

## 2019 Call for Applications (revised 1-3-18)

#### Call for Applications 2019\*: New changes and Requirements

- Submission of a letter of intent (LOI) is required even if you are resubmitting an application.
- All **new** applications received for the 2019 call for applications must clearly address tobacco or a tobacco-related disease.
- In addition, High Impact Research Project Awards must clearly address tobaccorelated health disparities or new and emerging tobacco products.
- Applications initially submitted under the 2018B call for applications are eligible for resubmission in response to the 2018 call's priorities.
- Predoctoral and Postdoctoral Fellowship applications can be submitted twice a year.
- Follow all instructions and submit ALL required forms to avoid administrative rejection.
- Applications may be rejected based on programmatic or administrative review.
- Go to <a href="http://www.trdrp.org">http://www.trdrp.org</a> for LOI/Application instructions and information on how to access the application submission system.

#### Introduction

The Tobacco-Related Disease Research Program of California (TRDRP) administers the portion of state retail taxes on tobacco products that are designated for research within California. This unique source of funding supports investigators at eligible California institutions whose research contributes directly to the elimination of smoking and tobacco use and mitigates its human and economic costs in California.

In November 2016, California voters passed Proposition 56 — the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 — which increased the retail tax on tobacco products by \$2. Under the 2018 call for applications, TRDRP awarded over \$80 million dollars to over 120 scientifically meritorious projects with an overall funding rate of 19 percent. For the 2019 call for applications, TRDRP will have closer to \$57 million in allocated funds available to award. This call for applications narrows the scope of research requested in order to better align our funded awards with our mission and the funds available.

<sup>\*</sup> The 2019 call for applications refers to applications that will be awarded in calendar year 2019, although some applications and other processes will occur in calendar year 2018.

#### Highlights of the 2019 Call for Applications

Research priorities. All applications must address one or more of TRDRP's eight research priorities.

- 1. Social and behavioral prevention and treatment
- 2. Cancer prevention, treatment and biology
- 3. Cardiovascular and cerebrovascular diseases
- 4. Environmental exposure and toxicology
- 5. Neuroscience of nicotine addiction and treatment
- 6. Oral diseases and dental health
- 7. Pulmonary biology and lung diseases
- 8. State and local tobacco control policy research

Please see Appendix A for details.

**Tobacco-related disease remains a research focus.** In addition to tobacco policy, treatment, and prevention research, TRDRP is only accepting applications for research projects that substantially focus on tobacco-related diseases. The criteria for determining whether a proposal is eligible include:

- 1. Projects in which tobacco constituents or tobacco-related products are integral to the proposed study.
- 2. Studies focused on cancers that the Surgeon General has causally linked to tobacco or tobaccorelated products.
- 3. Studies focused on oral diseases, cardiovascular diseases, pulmonary diseases, and other diseases that the Surgeon General has causally linked to tobacco or to tobacco-related products.
- 4. Observational or laboratory studies of co-use of tobacco products with other substances including cannabis.
- 5. Health behavior and health policy research focused on tobacco prevention, treatment, or regulation.

New High Impact Research Projects must directly address tobacco-related health disparities or new and emerging tobacco products. In an effort to more closely align our most generous awards with the most urgent questions in tobacco control, High Impact Research Projects submitted for the first time in cycle 2019A must focus on tobacco-related health disparities or research on new and emerging tobacco products. Please refer to the High Impact Research Project description for eligibility criteria.

**Cannabis use and tobacco-related diseases.** There remains a critical need to understand the interaction of cannabis and tobacco. The biological and population level impact of these products in combination is of particular interest to inform effective management of health and health policy. New applications that include cannabis must also be related to tobacco or tobacco-related disease. Please refer to the <a href="https://research.com/TRDRP">TRDRP cannabis research policy</a> for additional guidance. (trdrp.org/funding-opportunities/cannabis-research-considerations.html)

NOTE: For studies involving cannabis, investigators are strongly encouraged to refer to their institutional policy on conducting cannabis research before designing studies to avoid conflicts with federal and state regulations. Please refer to the <u>TRDRP cannabis research policy</u>. (trdrp.org/funding-opportunities/cannabis-research-considerations.html). Also, applicants are required to describe the status of their Drug Enforcement Agency (DEA) license for the use of a Schedule I drug in their application, if research using cannabis is proposed.

Changes to proposal requests in 2019 call for applications. TRDRP will accept proposals during two cycles of applications: cycle 2019 A and cycle 2019B. All award types will be accepted in cycle 2019A, while award types will be limited in cycle 2019B. In cycle 2019B, TRDRP will accept new proposals and resubmissions for Predoctoral and Postdoctoral Fellowship Awards, but will only accept resubmissions for the New Investigator Research Awards, High Impact Pilot Research Awards, and High Impact Research Project Awards. No new proposals will be accepted for New Investigator Research Awards, High Impact Pilot Research Project Awards in cycle 2019B call for applications.

**Out-of-state expenses.** Due to the mandate that Proposition 56 research dollars must be used within California, a close review of out-of-state budget justification requests will be made. Only a very limited number of projects with out-of-state expenses can be funded.

Letter of Intent (LOI) process. Submission of an LOI is required for all new and resubmitted applications. LOIs will be programmatically reviewed by TRDRP staff to verify consistency with the requirements and adherence with TRDRP research priorities as described in this call. Applicants who submit **new** proposals for the 2019 call for applications that do not comply with the tobacco-related disease research requirement or the High Impact Research Project requirements described above will not be invited to submit a full application. Invited full applications will have to be substantially similar in their focus on these eligibility requirements as described in the LOI, or will be rejected on programmatic grounds. Resubmissions of proposals initially submitted in response to the 2018 call for applications do not have to comply with these eligibility requirements. TRDRP encourages applicants to contact TRDRP program officers with questions regarding eligibility requirements before submitting an LOI or application.

Once an LOI is approved, the applicant will be notified and the application materials will be made accessible to the applicant.

## **KEY DATES**

#### TRDRP will accept applications during two cycles for the 2019 call for applications

Cycle	2019A	2019B*	
Call open	Monday, July 16, 2018	Monday, January 7, 2019	
LOI submission deadline (approved on a rolling basis)	Thursday, August 16, 2018 12 p.m. PT	Thursday, February 7, 2019 12 p.m. PT	
Due date for new applications and resubmissions*	Thursday, September 27, 2018 12 p.m. PT	Thursday, March 14, 2019 12 p.m. PT	
Applicants notified	Week of January 28, 2019	Week of July 15, 2019**	
Awards start	April 1, 2019	Monday, September 2, 2019**	

<sup>\*</sup>In cycle 2019B, TRDRP is accepting **new** and resubmitted Predoctoral and Postdoctoral Fellowship Award applications and **only resubmitted** New Investigator Research Award, High Impact Pilot Research Award, and High Impact Research Project Award applications.

#### To get started:

- 1. Determine your <u>eligibility for funding.</u> (http://trdrp.org/funding-opportunities/index.html#eligibility)
- 2. Explore our <u>eight research priorities.</u> (trdrp.org/research-priorities/index.html) (All applications must address one or more.)
- 3. Review the <u>2019 call for applications award types</u> (trdrp.org/funding-opportunities/award-mechanisms/index.html) and <u>dates and deadlines</u>. (trdrp.org/funding-opportunities/dates-and-deadlines.html)
- 4. Familiarize yourself with our <u>letter of intent and application processes.</u> (trdrp.org/funding-opportunities/award-processes/index.html)
- 5. Contact a program officer (trdrp.org/about/staff.html) with any questions.
- 6. Use SmartSimple (ucop.smartsimple.com) to submit your LOI and application.

All applicants should review the RFP, LOI Instructions, and Application Instructions in their entirety, and must complete all necessary materials using the appropriate templates and forms. Failure to comply with provided instructions or to submit complete forms may result in administrative rejection of the application.

<sup>\*\*</sup>Postdoctoral Fellows will be notified of their award status in June 2019 and will have a July 1, 2019 start date

# 2019 Call for Applications: Grant Award Types See Appendix B for details

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Grant Types	Purpose of Award	Maximum Award/Year (Direct Cost)	Maximum Award Duration (up to X years)	
High Impact Research Project Award	Conduct research that will address tobacco- related health disparities or new and emerging tobacco products.	\$250,000/year	3	
High Impact Pilot Research Award	Gather preliminary data or demonstrate proof-of- principle with potential for high impact within one or more stated research priorities.	\$200,000/year	2	
New Investigator Award	Support and enable new investigators to initiate an independent research program with potential for high impact within one or more stated research priorities.	\$200,000/year	3	
Postdoctoral Fellowship Award <sup>1</sup>	Support postdoctoral research training under a designated mentor to conduct high impact research within one or more stated research priorities.	See Appendix B	3	
Predoctoral Fellowship Award	Support doctoral student research training with a designated mentor within one or more stated research priorities.	See Appendix B	3	
GRANT TYPES WITH ROLLING DEADLINES⁴				
Student Research Supplement <sup>2</sup>	Allow active research training and participation by undergraduate and Master's degree students under the mentorship of a currently-funded TRDRP PI of a non-training award. Supplements are above the award mechanism cap.	\$20,000	1	
Cornelius Hopper Diversity Award Supplement <sup>3</sup>	Train promising individuals from underrepresented communities and/or those who wish to pursue careers in one or more stated research priorities focused on underserved communities.	\$20,000/year	2	
Mackay California- Pacific Rim Tobacco Policy Scholar Award <sup>4</sup>	Build leadership among mid-career researchers to foster evidence-based tobacco control policy with relevance to California and the Pacific Rim (Asia, Pacific Islands and Latin America).	\$250,000/year	3	

Dissemination Award <sup>4</sup>	Support small scientific conferences and other research dissemination activities for results from TRDRP-funded research.	\$5,000	1
Scientific Conference Award <sup>4</sup>	Support in-person scientific conferences that disseminate TRDRP-funded research and include new and emerging issues championed by TRDRP investigators and colleagues.	Up to \$50,000/year	2

<sup>&</sup>lt;sup>1</sup>Postdoctoral stipend or salaries are commensurate with the current NIH postdoctoral experience scale or the rates set by their institution with institutional documentation of the alternate payment scale. Award duration is capped at three years for all awards at the start year of funding. An institutional allowance is allowable upon request.

