projects. The academic partner has the responsibility of placing the jointly identified research question in its proper scientific context. Additionally, the research process should allow the academic partner to learn more about the community/school and community/school members to learn more about the academic institution.
- **Environment:** The community and/or school environment in which the work will be done should contribute to the probability of a successful intervention and collaboration. The proposed intervention should take advantage of unique features of the target community/school to bolster collaborative arrangements. Applicants should demonstrate evidence of academic institutional support and community/school support.

## **POSTDOCTORAL FELLOWSHIP AWARD (FT)**

**Purpose:** These are awards for individuals to obtain postdoctoral research training under a designated mentor. The application must be prepared and submitted exclusively by the fellow and must outline an original research project (separate from the project of a mentor). Letters of support addressing the candidate's training, potential, and the commitment of the mentor and the department to the candidate's career development are essential. To be eligible, the candidate must be recognized by the applicant institution as a postdoctoral fellow no later than August 1, 2013. U.S. citizenship is not a requirement. The fellow must commit a minimum of 75 percent time to the research project.

**Maximum Award:** \$45,000 annual direct costs per year averaged over the duration of the award. Indirect costs are not allowed.

**Maximum Duration:** 3 years

**Review Criteria:**

- **Significance:** Does the study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?
- **Approach:** Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the proposed work feasible?
- **Innovation:** Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator's Independence and Potential:** Discuss the candidate's potential for establishing an independent research career. Specifically cite previous training and experience, and letters of recommendation.
- **Career advancement:** Discuss the likelihood that the proposed training experience will contribute significantly to the development of the candidate's career potential as an investigator in research on tobacco use and/or tobacco-related disease.
- **Advisor's commitment:** Discuss the quality of the training resources and environment, particularly the advisor and the department, citing advisor's letter of support.

**DISSERTATION RESEARCH AWARDS (DT)**

This award is intended to support the dissertation research of a doctoral candidate pursuing tobacco-related research. Applications in all relevant research areas are welcomed, but applications in the social/behavioral sciences and in public policy are encouraged. The award is designed for students advanced to candidacy no later than August 1, 2013, and initiating their dissertation research. The applicant and principal mentor must be affiliated with an academic research institution. U.S. citizenship is not a requirement. The candidate must commit a minimum of 80 percent time to the research project.

**Maximum Award:** \$20,000 annual direct costs averaged over the duration of the award for stipend, supplies, and domestic travel. An additional maximum of \$10,000 per year is allowed for tuition/enrollment fee remission, fringe benefits, and health insurance. No equipment purchases are allowed. Indirect costs are not allowed.

**Maximum Duration:** 2 years

**Review Criteria:**

- **Significance/Approach/Innovation:** Does the study address an important problem? Are the conceptual framework, design (including composition of study population), methods, and analyses adequately developed, well-integrated and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Is the proposed work feasible? Is the proposed work appropriate to the experience level of the principal investigator? Are the aims original and innovative?
- **Academic Qualifications:** Discuss the quality of the academic record and the prior research experience of the applicant.
- **Resources and Environment:** Discuss the qualifications and the research/training experience of the applicant's sponsor or research advisor.
- **Advisor's Commitment:** Discuss the match between the research interests of the student and the research advisor/sponsor; the commitment of the research advisor and other mentors to the candidate, citing letters of support.

**REVIEW CRITERIA FOR ALL RESEARCH AWARD MECHANISMS**

- **Protection of Human Subjects from Research Risk:** If human subjects are involved protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of Women, Minorities and Children in Research:** If human subjects are involved the adequacy of plans to include subjects of both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.

- **Care and Use of Vertebrate Animals in Research:** If vertebrate animals are involved in the project, plans for their care and use will be assessed.

### **SPECIAL PROJECTS – CONFERENCE SUPPORT (ST)**

Support can be requested for scientific conferences to assess tobacco's impact on California populations; or to allow tobacco investigators to evaluate, in a timely manner, new and breaking trends in tobacco control or tobacco-related disease research. In order to qualify for funding, the planned activities must be directly related to one or more of TRDRP's Research Priorities. The activity must primarily take place in California, involve California investigators, and include, where applicable, discussants and speakers funded by TRDRP. Proposals may be submitted at any time and should be submitted on proposalCENTRAL. Applications for Conference Awards will go through a separate review process. The TRDRP Scientific Advisory Committee will make recommendations regarding funding. Conference grants will be limited in number, scope, cost, and duration. Please contact a TRDRP Program officer regarding the appropriateness of your proposal prior to submission.

### **Cornelius Hopper Diversity Award Supplement (CHDAS)**

This supplement is for the training of promising individuals who are or who want to pursue careers in the field of tobacco-related disease research or in tobacco control. Supplements may be requested only for trainees living in California and include those: (a) from socioeconomic, cultural, ethnic, racial, linguistic, and geographic backgrounds who are and/or have been underrepresented in tobacco research; or (b) pursuing a research interest focusing on cultural, societal, or educational problems as they affect underserved segments of society

Investigators must have at least one year left on their TRDRP award to ensure the best conditions and results for prospective trainees. Therefore, the CHDAS is available only after the first year of the grant application.

### **Eligible Principal Investigators**

The CHDAS is available to current principal investigators of:

- California Awards
- Research Project Awards
- CARAs
- SARAs
- New Investigator Awards
- Exploratory/Developmental Awards

### **Eligible Trainees:**

- **Undergraduate students**
- **Community members**
- **School personnel**
- **Graduate students**
- **Medical students**

The supplement cannot be transferred from one person to another; the award can be used only for the originally identified trainee. CHDAS trainees must live and be trained in California.

