

# TRDRP

## 2012 Call for Applications

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### PURPOSE

The purpose of this 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. 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 the use of nicotine and tobacco products, particularly among the most heavily affected of California's diverse populations.

### BACKGROUND

The science and practice of tobacco control is a dynamic, rapidly evolving, and radically different field from that of just a few years ago. As a result of the [Family Smoking Prevention and Tobacco Control Act of 2009](#), the U.S. Food and Drug Administration (FDA) now has authority to oversee and regulate tobacco products. At the same time and in response to regulatory and market pressures, the tobacco industry has intensified the development and marketing of a host of new products. Harm reduction claims, often made by health professionals, are increasingly associated with some of these new products. Yet little research has been done to determine the long term health effects and addiction potential of inhaled vaporized nicotine or the ingestion of orally-delivered nicotine. The FDA's responsibility to protect the health of the public provides an unprecedented role for the government and multiple research opportunities for the scientific community. It is clearly a daunting task and one that will require the efforts of many investigators from a broad range of fields. In this Call for Applications, TRDRP encourages researchers

throughout California to contribute their creativity and expertise to this massive undertaking.

Despite this new regulatory power at the federal level and the early leadership by the State, it is also apparent that California has slowed in its own tobacco control momentum. 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 aggressively 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 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.

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<sup>1</sup> Campaign for Tobacco Free Kids. *Key State-Specific Tobacco-Related Data & Rankings*. Available at: <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., Messer, K., White, M.M., Kealey, S., & Cowling, D.W., (2010) *California's Leadership in Tobacco Control Results in Lower Lung Cancer Rate, Cancer, Epidemiology, Biomarkers, and Prevention*, 10.1158/1055-9965.EPI-10-0563, 2010

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

<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. Available at: <http://www.cdc.gov/media/pressrel/2010/r100423.htm>

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. However, the cost of biomedical research has escalated and TRDRP is challenged to focus its limited and declining research dollars most effectively. Given the substantial resources already devoted to the development of disease treatments by both the federal government and the commercial sector; the high treatment cost of late stage tobacco-related disease; and the increased efficacy of treatment at the early stages of disease, the program is strategically shifting its focus to the early detection and secondary prevention of tobacco-related disease.

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>5 6</sup> California is composed of a sizable majority of these populations, including the 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>7</sup> Despite the significance of health disparities within tobacco control and tobacco-related disease, relatively little is known about the causes of population differences observed in exposure and susceptibility to, and the consequences of, tobacco use.<sup>8</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.

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<sup>5</sup> Fagan P., King G., Lawrence D., Petrucci S. A., Robinson R. G., Banks D. *et al.* Eliminating tobacco-related health disparities: directions for future research. *Am J Public Health* 2004; **94**: 211–17.

<sup>6</sup> Conway TL, Tobacco use and the United States military: a longstanding problem. *Tobacco Control*, September 1, 1998; 7(3): 219 - 221.

<sup>7</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>8</sup> Fagan P., Moolchan ET, Lawrence D, Fernander E, & Ponder PK. Identifying health disparities across the tobacco continuum. *Addiction*, 2007, 102 (Suppl. 2), 5–29.

## New TRDRP Program Framework

As a result of an extended strategic planning process involving advice and input from many stakeholders, including tobacco researchers, tobacco control activists, and members of the program's Scientific Advisory Committee (SAC), TRDRP has adopted a set of new strategic goals, the first of which is "to fund high priority areas of research."

### PRIORITY RESEARCH OBJECTIVES

Our research priorities for 2012 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 new research priorities:

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

*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>9</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

*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:

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<sup>9</sup> Matt GE, Quintana PJE, Zakarian JM, Fortmann AL, Chatfield DA, Hoh E, Uribe AM, Hovell MF. 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

- 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

*Secondhand Smoke* - 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 and a solid scientific underpinning for relevant tobacco control efforts in such areas is lacking. Research is needed to understand the exposure and health risks associated with SHS exposure in public spaces such as casinos, outdoor public spaces and multi-unit housing as well as 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, businesses and outdoor public spaces.
- The pragmatic and ethical implications of policies banning the smoking of addictive products in public spaces
- 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 SHS and environmental impact policies.