<sup>&</sup>lt;sup>2</sup>Student Research Supplement applications will be accepted for non-mentored grants such as the High Impact Research Project Award, High Impact Pilot Research Award, New Investigator Award or Community Practice-Based Research Award as part of the mentoring PI's annual progress report. Funded supplements are eligible for competitive renewals for up to \$20,000/year through the duration of the parent grant.

<sup>&</sup>lt;sup>3</sup>Cornelius Hopper Diversity Award Supplement applications will be accepted as a part of the mentoring PI's annual progress report.

<sup>&</sup>lt;sup>4</sup>Applications for the Mackay California-Pacific Rim Tobacco Policy Scholar Award, Dissemination Award and Scientific Conference Award may be submitted at any time during the year. Please contact TRDRP staff for details.

## TRDRP FUNDING POLICIES AND PROCEDURES

## **Resubmission Policy**

A resubmission is an unfunded application submitted as a new application in the previous year to any TRDRP peer review panel that is revised and resubmitted to respond to the critiques under the currently reviewed grant cycle. Please note that TRDRP will accept only a single resubmission of the same or very similar project, regardless of change in application title. Resubmissions are only allowed once during the next two subsequent grant cycles.

An application in grant cycle **2019A** can be submitted as a resubmission if a similar application was submitted and reviewed in either of the two grant cycles in 2018 call for applications. An application in grant cycle **2019B** can be submitted as a resubmission if a similar application was submitted and reviewed in cycle 2018B or cycle 2019A.

Applicants are still required to inform TRDRP of their intent to resubmit through an LOI submission, and must note it as a resubmission (please refer to the LOI/Application instructions for the specific award type). All other applications are considered new applications.

High Impact Research Project Award applications submitted under 2018 call for applications may resubmit under the 2019 call for applications using the requirements that existed in the 2018 call for applications.

## **Multiple Submissions Policy**

TRDRP will accept up to one application per award type per applicant per grant cycle, provided that the proposed research topics and aims are significantly different for each LOI/application. Applicants may not submit more than one application under a specific award type, and may not submit multiple applications across different award types with a similar research subject. TRDRP reserves the right to reject any LOI or application due to multiple submissions by the same applicant. Unless otherwise stated, Supplement awards are not subject to the multiple submission policy. If more than one submission is deemed meritorious and selected for funding, TRDRP reserves the right to decide which proposal to fund and will not fund an applicant as PI for more than one award of any type in the same grant cycle.

## **TRDRP Eligibility Criteria**

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 sponsoring institution, in accordance with its own policies and procedures, should designate the principal investigator (PI). The PI must supervise the research project and any trainees directly and in person. U.S. citizenship is not a requirement for eligibility.

In accordance with UC policy (<a href="https://policy.ucop.edu/doc/2500500/ReqSubmitProp-Awar">https://policy.ucop.edu/doc/2500500/ReqSubmitProp-Awar</a>), PIs who are UC employees and who receive any part of their salary through UC must submit grant proposals through their UC campus contracts and grants office. Exceptions must be approved by the UC campus where the PI is employed.

**Applicants at California-based Nonprofit Institutions:** TRDRP will accept applicants from PIs at non-profit organizations or institutions, provided that the organization can manage the grant and demonstrate financial health. The organization must also meet our liability insurance requirements. If the application is recommended for funding, RGPO will collect additional information, such as tax ID numbers and financial reports, to review the organization during the pre-funding process to ensure all financial management and project management eligibility criteria can be met.

### **Applicant Appeal Policy and Procedures**

The only basis on which an appeal regarding a decision concerning the funding of a grant application will be considered is in the case of an alleged error in, or violation of, the peer review process and procedures. For example, the principal investigator may believe that he or she has a conflict of interest with a member of the review panel that was not known to the program at the time of the review. Appeals based on substantive disagreement with the peer review evaluation will not be considered. In such cases, applicants may resubmit applications in a subsequent grant cycle.

Before submitting appeals, applicants are encouraged to talk about their concerns informally with the appropriate program officer and program director.

Appeals must be submitted in writing to the vice president of Research and Graduate Studies, University of California, Office of the President, within thirty (30) days of receiving the Summary Statement. The vice president may, if an applicant shows good cause, grant a reasonable extension of time for the submission of the request for review. The appeal must contain a complete statement of the basis for the appeal, including pertinent facts, supporting arguments, and documentation. If the application was submitted through an institution, the appeal must be submitted officially through that institution, and it must be signed by the official authorized to sign for the institution, as well as by the principal investigator. No appeal shall affect any authority of the University of California, Office of the President, the vice president of Research and Graduate Studies, the executive director of the Research Grants Program Office, or the applicable program director.

Upon receipt of an appeal, the vice president of Research and Graduate Studies shall make a decision as to whether the dispute is reviewable under this appeals policy and notify the applicant, the program director and the executive director of the Research Grants Program Office of the determination. If the appeal is reviewable, it shall be transmitted to an appeal review committee appointed by the vice president. This committee will be comprised of two persons who are knowledgeable about both the type of research in question and the review procedures. The appeal review committee shall provide the applicant an opportunity to submit additional statements and documentation relevant to the appeal review committee's deliberation of the issues. The appeal will consider the application as submitted. Therefore, such supplemental appeals materials may not include additional data or clarification of the original application. The appeal review committee may, at its discretion, invite the applicant and any other person(s) to discuss the pertinent issues with the committee and submit such additional information as the committee deems appropriate. The committee may also request information from the program director regarding the review procedures or other issues raised in the appeal.

Participants in an appeal review (i.e., committee members and outside experts) and any materials considered will be subject to the same rules of confidentiality that govern the initial handling and evaluation of the application.

Based upon its review, the committee will prepare a written decision to be signed by the members. The appeal review committee shall send the written decision as advice to the vice president, who will render a final written decision and transmit it to the applicant, the members of the appeal review committee, the program director and the RGPO executive director. No further appeals within the

University of California are available.

#### **Submission Process**

Submission of a Letter of Intent (LOI) is required to apply for all research awards. The LOI must be submitted electronically. Applicants will have access to the application materials if the LOI is approved, at which time applicants will receive an email notification. LOI submission instructions should be strictly followed as stated.

All applicants should review the RFP, LOI Instructions, and Application Instructions in their entirety, and must complete all necessary materials using the appropriate templates and forms. Failure to comply with provided instructions or to submit complete forms may result in administrative rejection of the application.

## **Review Process and Funding Decisions**

Applications will be grouped by priority area and reviewed in a study section by experts from outside of California. The criteria for evaluating applications are described under each specific award type section. TRDRP and its Scientific Advisory Committee will prioritize funding scientifically meritorious applications that are well-aligned with the priority areas described in this call for applications, that provide a balance across these priorities, and that are within the extent of funding that is available.

For more information about the funding process visit the <u>TRDRP website</u> (trdrp.org/funding-opportunities/review-process/index.html).

## TRDRP CONTACTS

Questions regarding scientific issues or TRDRP policies should be directed to the appropriate TRDRP program officer:

#### **Social Behavioral Sciences and Public Health**

Norval Hickman, PhD, MPH (510) 987-9032, Norval.Hickman@ucop.edu

#### **Tobacco Control Policy Research**

Raymond Boyle, PhD (510) 987-9959, Raymond.Boyle@ucop.edu

#### **Cancer Prevention, Treatment and Biology**

Katherine McKenzie, PhD (510) 987-9876, Katherine.McKenzie@ucop.edu

#### **Biomedical and Environmental Sciences**

Tracy Richmond-McKnight, PhD (510) 987-9811, <u>Tracy.Richmond-McKnight@ucop.edu</u>

#### Biomedical, Cardiovascular and Oral Disease

Ginny Delaney, PhD (510)587-6292, Ginny.Delaney@ucop.edu.

#### **Biomedical, Neuroscience and Lung Disease**

Uta Grieshammer, PhD (510) 987-9636, <u>Uta.Grieshammer@ucop.edu</u>

Inquiries regarding LOI/application forms and instructions should be directed to:

#### **Research Grants Program Office (RGPO)**

RGPOGrants@ucop.edu (510) 987-9386

## **APPENDIX A: RESEARCH PRIORITIES**

All applications must address one or more of TRDRP's eight research priorities.

- 1. Social and behavioral prevention and treatment
- 2. Cancer prevention, treatment and biology
- 3. Cardiovascular and cerebrovascular diseases
- 4. Environmental exposure and toxicology
- 5. Neuroscience of nicotine addiction and treatment
- 6. Oral diseases and dental health
- 7. Pulmonary biology and lung diseases
- 8. State and local tobacco control policy research

#### 1. Social and behavioral prevention and treatment

**Purpose:** Advance innovative research and collaborations that prevent or reduce tobacco use and the impact of tobacco-related diseases among California's priority groups (see a list of priority groups under "High Impact Research Project Award", p22).

**Background:** Tobacco use continues to cause disproportionately high rates of morbidity and mortality from cancers, cardiovascular and lung diseases, oral diseases, and reduced quality of life for California priority groups. Tobacco-related health disparities (TRHDs) devastate individuals, families, communities and the economy.

#### Social determinants of health

Multiple complex factors contribute to TRHD. Tobacco-related research should consider the social determinants of health or the impact of the physical environment (e.g., poverty) in which people work, live and socialize on tobacco use and tobacco-related diseases. Understanding and reducing TRHD requires consideration of intersectional groups and the interaction of individual, interpersonal/social, community/neighborhood, institutional, and policy factors across the tobacco use continuum and over the life span. Cultural factors and experiences with discrimination are important to consider when addressing the impact of environment, structural factors and institutional/government policy on health.

#### Collaborations and community engagement

TRDRP encourages researchers and academic institutions to collaborate closely with: nonprofits; community organizations, health centers, and advocates; community residents; American Indian tribal organizations; immigrant service organizations; employment development agencies; post-incarceration service agencies; and policymakers at all levels of the research process.

Community-based organizations with the infrastructure to manage grant funding are encouraged to play a lead role on a community-academic participatory research project; however, community organizations should serve on a research project at a level that appropriately considers their capacity and available resources. Collaborative research partnerships are needed:

- Between health care practitioners and academic researchers to develop a standard process for addressing tobacco use in clinical settings that serve priority groups and to promote systems level change in cessation-related activities and healthcare policy
- To build capacity and leadership among community-based organizations and other nonprofits for scientific research
- To train and prepare the next generation of leaders and advocates in tobacco control research

TRDRP particularly encourages researchers to work with tribal leadership on commercial tobaccorelated issues. In pursuing this line of research, investigators are expected to distinguish commercial from ceremonial tobacco use, respect the sovereignty of all American Indians' lands, and seek cooperation at all levels when working in these venues, including with tribal members and tribal leaders.