Overall, trainees should demonstrate high potential and promise for a career in tobacco control or tobacco-related disease research. Principal investigators should encourage trainees from socioeconomic, cultural, ethnic, racial, linguistic, and geographic backgrounds who would otherwise not be adequately represented in their field or who are from underserved communities. However, in accordance with state law, preference will not be given to applicants based on race, color, ethnicity, gender, or national origin.

**Maximum Supplement Amount:** \$15,000 annual direct costs. Indirect costs are allowed for the TRDRP portion in accordance with TRDRP policy.

**Allowable Expenditures:** Salary, fringe benefits, tuition, and enrollment fees for the trainee, domestic travel, and indirect costs, where appropriate. Award funding cannot be used for equipment.

**Maximum Duration:** 2 years

**Review Criteria:**

- Trainee must demonstrate a commitment to tobacco research and tobacco control, including pursuit of a research or tobacco control career centered on tobacco-related disease.
- Trainees should document barriers, both current and past, that may prevent her or him from realizing a career in tobacco-related disease research or tobacco control. For example, the absence of a family member who attended college; matriculation at school with poor curricular support and financial backing for higher education; having a physical or learning disability; and/or working long hours while attending school.
- Trainees should describe **in their own words** the extent that their research interests focus on cultural, societal, health or educational disparities as they affect underserved segments of our state. Additionally, describe how the

proposed research or tobacco control training will be used toward ending California tobacco-related disease disparities.

- Principal investigators and trainees must construct a detailed, well-rounded training experience. This should include, but not be limited to: scientific research methods that will be learned; classes, seminars and symposia that will be attended; the identification of a relevant research question to be pursued; research team meeting participation; other mentor-like relationships the trainee will have with research team members; and, if applicable, any relevant involvement in the community, school, etc.
- Principal investigators should document the exact amount of time that they will regularly meet with the trainee. Investigators should also identify other members of the research team that will play a mentoring role and specify their time commitment to mentoring the trainee and their contribution to the trainee's learning experience.

## **GENERAL ELIGIBILITY**

Investigators from California not-for-profit organizations are eligible for TRDRP funding, including but not limited to colleges, universities, hospitals, laboratories, research institutions, local health departments, community-based organizations, voluntary health agencies, health maintenance organizations, and other tobacco control groups. The Principal Investigator should be designated by the sponsoring institution in accordance with its own policies and procedures.

The Principal Investigator must supervise the research project and then trainee directly and in person. Although the research undertaken with TRDRP funds must be conducted primarily in California, part of the work may be done outside California if the need to do so is well-justified (e.g., it is integral to the achievements of a specific aim), and the results of such work may be applied to understanding the causes and/or improving the prevention and treatment of tobacco-related diseases in California.

In accordance with University of California policy, Principal Investigators who are University employees and who receive any part of their salary through the University must submit grant proposals through their UC campus contracts and grants office (see "[Policy on the Requirement to Submit Proposals and to Receive Award for Grants and Contracts through the University](#)," University of California Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the Principal Investigator is employed. US citizenship is not a requirement for eligibility.

## SUBMISSION

Submission of a Letter of Intent (LOI) is required to apply for all research awards except for Special Projects and Cornelius Hopper Diversity Award Supplements. You will have access to the application web pages when the LOI is approved in proposalCENTRAL, at which time you will receive a notification e-mail. To be accepted for a full application a Letter of Intent (LOI) must address one or more of TRDRP's five research priorities.

LOIs and proposals must be submitted using the online system, proposalCENTRAL at <https://proposalCENTRAL.altum.com/>. To submit an LOI:

1. Go to proposalCENTRAL.
2. Log in to the system.
3. Click on the "Grant Opportunities" tab (far right, gray).
4. Click on University of California Tobacco-Related Disease Research Program and find the row for the award type in which you are interested.
5. Click on "Apply Now" on the far right.
6. On the title page (**LOI Section 1**), enter the title (60 characters or fewer including spaces). Note: this and other parts of the application can be edited later.
7. Select the Research Priority using the radio buttons.
8. Click on "Save". This creates a record of your LOI in the system that can be accessed in later visits for additional work or editing under the "Manage Proposals" tab (far left tab on the main screen, blue).
9. Click on **LOI Section 2**, "Download Templates and Instructions" in the gray sidebar on the left. Follow the instructions to complete the process.

For technical help with proposalCENTRAL, please email [pcsupport@altum.com](mailto:pcsupport@altum.com) or call 800-875-2562 (Toll-free U.S. and Canada). ProposalCENTRAL customer support is available Monday – Friday from 8:30am - 5:00pm (EST)

## KEY DATES

<b>PI Letter of Intent (LOI) Submission Window</b>	<i>Sept 5 through Nov 13, 2012</i>
<b>PI Letter of Intent (LOI) Submission Approvals</b>	<i>Sept 12 through Nov 20, 2012</i>
<b>Full Proposal and Signature Page Submission Deadline</b>	<i>Jan 24, 2013 (12:00 Noon PT/3 PM ET)</i>
<b>Expected Notification of Review Outcome</b>	<i>June 2013</i>
<b>Research Commences</b>	<i>Aug 1, 2013</i>

## CONTACT INFORMATION

Questions regarding scientific issues or TRDRP policies should be directed to the appropriate TRDRP Program Officer:

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Inquiries regarding application forms and instructions may be directed to the Research Grants Program Office (RGPO): [RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu) or (510) 987-9386

For technical help with online grant submission contact the proposalCENTRAL Help Desk: [pcsupport@altum.com](mailto:pcsupport@altum.com) or (800) 875-2562 (Monday-Friday from 8:30am - 5:00pm EST)