**Advance innovative research in nicotine addiction and 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 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.

*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>10</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.

*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

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<sup>10</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.

- Improve the efficacy of Varenicline and/or develop more efficacious partial antagonists and partial agonists
- 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

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

The [Family Smoking Prevention and Tobacco Control Act of 2009](#) granted the FDA the power to require appropriate testing of evaluation of tobacco products in order to enact product standards to control and reduce the level and delivery of toxic compounds. The FDA was also given the authority to assess putative and proposed modified risk products and drugs or other products used to treat tobacco dependence. The agency is further authorized to establish tobacco product standards and conduct periodic consumer perception testing. Such information is not only essential at the federal regulatory level but will also be useful to state and local tobacco control programs to educate consumers and inform regulatory policy.

Products on which research is needed include 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
- Cigarette design features other than nicotine that may contribute to its reinforcing effect
- New 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

## **Prevent and reduce the use of tobacco products and tobacco-related health disparities in California's disproportionately impacted populations.**

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 socio economic status are at increased risk for lung cancer. Understanding how and why different sub-populations of Californians use tobacco products and whether there are discernable 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, 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 and the subsidization of tobacco products on military bases



## Sub-Priority 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 has launched a research initiative aimed at understanding and mitigating the health disparities faced by African Americans in California. In November of 2010, TRDRP convened a group of scientists and activist to discuss and assess the outstanding research issues facing this population. That meeting identified that African Americans have one of the highest smoking rates (> 19%) of any group and die disproportionately in greater numbers for heart disease, stroke, lung cancer and other tobacco related disease. 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>11</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>12</sup>

Given these sobering statistics and with the input from numerous stakeholders and advisors, the TRDRP is setting aside \$1,000,000 annually over the next 3 years to expand the research on African American smoking and tobacco use in California. As a result of the initiative's extensive input process, the following five research questions/areas have been prioritized for support as part of this initiative in order of preference.

- Why do African Americans smoke more menthol cigarettes? What are the social determinants driving this preference? What are menthol

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<sup>11</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>12</sup> Max W, Sung H., Tucker, L. & Stark B. The disproportionate cost of smoking for African Americans in California. American Journal of Public Health, January 2010, Vol 100, No. 1, 152-158.

analogues and what would be the reactions to a potential ban on menthol.

- African Americans and quitting; best practices for African American cessation. Investigate the practice of African American health care providers and smoking cessation advice.
- The impact of the current economic situation on tobacco use in the African American community. Are tobacco taxes regressive in the African American community?
- What is the relationship between stress and tobacco use in the African American community?
- What is the prevalence of smoking and tobacco use in California's African American community?

### **Advance the ability of communities throughout California to assess and limit the influence of the tobacco industry**

The tobacco industry in California has been inordinately successful in blunting tobacco tax increases and in blocking other policy advancements. The tobacco industry poured over \$100 million dollars into the defeat of Proposition 86, which would have raised cigarette taxes by \$2.60 and has begun significant investments in the opposition to the [California Cancer Research Act](#). The tobacco industry is a fixture in Sacramento, doling out monies to Assembly members, State Senators, Statewide office holders and other governmental officials. The Center for Tobacco Policy & Organizing of the American Lung Association in California has documented all this very well.<sup>13</sup> However, there are still major gaps in our understanding of how the tobacco industry influences state and local policy and how the state, local jurisdictions, and communities might act to limit this influence.