#### **Examples of relevant research topics:**

#### Optimizing tobacco-related prevention and treatment interventions

- Impactful cessation research that results in sustainable systems change in healthcare management of nicotine dependence
- Theoretical frameworks that support culturally sensitive health communications
- Innovative health messaging strategies and communication toolkits for poly-tobacco use
- Culturally tailored tobacco treatments delivered and evaluated in comprehensive health care programs (e.g., cancer treatment or patient-centered medical home health care models)
- Social media and mobile technologies in health communications about tobacco use and the couse of tobacco and cannabis
- Testing NRT and other interventions with smokers using less than 10 cigarettes per day.
- Testing multiple NRT combinations in cessation studies
- Randomized controlled trials and quasi-experimental studies that compare tobacco-related health communications between and within priority groups
- Scientific evaluation of health messaging based on community practice-based knowledge or testing evidence-based interventions successful for other health issues (e.g., asthma, weight or diabetes management messages) for effectiveness in tobacco prevention

#### Harm reduction interventions

- Extent to which of electronic nicotine delivery systems are successfully used as cessation aids for priority groups
- Interventions focused on sustained abstinence among successful cigarette quitters
- Characterizing health effects and changes in dependence from long-term nicotine use or the couse of cannabis and tobacco products
- Health communication development for harm reduction strategies

## Prevent and reduce child, adolescent and young adult tobacco use and secondhand smoke exposure

- Developing metrics to assess youth tobacco prevention activities that account for variability in intervention delivery
- Scientific evaluation of practice-based tobacco prevention interventions conducted in diverse school, after school, and non-traditional education settings
- Targeted health communications for menthol and flavored tobacco and cannabis prevention
- Youth-tailored communication toolkits for new and emerging tobacco products (e.g., JUULs, "heat-not-burn" tobacco sticks) and cannabis products
- Reducing youth exposure to secondhand tobacco and cannabis smoke and vapor

## Surveillance of health effects and contextual factors of new and emerging tobacco product use and cannabis use

- Health effects of the co-use of cannabis and tobacco products
- Development of typologies, measures and theoretical models for e-cigarette, poly-tobacco or cannabis use disorders
- Theoretical frameworks for problem e-cigarette or cannabis use that identify correlates of problematic use including social determinants of health factors and culture-related factors
- Statistical models estimating the population level social and health-related effects of tobaccocannabis co-use

#### 2. Cancer prevention, treatment and biology

**Purpose:** (1) Advance the development and dissemination of effective cancer prevention strategies to California populations that are disproportionately impacted by cancer. (2) Foster and implement evidence-based health care policies and practices that show promise for reducing cancer-related deaths and cancer health disparities in California. (3) Promote high-impact translational research aimed at bringing new therapies and patient care strategies to community clinical settings. (4) Provide continued support for basic research into the molecular genetic mechanisms in tobacco-related cancer pathophysiology.

**Background:** Despite the overall decline in cancer death rates that was recently announced in the NIH's "Annual Report to the Nation on the Status of Cancer," the death rate for patients with tobaccorelated cancers remains high. Moreover, disparities in cancer incidence and death rates persist even with greater public knowledge of cancer prevention and recent innovations in cancer screening and treatment. The impact of these cancer health disparities extends beyond the affected communities to all Californians because of increased health care costs and strain on health care resources in the state.

Racial-ethnic minorities such as African Americans, Californians who live in rural areas or have household incomes below the poverty line and members of the LGBT community all smoke at disproportionately high rates and thus have higher rates of cancer diagnoses and mortalities. These facts underscore the need for impactful research on the effective dissemination of community-focused cancer prevention strategies and implementation of evidence-based policy and practice interventions that can reduce the cancer burden in specific communities and in California as a whole. The persistent high rate of cancer incidence and death among tobacco users also underscores the need for continued research into the etiology and cure for tobacco-related cancers.

TRDRP will support research into the causes, early detection, and effective treatment, care, prevention, and potential cures of cancers that the Surgeon General has designated as caused by tobacco related products. TRDRP will prioritize funding in the following areas:

## Development and dissemination of cancer prevention strategies for California's diverse communities

In California, African Americans have the highest cancer death rates, followed by non-Hispanic whites, Hispanics and Asian/Pacific Islanders, respectively. Cancer incidence follows a similar trend. These disparities persist despite the overall reduction in cancer incidence and death rates in California over the past few decades. Research is needed to translate new discoveries in cancer biology into cancer prevention strategies for California's diverse communities. Dissemination research of effective methods for bringing existing prevention programs into the community is also needed. There is a critical need for effective interventions that can be implemented in a community setting or that are targeted to specific cultures and communities that bear a high cancer burden. Behavioral, clinical and pre-clinical studies are all welcome, as well as studies that combine more than one approach.

#### Implementation of evidence-based policy and/or practice changes within California

Very often, personal health care decisions, such as whether or how often to undergo cancer screening or whether to participate in clinical trials, are influenced by policies governing health care insurance coverage and practice recommendations provided by health care providers. Recent studies have shown that changes in some current policy and practice recommendations may result in improved cancer surveillance and/or survival in underserved communities. Research is needed to determine and overcome the barriers to implementing system change and to design strategies to bring innovative health care solutions to all Californians.

#### Translational research studies of new treatment strategies

TRDRP will accept proposals for studies of new agents or methods for treating tobacco-related cancer. These include pre-clinical animal studies to small human clinical trials. Emphasis is on therapeutic

strategies that can be implemented in remote, under-resourced clinics that are often found in underserved communities. TRDRP will continue to support innovative research on early detection and diagnosis methods due to the proven survival benefit of identifying, characterizing and tailoring treatment for early-stage cancer. Studies of innovative patient care strategies to improve patient prognosis, response to therapy and/or quality of life also are encouraged. Projects focusing on palliative care interventions for seriously ill cancer patients and their families are particularly needed.

## Basic research studies of the molecular genetic mechanisms of cancer pathogenesis, progression and resistance to therapy

Molecular genetics studies of the initiation and malignant progression of cancer in patients are needed to develop effective early detection techniques and precision medicine therapeutic strategies. As new therapies are developed, attention also must be given to understanding the basic mechanisms of drug resistance, which often leads to disease recurrence even with the most effective therapies. TRDRP will accept proposals on research of cancers that are directly related to tobacco use.

#### **Examples of relevant research topics:**

- Multi-county dissemination of an evidence-based cancer prevention program designed for Vietnamese males
- Evaluation of emergency room intake procedures and their ability to identify patients at risk for cancer and inform those patients of the benefits of cancer screening
- Development of a combined behavioral and medical health care team approach to increasing the racial and ethnic diversity of clinical trial cohorts
- Evaluation of the quality/effectiveness of information about lung cancer screening and proximity to low-dose CT services in California's Central Valley
- Therapeutic efficacy studies of new biologics in small or large animal models
- Development of "theranostic" molecular imaging methods for simultaneous diagnosis and treatment of cancer
- Characterization of newly discovered genetic or epigenetic alterations in oral cancer
- Pathways in the development of resistance to PD-1/PD-L1 targeted immunotherapies
- Evaluation of the effects of e-cigarette smoking on the disease progression of small cell lung cancer

#### 3. Cardiovascular and cerebrovascular diseases

**Purpose:** Support innovative, timely and high impact research to better understand basic, translational or clinical sciences of disorders of the heart, blood vessels, and cardiac and brain vasculature, collectively called cardiovascular disease (CVD) and cerebrovascular accident (CVA) or stroke.

**Background:** CVD is a leading cause of global deaths contributing to as much as one third of deaths, according to the World Health Organization's Global Status Report on Noncommunicable Diseases, 2014. In California, the Department of Public Health recently reported that CVD remains the leading cause of death in the state, and over eight million Californians live with CVD or CVA-related conditions or diagnoses. The national economic burden of CVD and related diseases will increase by year 2030 to an estimated \$918 billion, according to a 2016 report from the American Heart Association. Scientific evidence shows clearly that tobacco use is the leading preventable cause of death globally, and it increases risks of multiple diseases, including cancer, pulmonary and cardiovascular disease.

Health disparities exist among Californians diagnosed with CVD and CVA. According to the 2012 California Health Interview Survey, Native Americans and African Americans reported substantially higher rates of CVD than other ethnic groups. In addition, Californians with less education and those living in poverty also reported higher rates of cardiovascular disease. As reported in the 2016 "Burden of Cardiovascular Disease in California," between 2000 and 2014 death from CVD was substantially higher among African Americans and Pacific Islanders as compared to other racial/ethnic groups.

Among Californians, strokes occur most frequently among African American and multiracial adults over 65. Between 2000 and 2014, death resulting from stroke was higher among African Americans and Pacific Islanders than other racial/ethnic groups. Research into interventions to reduce CVD and CVA among these and other priority groups is urgently needed.

The emergence of electronic cigarettes and other tobacco products that deliver nicotine aerosolized in various solvents raises new critical questions. In addition, a new category of tobacco products, called "heat-not-burn" has been touted to reduce health risk relative to combustible tobacco products in global markets. Use of these new and emerging tobacco products has soared in the last few years, particularly among adolescents, and is expected to overtake the conventional cigarette market within the next decade. Due to the rapid uptake of these products among young people and the lack of existing regulation of these products, research is vital to understand more about the toxicity profile of these products and their potential for harm. The National Academies of Sciences, Engineering and Medicine recently published a consensus study report reviewing the available evidence of the health effects related to the use of e-cigarettes and identifying gaps and opportunities for future research. The report states that "There is no available evidence whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima-media thickness and coronary artery calcification)."

TRDRP support for this priority focuses on (1) understanding and identifying functional pathways of normal and diseased cells of the heart and vasculature; (2) identifying mechanisms by which ecigarettes and other new and emerging tobacco products may disrupt these pathways; (3) innovative treatments to improve health outcomes of those who suffer from CVD and CVA; (4) new interventions to decrease CVD and CVA health disparities among priority groups (see a list of priority groups under "High Impact Research Project Award", p22).