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

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<sup>13</sup> The Center for Tobacco Policy & Organizing. Tobacco Money & Politics. Available at: <http://www.center4tobaccopolicy.org/tobaccomoney>

## MECHANISMS OF SUPPORT

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

### Overview of Current 2012-2013 Mechanisms:

2012-2013 Grant Mechanisms	Purpose	Max Amount	Max Duration (Yrs)	LOI Due	Application Due	Award Start
<b>Research Project (RT)</b>	Full Research Projects	Up to \$525,000	Up to 3			
<b>Exploratory &amp; Developmental (XT)</b>	Pilot and Exploratory Research Studies	\$250,000	Up to 2			
<b>Participatory Research - (Pilot CARA/SARA)</b>	Preliminary Studies for Participatory Projects	\$250,000	2	Dec 9 2011	Jan 11 2012	Aug 1 2012
<b>Participatory Research - (Full CARA/SARA)</b>	Community or School and Academic Collaborative Research Projects	\$525,000	3			
<b>Postdoctoral (FT)</b>	Postdoctoral Career Development	\$135,000	3			
<b>New Investigator (KT)</b>	Not Offered	Not Offered	Not Offered			
<b>Dissertation (DT)</b>	Pre-doctoral Research Training	\$60,000	2			
<b>Special Projects (ST)</b>	Research Dissemination and Infrastructure	Variable	2	Not Required	Continuous	Variable
<b>Cornelius Hopper Diversity Supplement (CHDAS)</b>	Research Training	\$30,000	2	Not Required	April 16 2012	Aug 1 2012

**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. Applicants may request any amount in direct costs up to a total of \$525,000. Higher budgets must be fully justified and should be requested only for projects that will be conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena linked to medical treatments or methods) for which an investigator (or colleague) directly interacts with a significant number of study participants. Full indirect costs are allowed to eligible (non-UC) institutions.

**Maximum Award:** Average annual direct costs cannot exceed \$175,000.

**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 \$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 eligible (non-UC) institutions.

**Maximum Duration:** 2 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?
- **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 are for 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.

The applicant partners must demonstrate the use of methods that are relevant, culturally sensitive, and appropriate in terms defined and accepted by the participating communities/schools. The expectations for each of the partners must be clear. Establishing a high level of contact and communication between community or school staff and the researchers is imperative and must be described. Both 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 the results. There should also be a systematic plan developed by the partners for disseminating results to the scientific community, other community/school programs engaged in similar work, and most importantly, to the target population. 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.

**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 or community schools.

**Supplemental Funding** by means of a contract from the California Department of Education (CDE) is available as part of a SARA for schools that are operated by a district or county office of education that has a valid County-District-School Code in the California Public School Directory. Additionally, to be eligible for these contracted supplemental funds, the applicant agency must be certified by CDE as having met tobacco-free school district criteria on or before August 1, 2012. School districts and county offices of education are eligible to apply for these supplemental

funds on behalf of schools under their jurisdiction that they select for this research. For each SARA-related application, either the school district or the county office of education must be the fiscal agent for the CDE funds. CDE's funding amount is inclusive of indirect costs.

### **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, detailing the research plan and methods, and collecting pilot data.

### **Maximum Award**

**Pilot CARA:** \$250,000 total direct costs. Indirect costs are allowed in accordance with TRDRP policy.

**Pilot SARA:** \$250,000 total direct costs. For eligible school partners an additional \$15,000 per year is provided by CDE. Indirect costs are allowed for the TRDRP portion in accordance with TRDRP policy.

**Maximum Duration:** 2 years

### **Review Criteria:**

- **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 adequately developed, well-integrated, and appropriate to the aims 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? Are the research methods sufficiently rigorous yet incorporate perspectives and beliefs of community residents/school or school population of interest? Does the proposal delineate how the research findings will be disseminated within the target community or school, to other communities/schools and within academic circles? 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 community/school participants involved in analytic issues: interpretation, synthesis, and the verification of conclusions? Will the proposed study empower the community or school to address political, social and economic 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 participatory 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.