#### Sub-focus areas:

- Molecular and cellular pathways of initiation and progression of cardiovascular diseases, such as atherosclerosis, hypertension, and coronary heart disease
- Factors associated with increased risk of heart failure
- Molecular and cellular pathways of initiation and progression of cerebrovascular diseases (e.g. receptor biology of transient ischemia)
- Mechanisms by which tobacco use promotes development or complications of CVD or CVA, especially by pathologic effects on vascular function, inflammation, oxidation, thrombosis or cell metabolism
- Determining the causal link (if any) between atrial fibrillation (AF) and tobacco or new and emerging tobacco related products
- Innovative and novel approaches to risk evaluation, prevention, diagnosis and treatment using:
  - New diagnostic tools, assays, devices, technologies or treatments
  - Genetics, epidemiology, big data-based population science approaches or other assays
  - New interventions to prevent cardiovascular disease, especially in priority groups
- Correlative studies to better understand the shared and causative parameters of heart disease and periodontitis; related oral vasculature, especially in the context of tobacco use
- Research to determine whether e-cigarette and new and emerging tobacco product use is associated with
  - Clinical cardiovascular outcomes such as coronary heart disease, stroke, and peripheral artery disease and atherosclerosis (including subclinical atherosclerosis pathologies such as carotid intima media-thickness and coronary artery calcification)
  - o Long-term changes in heart rate, blood pressure, and cardiac function

#### **Examples of relevant research topics:**

- Mechanisms of atherosclerosis and coronary heart disease
- Innovative treatments to prevent and reduce the harm caused by cardiovascular and cerebrovascular events
- Cerebrovascular studies focused on vasculature, thrombotic or embolic stroke, ischemia, blood brain barrier and targeted therapies
- Effects and mechanisms of tobacco toxicants and oxidative stress on endothelial function
- Effect of nicotine, sub-micro particles and other constituents of tobacco products and aerosols on:
  - Endothelial function
  - Vascular function/vasoconstriction
  - Inflammatory responses
- Studies on and solutions for vulnerable populations that are disproportionately affected by cardiovascular disease due to exposure to tobacco smoke

#### 4. Environmental exposure and toxicology

**Purpose:** Support innovative and high impact research that advances policies to reduce environmental exposure to the toxic effects of tobacco smoke and its residue; assess and eliminate the environmental impact of cigarette waste; examine toxicology and the exposure science of new and emerging tobacco products.

**Background:** The changing landscape of tobacco product availability has further complicated tobacco control, public understanding of risk evaluation and new policy approaches. In addition to combustible cigarette use, a plethora of new electronic tobacco products, such as electronic cigarettes, "heat-not-burn" devices and "modified risk tobacco products" (MRTP), are now sold with claims to reduce risk from tobacco use or exposure. Scientific evaluation of these products is needed to better define exposure risks and toxicological profiles.

Co-use of cannabis (marijuana) and tobacco is expected to increase in California, as Proposition 64 now legalizes the recreational use of cannabis. Increased co-use in outdoor or indoor environments requires reassessment of potential exposure health risks. Novel and well-established evaluation methods are needed to characterize patterns of exposure and risk in these venues.

This research priority is crucial to understanding how exposure to tobacco and its toxicants may lead to a toxicology paradigm that defines human health risk. TRDRP support will establish composite scientific evidence and assist policymakers in developing health-friendly strategies in environment and tobacco control.

#### Sub-focus areas:

- E-cigarettes, new products and indoor environment
- Secondhand smoke (SHS)
- Thirdhand smoke (THS)
- Tobacco product waste pollution

#### **Examples of relevant research topics:**

- Toxicity levels and markers of exposure to electronic cigarette constituents and aerosol
- Current local policy approaches to controlling aerosol and tobacco smoke exposure in multiunit housing, indoor public spaces and other consumer settings such as cars, casinos and hotels
- Policies to minimize involuntary exposure to SHS and health risks in all public settings
- Characterization of biomarkers of exposure from all tobacco products

- THS, pathways of exposure characterization, risk evaluation and toxicology
- Approaches to public and community dissemination of THS science evidence
- Epidemiology of tobacco use and exposure, field measurements and factors of risk assessment
- Toxicology and risk profiles of new tobacco products
- New paradigms of exposure science related to cannabis
- Other environmental pollutants contributing to tobacco-related disease
- New product environmental wastes and bioaccumulation
- Environmental and economic impact of the production, sale and use of new products and their related waste
- New policy approaches to reduce or mitigate tobacco product waste at the municipal, county and state levels

NOTE: TRDRP currently funds a statewide research consortium on <a href="thirdhand-smoke-research">thirdhand-smoke-consortium</a>. TRDRP invites additional innovative research on THS under this call. Applicants who plan to pursue THS research are encouraged to conceptualize an approach that may benefit from the existing THS research capacity, infrastructure and methodologies generated through this consortium. Please contact TRDRP staff for additional information.

#### 5. Neuroscience of nicotine addiction and treatment

**Purpose**: Advance innovative research that addresses the biology of nicotine addiction and treatment, with a goal of understanding and reducing tobacco use in populations that consistently have the highest smoking rates.

**Background**: Nicotine dependence is the most common form of chemical dependence in the U.S., and studies have shown nicotine to be as addictive as heroin, cocaine and methamphetamine. Many smokers find it nearly impossible to quit, despite the well-known link between cigarette smoking and devastating diseases such as cardiovascular disease, respiratory disease and cancer.

Nicotine replacement therapies (NRTs) have proven useful for reducing cravings and blunting withdrawal symptoms, but only 30 to 40 percent of those who use these therapies successfully quit. Why can some smokers quit cold turkey while others are unable to quit even when combining multiple NRTs and complying with behavior-modifying strategies? Is there a genetic difference between individuals that determines how nicotine and NRTs affect the brain's biochemistry? Do some individuals have baseline neurochemical differences due to their exposure to nicotine and/or other addictive substances in their developmental years? Understanding the biological differences between highly-addicted and less-addicted smokers can lead to more effective cessation therapies that are tailored to the individual smoker. In addition, new approaches using novel biologics or behavior modification techniques are needed to combat persistent cigarette consumption among Californians. New and emerging tobacco products, especially e-cigarettes, are being promoted as potential cessation aids, but studies are needed to confirm these assertions and establish potential mechanisms by which novel products and approaches support effective cessation.

An important area of interest is the harm potential of nicotine, flavorings and other constituents in new and emerging tobacco products, such as e-cigarettes and "heat-not-burn" (e.g. iQOS). Because use of these devices is particularly popular among youth and young adults, key research is needed to understand the long-term effects of various inhaled constituents on the developing brain. Research that can inform FDA regulations on new and emerging tobacco products is of particular interest.

The co-use of nicotine with other substances such as alcohol and cannabinoids is another key area of research, especially in light of the recent legalization of cannabis in California. Adolescents are

particularly susceptible to addictions because of the formative stage of their brain development, and they often experiment with multiple substances of abuse, consumed separately or combined in new nicotine delivery devices. It is important, therefore, that we understand the biology and behavioral aspects of co-use of nicotine with other substances of abuse among adolescents.

TRDRP has a strong interest in supporting research that aims to understand and reduce health disparities and requests studies that focus on one or more groups that are disproportionately affected by tobacco use (see a list of priority groups under "High Impact Research Project Award", p22).

#### Sub-focus areas:

- Biology and behavior of nicotine dependence
- Biology and behavior of cessation
- Harm potential of new and emerging tobacco products on the developing brain
- Biology and behavior of co-use of nicotine with other substances of abuse

#### **Examples of potential research topics include:**

- Multi-parametric risk factors of nicotine addiction and response to treatment in vulnerable populations
- Biological and behavioral characterization of individual tobacco users, personalized treatment for tobacco use disorders
- Neuroimaging or other clinical studies of the acute effects of nicotine alone or co-use with other substances on human brain structure and function
- Studies of brain connectivity and interaction between neural pathways utilized by different agonists (e.g., glutamatergic, cholinergic, dopaminergic, etc.) in tobacco users
- Addictive potential of flavorings and other constituents of e-cigarette aerosol
- The neurological effects of complete switching from combustible to e-cigarettes in veterans
- Studies of the side effects of existing cessation drugs in priority populations such as various racial/ethnic, sexual and socioeconomic sectors that are often not fully represented in clinical trials

NOTE: While submission of projects focused on co-use of tobacco with other substances of abuse is welcome, studies in "Neuroscience of nicotine addiction and treatment" addressing non-tobacco substances (e.g. cannabinoids) only are not eligible under this call.

#### 6. Oral diseases and dental health

**Purpose:** Support innovative and high impact research that advances the understanding of tobacco impacts on dental health and developing approaches to detect and prevent tobacco-related oral disease.

**Background:** Cigarette smoking and use of other tobacco products cause oral and dental diseases, including gum diseases, bone loss and cancers of the mouth and throat. Oral cancer risk for smokers and smokeless tobacco users is substantially higher compared to non-smokers.

This priority area will support research on early detection, prevention and treatment of tobacco-related oral diseases. Oral diseases in tobacco and non-tobacco users are preventable in many cases, but advances in early-stage basic research are still lacking to inform treatment.

The 2014 Surgeon General's Report "The Health Consequences of Smoking – 50 Years of Progress" listed the evidence as suggestive but not sufficient to infer a causal relationship between dental caries (cavities) and active cigarette smoking. In addition, the pathways from tobacco use (combusted or vaporized) to oral disease initiation, progression and prognosis are less clear.

The National Academies of Sciences, Engineering and Medicine recently published a consensus study report reviewing the available evidence of the health effects related to the use of e-cigarettes and identifying gaps and opportunities for future research. This report states that "there is limited evidence suggesting that nicotine- and non-nicotine-containing e-cigarette aerosol can adversely affect cell viability and cause cell damage of oral tissue in non-smokers." Thus, California-based researchers are invited to explore innovative fronts in research on combustible and new and emerging tobacco product-induced oral disease.

According to the 2017 report "Status of Oral Health in California," significant health disparities exist for oral diseases. African American men are more likely to die from oral cancer than non-Hispanic white males, partly because their cancers are diagnosed at a later stage. In addition, rural areas of California generally have higher incidence and mortality rates for oral cancer. Research into diagnostic tools that are accessible to these priority groups is urgently needed.