**Full CARA:** \$170,000 average annual direct costs. Indirect costs are allowed in accordance with TRDRP policy.



**Full SARA:** \$170,000 average annual direct costs. For eligible school partners an addition \$50,000 per year is provided by CDE. Indirect costs are allowed for the TRDRP portion in accordance with TRDRP policy.

**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, 2012. 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, 2012, 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 (ST)

**Infrastructure Award:** These grants are designed to support electronic, biological, clinical, and informational support systems that would serve as a resource for tobacco-related disease researchers in the state of California and nationally.

Examples include electronic archiving of key industry documents; human tissue repositories for the genetic analysis of tobacco addiction susceptibility; unique analytical resources specifically targeted to new tobacco product evaluation. 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. A maximum of \$250,000 may be requested. Indirect costs are allowed in accordance with TRDRP policy. The TRDRP Scientific Advisory Committee will make recommendations regarding funding. Please contact a TRDRP Program Officer regarding the appropriateness of your proposal prior to submission.

**Maximum Award:** Average annual direct costs cannot exceed \$125,000

**Maximum Duration:** 2 years

### Review Criteria

- **Impact/Benefit:** Will the resource fill a critical need? How will scientific knowledge or clinical practice be advanced? What will be the effect of this resource on the concepts, methods, technologies, treatments, services, or preventative interventions that drive the fields of tobacco-related diseases, tobacco control, social & participatory research, nicotine addiction, prevention or policy?
- **Justification of Need:** Is the need for the resource clearly and adequately justified? Is it essential and appropriate? Will it have a significant impact on the fields of tobacco-related diseases, tobacco control, social & participatory research, nicotine addiction, prevention or policy?
- **Institutional Commitment:** What is the evidence of institutional commitment to support the resource? Is institutional infrastructure (technical support, space, environment and utilities) available to support it? Is there an institutional track record for making the resource available? Is the financial plan for fully funding the resource and long-term operation and maintenance reasonable? Is there appropriate documentation (letters from institutional officials)?
- **Leadership and Administration:** Are the experience and qualifications of the principal investigator and/or leadership team adequate? Are the sharing arrangements equitable? If needed, are the policies to manage human subject, animal or biohazardous materials projects adequate?

**Conference Award:** 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. 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**

All California individuals are eligible for the CHDAS training opportunity, including undergraduate students, community members, school personnel, graduate students, postdoctoral fellows, and 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 career centered on tobacco-related research.
- Trainees should document barriers, both current and past, that may prevent her or him from realizing a career in tobacco-related disease research. 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, if applicable, 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 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.

## **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 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 1 through Dec 9, 2011</i>
<b>PI Letter of Intent (LOI) Submission Approvals</b>	<i>Sept 6 through Dec 15, 2011</i>
<b>Full Proposal Submission Deadline</b>	<i>Jan 11, 2012 (12:00 Noon PT/3 PM ET)</i>
<b>Signature Page Submission Deadline</b>	<i>Jan 18, 2012 (5 pm PT)</i>
<b>Expected Notification of Review Outcome</b>	<i>June 2012</i>
<b>Research Commences</b>	<i>Aug 1, 2012</i>

## CONTACT INFORMATION

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

### **Biomedical Sciences**

M.F. Bowen, Ph.D.

(510) 987-9811

[mf.bowen@ucop.edu](mailto:mf.bowen@ucop.edu)

### **Social/Behavioral and Neuroscience**

Phillip Gardiner, Dr. P.H.

(510) 987-9853

[phillip.gardiner@ucop.edu](mailto:phillip.gardiner@ucop.edu)

For information regarding proposals on  
**Environmental Science or Public Health & Policy:**

Phillip Gardiner, Dr. P.H.

(510) 987-9853

[phillip.gardiner@ucop.edu](mailto:phillip.gardiner@ucop.edu)

Bart Aoki, Ph.D. - Director

(510) 987-9537

[bart.aoki@ucop.edu](mailto:bart.aoki@ucop.edu)

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)