Building the health workforce to address oral diseases and dental health is also a priority for TRDRP. Research that addresses health disparities, fosters partnerships to conduct effective prevention and treatment interventions for oral diseases in California's diverse communities is also highly encouraged. Translational science to speed discovery from the bench to the community clinic to prevent and improve oral disease outcomes is an additional focus.

#### **Sub-Focus areas:**

- Molecular and cellular aspects of tobacco-related oral disease
- Tools and diagnostic methods of early detection of tobacco-related oral diseases
- Oral epithelial dysplasia as a risk for oral cancer; biology and early detection
- Oral microbial biofilms and disease progression as they are impacted by combustible and new and emerging tobacco product use
- Basic and applied research in periodontitis, chronic and opportunistic infections of the mouth
- Tobacco-related oral disease prevention and early diagnosis through community-clinic partnerships

#### **Examples of relevant research topics:**

- Manifestation and systemic inflammations of oral mucosa or periodontal disease
- Pathophysiology and biomarkers of oral squamous cell carcinoma (OSCC)
- Periodontitis and tooth loss as a result of use of tobacco products
- Pathobiology of human periodontitis and related immune system signaling pathways
- Role of oral microbial entities in oral cancers, inflammatory and degenerative aspects of progression
- Potential causal pathways from combustible and new and emerging tobacco product use to oral diseases and conditions
- Research into interventions to reduce oral cancer incidence and mortality among priority groups

#### 7. Pulmonary biology and lung diseases

**Purpose**: Support innovative, timely and high impact research addressing basic, translational or clinical aspects of tobacco-related pulmonary biology and lung diseases.

**Background**: Tobacco smoke is a key factor in the development and progression of chronic obstructive pulmonary disease (COPD), one of the leading causes of death in the United States. The prevalence of COPD has a large social and economic impact in California, creating an enormous amount of human suffering especially in disproportionately affected populations such as people of low socioeconomic status, American Indian/Alaska Natives, multiracial non-Hispanics, and women.

Under this priority, TRDRP supports research crucial to understanding the effects of tobacco products on the lung, the etiology and mechanisms of pulmonary diseases that are caused by tobacco use or exposure, and studies that translate this knowledge into improved diagnostics and treatments.

An important area of research relates to new and emerging tobacco products. A recent consensus study report by the National Academies of Sciences, Engineering and Medicine concluded that switching from combustible tobacco cigarettes to e-cigarettes reduces exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes. However, e-cigarettes contain highly variable amounts of potentially toxic substances and there is no available evidence whether or not e-cigarettes cause respiratory diseases in humans. The continuously changing landscape of electronic nicotine delivery systems poses a particular challenge to understanding their health effects, and TRDRP is especially interested in studies that investigate the pulmonary effects of new and emerging tobacco products, as compared to never use (what is the harm) and as compared to exposure to combustible tobacco smoke (is there a relative benefit, is there additional harm). Research that can inform FDA regulations on new and emerging tobacco products is of particular interest.

In light of the recent legalization of cannabis in California, it is important to understand the effects of couse of nicotine with cannabinoids. TRDRP invites proposals for the study of the pulmonary effects of smoking cannabis on tobacco-related lung diseases, and of co-use of nicotine with cannabinoids or other substances of abuse.

TRDRP has a cross-cutting emphasis on research to reduce health disparities and invites proposals that seek to improve our understanding and treatment of tobacco-related lung diseases in groups disproportionately affected by tobacco use and exposure (see "Details on Grant Award Types" for a list of priority groups).

#### Sub-focus areas:

- Mechanistic studies to better define the effects of tobacco and its constituents on lung biology
- Mechanistic studies to better define the etiology and progression of tobacco-related lung diseases
- Development of diagnostic and therapeutic approaches for the prevention and treatment of tobacco-related lung diseases
- Acute and chronic lung disease related to new and emerging tobacco products
- Acute and chronic lung disease related to co-use of different tobacco products and of tobacco products with other substances of abuse
- Effects of pre-natal and neonatal exposure to tobacco products on lung development and disease

#### **Examples of relevant research topics:**

- The molecular mechanisms and genetics of differences in COPD susceptibility and progression, including sex differences
- Epigenetic changes in alveolar epithelial stem cells in response to e-cigarette aerosol exposure
- Inflammatory responses to tobacco and cannabis exposure and mechanisms that lead to COPD
- Basic to clinical research to understand and develop therapeutic approaches for COPD in disproportionately affected populations
- The role of combustible tobacco smoke or new and emerging tobacco products in the development and exacerbation of asthma or idiopathic pulmonary fibrosis
- Development of wearable devices to diagnose tobacco-related lung disease and track its progression
- Big data / data-driven approaches to understanding factors contributing to COPD exacerbations
- Drug repurposing for the treatment of COPD

NOTE: Lung cancer-related research topics are being addressed under the "Cancer Prevention, Treatment and Biology" research priority.

#### 8. State and local tobacco control policy research

**Purpose**: Advance the ability of state agencies, legislative and regulatory bodies and local communities throughout California to evaluate, understand and implement science-informed tobacco control polices.

**Background**: The tobacco control policy landscape continues to change rapidly in the U.S. and globally. The following topical ideas are responsive to this priority area:

- Downstream effects from California's changing tobacco control policy landscape
- Menthol and flavored tobacco regulation
- Countering tobacco industry marketing and corporate social responsibility efforts
- Protecting youth from tobacco and cannabis exposure
- Tobacco control policy interactions with cannabis control policy
- Tobacco cessation treatment research that directly informs healthcare policy enhancements and sustainable systems change at the clinic, local and/or state level

#### **Examples of relevant research topics:**

#### Downstream effects from California's tobacco control and cannabis policy landscape

- Intended and unintended consequences of the state tobacco laws passed in 2016, including Proposition 56
- Retailer knowledge and compliance with new laws
- Characterizing effective policy approaches that support stronger local tobacco control ordinances
- Changes to the tobacco and vapor retail environment in response to recent California laws
- Policy impacts on narrowing or widening health disparities
- Extent to which end-game strategies can reduce tobacco-related disparities

#### Menthol and flavored tobacco regulation

- Research to evaluate local ordinances regulating menthol cigarettes and flavored tobacco
- Strategies to build support for minimum price and unit packaging
- Strategies to strengthen local regulation and accurate labeling of chemical constituents in flavored e-juices/e-liquids

#### Cessation treatment research that enhances healthcare policy and systems change

- Advancing ehealth and mHealth interventions for tobacco treatment and healthcare policy
- Studies that examine basic minimum income as a cessation mechanism
- Studies of tobacco treatment in locations such as pharmacies
- Testing enhanced smoking cessation treatment in healthcare settings
- Research to understand cut-down-to-quit as a treatment for smoking
- Cost benefit analyses of multiple NRT treatments for cessation

## **APPENDIX B: DETAILS ON GRANT AWARD TYPES**

## 1. High Impact Research Project Award

**Purpose:** Conduct next phase/fully developed research based on promising preliminary or formative data gathered through prior pilot research. High quality of innovation and clear potential for impact are also key components of this award. Proposals should include sound background information, hypotheses and substantial and promising preliminary or supporting data. Proposals should reflect a clear progression beyond the earliest phases of the work. Research project applications should not be exploratory in nature and lacking in previously developed strong supporting data.

In an effort to more closely align funding with the most urgent questions in tobacco control, High Impact Research Projects submitted for the first time in cycle 2019A must focus on tobacco-related health disparities or research on new and emerging tobacco products.

#### Eligibility criteria:

- 1. Research on reducing tobacco-related health disparities in priority groups and research that promotes a smoke-free life and environment among the following priority groups<sup>1</sup> (alphabetical listing) and other groups with high rates of tobacco use:
  - Current members of the military and veterans
  - Individuals employed in blue-collar jobs, agriculture, and the service industry
  - School-aged youth and young adults
  - Incarcerated and formerly incarcerated individuals
  - Individuals with mental illness, including substance use disorders
  - People of low socioeconomic status, including the homeless
  - People with disabilities
  - People with limited education including, high school non-completers
  - Pregnant and breastfeeding women
  - Racial/ethnic minorities (e.g., African Americans, American Indians and Alaska Natives, Asian Americans, Latinos, Native Hawaiians and other Pacific Islanders, and individuals identifying with multiple racial groups)
  - Rural residents
  - Sexual/gender minorities (e.g., Lesbian, Gay, Bisexual, Transgender people)
- 2. Research on new and emerging tobacco products including electronic cigarettes (e-cigarettes), electronic nicotine delivery devices (including heat not burn devices), nicotine gels, hookah (water pipe tobacco), dissolvable tobaccos, other new smokeless tobaccos (snus), atomizers, vaping tanks and mods.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup>Researchers may focus on other priority groups as long as they provide a rationale to support including other groups disproportionately impacted by tobacco use and tobacco-related diseases.

<sup>&</sup>lt;sup>2</sup>Researchers may focus on other new and emerging tobacco products as long as they provide an explanation of the new and emerging nature of the tobacco product they propose to study

#### **High Impact Research Project Award overview:**

- Must clearly address tobacco-related health disparities or new and emerging tobacco products
- Maximum award amount per year: \$250,000 (direct costs)
- Maximum duration: 3 years
- Allowable direct costs: Salaries, fringe benefits, supplies, sub-contracts\*, equipment\*\*, travel
- Travel:
  - Project-related travel: As needed (must be fully justified)
  - o Travel to TRDRP conference: \$750 (mandatory)
  - Scientific conference travel: \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP Conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25 percent.

\*All out-of-state sub-contracts and collaborations must be well-justified; please note that funding for out-of-state expenses are extremely limited and TRDRP does not encourage such expenses.

\*\*Any item costing \$5,000 or more

#### Award requirements:

- Applicants must have a PI-status at the sponsoring institution
- Awardees are required to commit at least 10 percent of their effort each year to activities supported by this award
- U.S. citizenship is not a requirement

#### Review criteria:

#### Criteria-1 (30 percent scoring weight)

- Responsiveness to intent of the award type: Does the study focus on health disparities and/or new and emerging tobacco products? Is the study fully developed rather than pilot or exploratory in nature? Does the study build upon work performed as part of prior pilot work? Do the aims expand and/or advance the scope of the prior study? Does the applicant describe previous research upon which the study is based and report reasonably compelling previous findings and supporting data for the conduct of the proposed project?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?
- Innovation: Does the research propose new paradigms, challenge existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies, adaptations of existing methods or technologies to new uses or with understudied populations? Does the proposed research represent more than an incremental advance? For example, does the project challenge existing interventions, clinical practice or policy; address an innovative hypothesis or critical barrier to progress in the field?

#### Criteria-2 (50 percent scoring weight)

• **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field of tobacco-related research or any of the stated research priorities?

• Research plan: Are the conceptual framework, design (including composition of study population and strength of recruitment plan), 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 strategies?

#### Criteria-3 (20 percent scoring weight)

- **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?
- Community engagement and communication plan: Does the applicant propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing about the nature and significance of the research and research outcomes? To what extent does the dissemination of findings include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

#### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project.
- 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 also will 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.

## 2. High Impact Pilot Research Award

**Purpose:** Gather preliminary data or demonstrate proof-of-principle to support the feasibility of a new paradigm or research hypothesis. High quality of innovation and clear potential impact are two key components of this award, with the ultimate goal of providing initial support for research with a strong rationale, resulting in the leverage of funding from other funding agencies.

- Maximum award amount per year: \$200,000 (direct costs)
- Maximum duration: 2 years
- Allowable direct costs: Salaries, fringe benefits, supplies, sub-contracts\*, equipment\*\*, travel
- Travel:
  - o **Project-related travel:** As needed (must be fully justified)
  - o **Travel to TRDRP conference:** \$750 (mandatory)
  - Scientific conference travel: \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- Indirect costs: Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25 percent.

\*All out-of-state sub-contracts and collaborations must be well-justified; please note that funding for out-of-state expenses are extremely limited and TRDRP does not encourage such expenses.

\*\*Any item costing \$5,000 or more

#### Award requirements:

- Applicants must have a PI-status at the sponsoring institution
- Awardees are required to commit at least 10 percent of their effort each year to activities supported by this award
- U.S. citizenship is not a requirement

#### Review criteria:

#### Criteria-1 (30 percent scoring weight)

- 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?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?
- Innovation: Does the research propose new paradigms, challenge existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies, adaptations of existing methods or technologies to new uses or with understudied populations? Does the proposed research represent more than an incremental advance upon published data? For example, does the project challenge existing interventions, clinical practice or policy; address an innovative hypothesis or critical barrier to progress in the field?

#### Criteria-2 (50 percent scoring weight)

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field of tobacco-related research or any of the stated research priorities?
- Research plan: Are the conceptual framework, design (including composition of study population and strength of recruitment plan), 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 strategies?
- Near-term leveraging potential: When the TRDRP-funded studies under a High Impact Pilot Research Award are completed, is there compelling promise and high likelihood that their results will constitute a larger R01-level or P01-level study with high probability of funding from another agency such as the NIH? With TRDRP funding of the proposal, can the applicant leverage funding from other sources to further develop this area of research within two to three years after initial funding?

#### Criteria-3 (20 percent scoring weight)

• **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?
- Community engagement and communication plan: Does the applicant propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing about the nature and significance of the research outcomes. To what extent does the dissemination of relevant results of funded research include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

#### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project
- 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 also will 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

### 3. New Investigator Award

**Purpose:** This award is specifically designed to support new investigators in an independent research program in their research career in the focus areas covered under TRDRP research priorities.

- Maximum award amount per year: \$200,000 (direct costs)
- Maximum duration: 3 years
- Allowable direct costs: Salaries, fringe benefits, supplies, sub-contracts\*, equipment\*\*, travel
  - Travel:
  - o **Project-related travel:** As needed (must be fully justified)
  - Travel to TRDRP conference: \$750 (mandatory)
  - Scientific conference travel: Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- Indirect costs: Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25 percent.

\*All out-of-state sub-contracts and collaborations must be well-justified; please note that funding for out-of-state expenses are extremely limited and TRDRP does not encourage such expenses.

\*\*Any item costing \$5,000 or more

#### Award requirements:

- TRDRP new investigator award applicants must have a PI-status at the sponsoring institution
- Please note that the New Investigator awards offered by the NIH are different than that from TRDRP. These are not mentored awards and require an independent PI status at the sponsoring institution. Applicants who do not currently have PI status are required to submit a letter from their Department Chair stating that the applicant will be granted PI status by the award start date.

- Awardees are required to commit at least 50 percent of their effort each year to activities supported by this award
- No more than five years should have elapsed since applicants completed formal postdoctoral training, or since the doctoral degree if no postdoctoral training. Some applicants may have lapses in their research or research training, or may have periods of less than full-time effort. TRDRP will consider requests to extend the new investigator eligibility period for reasons that can include: medical conditions, disability, family care responsibilities, extended period of clinical training, natural disasters, and active duty military service. These exceptions will be determined on a case-by-case basis at the sole discretion of TRDRP. Please briefly describe the reason for the requested extension and the number of months for the requested extension in your Letter of Intent.
- U.S. citizenship is not a requirement

#### Review criteria:

#### Criteria-1 (30 percent scoring weight)

- Responsiveness to intent of the award type: Is the study fully developed rather than pilot or
  exploratory in nature? Does the study build upon work performed as part of prior pilot work? Do
  the aims expand and/or advance the scope of the prior study? Does the applicant describe
  previous research upon which the study is based and report reasonably compelling previous
  findings and supporting data for the conduct of the proposed project?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?
- **Innovation:** Does the research propose new paradigms, challenge existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies, adaptations of existing methods or technologies to new uses or with understudied populations? Does the proposed research represent more than an incremental advance? For example, does the project challenge existing interventions, clinical practice or policy; address an innovative hypothesis or critical barrier to progress in the field?

#### Criteria-2 (50 percent scoring weight)

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field of tobacco-related research or any of the stated research priorities?
- Research plan: Are the conceptual framework, design (including composition of study population and strength of recruitment plan), 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 strategies?
- Near-term leveraging potential: When the TRDRP-funded studies under a New Investigator Award are completed, is there compelling promise and high likelihood that their results will constitute a larger R01-level or P01-level study with high probability of funding from another agency such as the NIH? With TRDRP funding of the proposal, can the applicant leverage funding from other sources to further develop this area of research within two to three years after initial funding?

#### Criteria-3 (20 percent scoring weight)

- New Investigator status and research team: Does the PI applicant strongly fit the criteria for the New Investigators Award? Is the research team 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?
- Community engagement and communication plan: Does the applicant propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing about the nature and significance of the research and research outcomes? To what extent does the dissemination of findings include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

#### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project
- 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 also will 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

## 4. Postdoctoral Fellowship Award

**Purpose:** Support the mentored training of postdoctoral level investigators with clear and direct commitment to and potential for contributing to the advancement of one or more stated research priorities.

- Maximum stipend amount per year: Up to \$60,000
- Maximum duration: 3 consecutive years
- Allowable direct costs include: Stipend, tuition & fees, institution allowance, and travel to TRDRP conference
  - Stipend: Postdoctoral stipend must adhere to NIH experience scale or the rates set by their institution with institutional documentation of the alternate payment scale
  - Tuition and Fees: Postdoctoral Trainees and Fellows will be provided 60% of the level requested by the applicant institution, up to \$16,000 per year
  - Institution Allowance: The applicant may request an institutional allowance to help defray the cost of fellowship expenses such as health insurance, medical liability or other special insurance, research supplies, equipment, books and travel to scientific meetings. These costs will be covered up to \$8,850 per year. The amount covers supplies and travel, including project-related travel, and scientific conference travel. The institutional allowance is a fixed amount and the institution is not required to account for these expenses on an actual cost basis.

- Travel to TRDRP Conference: All applicants should budget a separate one-time \$750 expense under year 1 for "Travel RGPO Meeting" to attend the TRDRP conference.
   This \$750 expense is not part of the institution allowance.
- Indirect Costs: Not allowed

#### A Note on Stipends and Employee Benefits:

Since TRDRP fellowships are not provided as a condition of employment with either TRDRP or the sponsoring institution, institutions may not seek funds, or charge individual fellowship awards, for costs that normally would be associated with employee benefits (FICA, workman's compensation, life insurance, union dues, and unemployment insurance).

#### Fellowship requirements:

- Postdoctoral stipend or salaries must adhere to NIH experience scale or the rates set by their
  institution with institutional documentation of the alternate payment scale. Award duration is
  capped at three years for all awards at the start year of the award year funding.
- A minimum 75 percent time commitment on the part of the postdoctoral fellow is required
- The candidate must be recognized by the applicant institution as a postdoctoral fellow no later than the award start date
- The application must be prepared and submitted exclusively by the fellow and must outline an original research project (distinct from the project of a mentor, whether funded by TRDRP or another source)
- A letter of support from the mentor and a minimum of two additional references are required.
  Letters of support should address the candidate's training, potential and the commitment of the
  mentor and the department to the candidate's career development. In addition, the mentor must
  provide their biosketch and a detailed mentoring plan that is prepared in consultation with the
  applicant.
- U.S. citizenship is not a requirement

#### Review criteria:

#### Criteria-1 (50 percent scoring weight)

- Qualifications of the applicant: Does the applicant present a strong academic background and research training? What is the potential for the applicant to become a successful independent researcher with a commitment to the field of tobacco-related research or any of the stated research priorities?
- Training plan: Does the proposed mentoring plan include effective ancillary activities that will
  enhance the training of the applicant as an independent researcher? Are additional experiences
  planned that will supplement the trainee's knowledge of their research field? Are there any
  didactic or interactive activities planned for increasing the trainee's knowledge base in tobacco
  research and tobacco control or any of the stated research priorities?

#### Criteria-2 (25 percent scoring weight)

- Mentor's qualifications and commitment: Based on the advisor and the department, as demonstrated by the mentor's biosketch, letters of support and training plan, the quality of the training resources and environment.
- **Environment:** Does the institutional 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 and commitment?
- Community engagement and communication plan: Does the fellow propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership

or by proactively informing about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

#### Criteria-3 (25 percent scoring weight)

- Research plan: Are the conceptual framework, design (including composition of study population and strength of recruitment plan), 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 strategies? Will the proposed research training experience significantly contribute to the development of the candidate's career potential as a researcher in the proposed area?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?

#### Other considerations

- 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 also will 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

## 5. Predoctoral Fellowship Award

**Purpose:** Support the mentored training of predoctoral level students with clear and direct commitment to and potential for contributing to the advancement of one or more stated research priorities.

- Maximum stipend amount per year: Up to \$30,000
- Maximum duration: 3 consecutive years
- Allowable direct costs include: Stipend, tuition & fees, institution allowance, and travel to TRDRP conference
  - o Stipend: Up to \$30,000 a year
  - Tuition and Fees: Predoctoral fellows will be provided 60% of the level requested by the applicant institution, up to \$16,000 per year. Fellows enrolled in formally combined, dual degree training will be provided 60% of the level requested by the institution, or up to \$21,000 per year.
  - Institution Allowance: The applicant may request an institutional allowance to help defray the cost of fellowship expenses such as health insurance, medical liability or other special insurance, research supplies, equipment, books and travel to scientific meetings. These costs will be covered up to \$4,200 per year. The amount covers supplies and travel, including project-related travel, and scientific conference travel. The institutional allowance is a fixed amount and the institution is not required to account for these expenses on an actual cost basis.
  - Travel to TRDRP Conference: All applicants should budget a separate one-time \$750 expense under year 1 for "Travel RGPO Meeting" to attend the TRDRP conference.
     This \$750 expense is not part of the institution allowance.
- Indirect Costs: Not allowed

#### A Note on Stipends and Employee Benefits:

Since TRDRP fellowships are not provided as a condition of employment with either TRDRP or the sponsoring institution, institutions may not seek funds, or charge individual fellowship awards, for costs that normally would be associated with employee benefits (FICA, workman's compensation, life insurance, union dues, and unemployment insurance).

#### **Fellowship requirements:**

- The proposal must reflect the applicant's own research project and is expected to clearly enhance the individual's potential to develop into a productive, independent research scientist
- Awardees are required to commit at least 75 percent of their effort each year to activities supported by this award
- The candidate must be enrolled in a doctoral program at the time of submission of the application
- The application must be prepared and submitted exclusively by the student and must outline an original research project (distinct from the project of a mentor, whether funded by TRDRP or another source)
- A letter of support from the mentor and a minimum of two additional references are required.
  Letters of support should address the candidate's training, potential and the commitment of the
  mentor and the department to the candidate's career development. In addition, the mentor must
  provide their biosketch and a detailed mentoring plan that is prepared in consultation with the
  applicant.
- U.S. citizenship is not a requirement

#### Review criteria:

#### Criteria-1 (50 percent scoring weight)

- Qualifications of the applicant: Does the applicant present a strong academic background and research training? What is the potential for the applicant to become a successful independent researcher with a commitment to the field of tobacco-related research or any of the stated research priorities?
- Training plan: Does the proposed mentoring plan include effective ancillary activities that will enhance the training of the applicant as an independent researcher? Are additional experiences planned that will supplement the trainee's knowledge of their research field? Are there any didactic or interactive activities planned for increasing the trainee's knowledge base in tobacco research and tobacco control or any of the stated research priorities?

#### Criteria-2 (25 percent scoring weight)

- Mentor's qualifications and commitment: Based on the advisor and the department, as
  demonstrated by the advisor's biosketch, the letters of support and training plan, the quality of
  the training resources and environment.
- **Environment:** Does the institutional 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 and commitment?
- Community engagement and communication plan: Does the fellow propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results of funded research include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

#### Criteria-3 (25 percent scoring weight)

- Research plan: Are the conceptual framework, design (including composition of study population and strength of recruitment plan), 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 strategies? Will the proposed research training experience significantly contribute to the development of the candidate's career potential as a researcher in the proposed area?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?

#### Other considerations

- 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 also will 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

## **6. Student Research Supplement**

**Purpose:** To foster undergraduate and master's student research and allow active research training and mentoring by providing additional supplement, in order to bring new workforce into the stated research priority areas of TRDRP.

Recipients of non-mentored grants (such as High Impact Pilot Award, High Impact Research Project Award, New Investigator Award, or Community Practice-Based Research Awards) are encouraged to consider participation by undergraduate and master's students under their mentorship. Students enrolled in a predoctoral degree program are not eligible for this supplement and should apply for the Predoctoral Fellowship Award. Request for Student Research Supplements must be submitted as part of an ongoing grant's scientific progress report to be considered for funding. Applications will be reviewed by TRDRP staff.

- Maximum supplement amount per year: \$20,000 (direct cost)
- Maximum duration: 1 year
- Allowable direct costs: Salaries, fringe benefits, tuition, enrollment fees for the trainee, supplies, domestic travel
- **Equipment:** Not allowed as part of this supplemental funding
- Supplies and Travel:
  - o **Project-related travel:** As needed (must be fully justified)
  - Travel to TRDRP conference: \$750 (mandatory)
  - Scientific conference travel: Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP Conference)
  - Supplies: Up to \$2200 (must be fully justified)
- Indirect Costs: Not allowed

#### Submission procedure requirements:

- Supplement Application for a currently funded TRDRP award: Please contact the Contracts and Grants team at the Research Grants Program Office for details by emailing RGPOGrants@ucop.edu.
- Supplement Application for a new TRDRP research application: Supplement will be considered by TRDRP staff if the grant is selected for funding. Supplement must be submitted as part of an ongoing grant's scientific progress report to be considered for funding.
  - Requirements of the supplement application include:
    - Identify your candidate providing rationale and supplement requirement to identify, train and foster new workforce into the stated research priority areas of TRDRP. If the candidate is listed in your grant application, please explain any funding overlap.
    - Include description of your track record as a mentor.
    - Training plan: Describe how the research experience will enhance the candidate's skills and knowledge and help him or her achieve career goals
    - Include candidate biosketch

## 7. Cornelius Hopper Diversity Award Supplement

**Purpose:** Train promising individuals from underrepresented communities and/or those who wish to pursue careers in one or more stated research priorities focused on underserved communities.

Application procedure for the Hopper Diversity Supplement: Request for the Hopper Diversity Supplement must be submitted as part of an ongoing non-mentored grant's scientific progress report (such as the High Impact Pilot Research Award, High Impact Research Project Award, New Investigator Award or Community Practice-Based Research Awards) to be considered for funding.

- Maximum supplement amount per year: \$20,000 (direct cost)
- Maximum duration: 2 years
- Allowable direct costs: Salary and benefits, tuition, enrollment fees for the trainee, supplies, domestic travel
- Equipment: Not allowed as part of this supplemental funding
- Supplies and Travel:
  - o **Project-related travel:** As needed (must be fully justified)
  - Travel to TRDRP conference: \$750 (mandatory)
  - Scientific conference travel: Up to \$2000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP Conference)
  - Supplies: Up to \$2200 (must be fully justified)
- Indirect costs: Not allowed

#### **Cornelius Hopper Diversity Award Supplement requirements:**

- The Hopper Diversity Supplements are intended to support the initial entry of individuals into the field of tobacco-related research or within the stated research priorities. Eligible trainees, working under the mentorship of a currently funded TRDRP investigator, may be undergraduate students, graduate students who have not advanced to candidacy, individuals who are working in the tobacco control field or proposed research area but do not have experience in research, community members, school personnel or health sciences students. Individuals who are eligible for TRDRP fellowships and other career development awards are encouraged to apply through those award types rather than asking for support through a Hopper Diversity Supplement. Individuals that have earned a doctoral or other advanced degree (e.g. Ph.D., M.D., M.P.H.) are not eligible to be supported by this supplement.
- Investigators must have at least one year remaining on their TRDRP award to ensure the best

- conditions and results for prospective trainees and Hopper Diversity Supplement applications must be submitted as part of an annual scientific progress report.
- The Hopper Diversity Supplement is available to principal investigators of any TRDRP award except for Postdoctoral Fellowship Awards, Predoctoral Fellowship Awards and Mackay Policy Scholar Awards.
- 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.

#### Supplement proposals will be evaluated for the strength and quality of the following:

- Trainee must demonstrate a commitment to and pursuit of a career in tobacco research and tobacco control or any of the stated research priorities.
- Trainees should document barriers, both current and past, that may prevent her or him from realizing a research career. For example, the absence of a family member who attended college; matriculation in an educational setting 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 previous and current research interests focus on cultural, societal, health or educational disparities as they affect underserved segments of our state. Additionally, describe how the research in the proposed area may contribute towards ending California tobacco-related disease or health 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 meet regularly
  with the trainee. Investigators should also identify other members of the research team who will
  play a mentoring role and specify their time commitment to mentoring the trainee and their
  contribution to the trainee's learning experience.

## 8. Mackay California-Pacific Rim Tobacco Policy Scholar Award

**Purpose:** The Mackay California-Pacific Rim Tobacco Policy Scholar Awards are opportunities for midcareer researchers from diverse disciplinary backgrounds to gain mentored experience and skills necessary to provide leadership in development and implementation of state, country and region-wide tobacco control policies. Mackay Scholar Awards are offered by the TRDRP as part of the program's mandate to support tobacco-related public policy research as well as its translation and application. These awards bear the name of Dr. Judith Mackay, in acknowledgement of her leadership and success in advancing tobacco control policies throughout the Asia-Pacific Rim and in recognition of the increasingly global nature of these policy challenges.

*NOTE:* Mackay California-Pacific Rim Tobacco Policy Scholar Award is open throughout the year. Please contact TRDRP staff for details.

The aim of this policy scholar grant award is to foster scientifically informed, evidence-based tobacco control policy and practice in California and the Pacific Rim region (Asia, Pacific Islands and Latin America) by building leadership and cross-regional partnerships among mid-career researchers. Scholars engage their professional and cultural competencies, strengthen their research and communications skills and develop partnerships and networks, while learning firsthand about policymaking and implementation at state, national and international levels.

#### **Eligibility:**

TRDRP seeks candidates with doctorates or equivalent degrees from diverse disciplinary, gender and cultural perspectives and with interest in, ties to and/or experience in the Pacific Rim region, including Latin America. Candidates are required to be at or beyond the mid-career stage (i.e. 5 years post-terminal degree), must reside in the state and hold an independent research position or visiting faculty appointment at a California applicant/host institution. Candidates with economics and legal backgrounds are particularly encouraged to apply.

- Maximum award amount per year: \$250,000 (direct cost)
- Maximum duration: 3 years
- Allowable direct costs: Salary and benefits, training/mentoring expenses, supplies, and travel
- Training/mentoring expenses: \$40,000
- Travel:
  - Travel to TRDRP conference: \$750 (mandatory)
  - Travel to scientific conferences, placement, and training sites: Up to \$10,000 per year (excluding a mandatory allocation of \$750 in one year of the award for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25 percent.

#### Policy scholar award requirements:

- Applicants must have a doctoral or equivalent degree
- Applicants must be at least 5 years post completion of his/her terminal research degree or 5
  years post-completion of medical residency (or the equivalent) at the start of the award
- Applicants must hold an independent research position (or a commitment for a visiting faculty appointment) at a California-based research institution. For the purpose of this award, "independent research position" means a position that automatically confers eligibility, by the applicant's institutional policy, for an investigator to apply for extramural grants, with an appropriate commitment of facilities to be used for the conduct of the proposed research.
- Awardees must commit at least 35 percent of their effort each year to activities supported by the Policy Scholar Award
- U.S. citizenship is not a requirement

#### **Key training elements:**

The recipient(s) of this award will identify key tobacco policy issues relevant to California policy priorities that also have relevance to policy efforts in one or more areas of the Pacific Rim. Examples of these policy issues include product pricing and taxation, trade agreements, regulation of new nicotine products and availability and accessibility of nicotine treatment, among others. It is envisioned that tobacco policy partners who originate in other Pacific Rim countries also will be identified (supported by other funding sources available to the applicant institutions or other TRDRP funder partners) as coparticipants in the training program in order to realize the potential for bi-directional learning and to strengthen the impact of these policy efforts.

Towards this end, the mentor(s) interest in and experience with California and Pacific Rim tobacco policy issues, as well as their access to regional and global training resources, are critical to the quality and impact of the scholar's experience, achievement of policy goals and long term career success. The application process includes a comprehensive description of the proposed mentors and training experience including:

- Clear process and deliverables to:
  - o Identify a key policy issue with relevance to California as well as the Pacific Rim
  - o Frame a policy position or positions
  - o Inform policy development and implementation through a range of channels and methods

- Training to strengthen policy research, leadership, and communication skills including:
  - Mentored development and implementation of a research project relevant to the scholar's tobacco policy objectives
  - o Mentoring with senior researchers and policy advocates (California and Pacific Rim)
  - Participation in state and/or regional tobacco control networks (e.g., Southeast Asia Tobacco Control Alliance)
  - o Government office placement (e.g., state legislature; finance or health agencies/ministries)
  - o Policy and research seminars
  - o Leadership training (e.g., Bloomberg)
  - o Media training (e.g., Stanford-NBC News, World Lung Foundation)
  - o Economics of tobacco (e.g., Asian Development Bank)
  - Litigation and legal challenges (e.g., Campaign for Tobacco Free Kids International Legal Consortium)

#### Review criteria:

#### Criteria-1 (40 percent scoring weight)

#### • Candidate's research background and professional accomplishment

- Solid and relevant research/professional education and employment/work experience in area of expertise, appropriate to mid-late career stage
- Record of grants and publications and/or presentations appropriate to mid-late career stage, field, and institutional setting

#### • Candidate's leadership and potential

- Prior leadership roles relevant to mid-late career stage (e.g., governance or faculty committees; advisory or editorial committees; active in professional societies, non-profit, or community initiatives)
- Skill/potential to organize, build consensus, lead projects and people toward positive outcomes
- Confidence, maturity and self-direction with the capacity, initiative and flexibility to work well independently as well as in groups, to make the fellowship a rich and positive experience, to apply skills learned through the fellowship and take advantage of networks developed.

#### Candidate's communication, interpersonal and outreach skills

- Excellent communication skills: articulate, cohesive, concise, rational flow of information, and clear in both context and detail
- Ability to convey research data and scientific knowledge in broader, non-scientific contexts
- Capacity to work effectively with diverse stakeholders and government officials outside research and scientific communities

#### Commitment to fellowship mission and opportunities

- Clarity of and commitment to objectives for applying to the fellowship, and how he/she imagines using the fellowship experience in the future to influence tobacco-related public policy in the California-Pacific Rim region
- Willingness and flexibility to tackle issues beyond area of expertise, openness and capacity to expand experience in the policy realm, and to interact with policymakers and regulators
- Realistic expectations, open-minded and adaptable to fellowship opportunities, as well as working through challenges

#### Criteria-2 (30 percent scoring weight)

#### • Mentor(s) research/scientific background and professional accomplishment

- Mentor(s) solid and relevant research/professional education and experience in area of expertise and evidence to the application of this background to the advancement of tobacco-related public policy, particularly in California and the Pacific Rim
- Mentor(s) solid and relevant grants and record of publications and/or presentations appropriate to tobacco-related public policy

### • Training program, experiences and opportunities

- Quality of training program in its ability to strengthen the candidate's ability to play a sustained leadership role in informing the tobacco-related public policy in the California-Pacific Rim region
- Extent to which institutional, regional, national and international collaborations and partnerships and existing resources are leveraged in the design and provision of training opportunities

#### Criteria-3 (30 percent scoring weight)

#### • Significance of the policy issue(s) of interest

- O Does the candidate's research and policy interest(s) address an important problem? If the aims of the application are achieved, how will they advance evidence-based tobacco policy in the California-Pacific Rim region? What will be the effect of these analyses and studies on the development of tobacco policy in general?
- Strength of the research plan
- Are the conceptual framework, design, methods and analyses adequately developed, well integrated, well-reasoned and appropriate to the policy aims of the project? Does the applicant acknowledge potential problem areas and consider alternative strategies?

#### 9. Dissemination Award

**Purpose:** To support small scientific conferences and other research dissemination activities for results from TRDRP-funded research.

• Maximum Award Amount: \$5,000

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 take place primarily in California and/or involve California investigators and include, where applicable, discussants and speakers funded by TRDRP. An online broadcast or archiving of an in-person conference (i.e., webcast or webinar) is eligible for support under this Dissemination award type. Proposals may be submitted at any time and will go through a separate review process. Dissemination 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.

#### 10. Scientific Conference Award

**Purpose:** Support in-person scientific conferences that will disseminate TRDRP-funded research and convene TRDRP investigators and colleagues from different disciplines. This flexible award type allows for conference meetings of varying scale and supports new emerging issues identified and championed by TRDRP.

NOTE: Scientific Conference Award is open throughout the year. Please contact TRDRP staff for details.

• Maximum award amount per year: \$50,000

• Maximum duration: 2 years

- **Maximum award amount:** \$100,000 (may vary depending on type of conference meeting(s) proposed)
- Allowable direct costs: Salaries, fringe benefits, supplies, travel, honoraria all conference
  costs subject to TRDRP approval based on programmatic budget policies. Applicants should
  indicate what proportion of the total conference budget the Scientific Conference Award will
  cover and the other sources of funding for the conference.
- Indirect costs: Not allowed

#### Award details:

- Award can support a single event or multiple conference meetings held in-person, which can be simultaneously broadcast live on the internet and/or archived for later viewing on the internet.
- In order to qualify for funding, the conference objectives must be directly related to one or more of TRDRP's broad <u>research priorities</u>. (trdrp.org/research-priorities/index.html)
- Conference meetings must take place in California and include TRDRP-funded researchers and colleagues representing multiple disciplines.
- Conference meetings should seek to increase the capacity of California scientists and disseminate TRDRP-funded research and other relevant findings.
- TRDRP staff will have substantial programmatic involvement in the oversight of conference awards. Applicants interested in applying for this award are required to discuss the conference plan with a TRDRP program officer (trdrp.org/about/staff.html) prior to proposal submission.
- The number of conference grants awarded each cycle will depend on results from the peer review, direct cost estimates for each award, demand for the award and the availability of funds.

#### **Submission:**

Interested applicants must contact a <u>TRDRP program officer</u> prior to application submission to discuss the conference concept. If it is determined that the conference concept is in line with TRDRP priorities, the program officer will send the applicant a template to complete the LOI via email. Once the LOI is received and approved, applicants will then be invited to apply, and at that time will have access to the full set of application materials. Proposals will undergo ad hoc peer review.

#### **Definition:**

A scientific conference is defined as a one-day or multiday in-person meeting that includes multiple scientific and/or policy presentations, involves multidisciplinary TRDRP-funded researchers and may include community advocates. The conference meetings should provide opportunities for TRDRP-funded researchers and their colleagues to exchange empirically-driven information, network and stimulate ideas for future research and/or tobacco control efforts in California. While an online broadcast or archiving of an in-person conference can be a component of this award type, a proposal for an exclusive online event (i.e., webcast or webinar) should be submitted under our Dissemination Awards.

#### Review criteria:

Reviewers will consider each of the review criteria below in the determination of scientific and technical merit for conference grant applications. In addition, geographic distribution of conference participants representing rural, southern and northern California regions will be considered in the review process.

#### Criteria-1 (50 percent scoring weight)

• Conference plan: Are the objectives, conference program, and logistical arrangements for the conference clearly described? To what extent are the format, agenda and speakers, including the principal topics to be covered, problems to be addressed and developments or contributions the conference might stimulate relevant to tobacco-related issues in California? Is sufficient justification provided for the conference, including the scientific need, timeliness and usefulness of the conference to the scientific community?

Applicants are required to submit a list of lead organizing committee members and key conference speakers with letters of commitment. Members of the organizing committee and the speaker roster can be modified later based on feedback from stakeholders and program staff.

Is the composition and role of the organizing committee well described? Are the names and credentials of key participants (i.e. speakers, presenters, session moderators) in the conference, including the basis for their selection and documentation of their agreement to participate provided? Does the estimate of the expected size and composition of the audience, as well as the method of selection seem appropriate? Is the geographic distribution of conference attendees considered such that there are opportunities for participation from rural, southern and northern California? For example, a single conference award could support a meeting(s) in northern California and one in southern California.

Are there plans to publicize the conference to all relevant stakeholders and publish the proceedings (with the latter plan not required)? Did the applicant clearly describe how the proposed conference is similar to and/or different from related conferences held on the subject during the past three years and how the proposed conference will advance the field beyond prior meetings? If this is one in a series of sequential conferences held by a permanent sponsoring organization, the applicant should briefly describe and provide evaluation data from the last conference in the series and clearly state the scientific contributions expected from the TRDRP-funded meeting(s).

Applications requesting two years of support must provide the following additional information for each year and each meeting requested, in as much detail as possible:

- o Conference topic(s), objectives and goals
- o Tentative dates, locations and participants (with as much detail as possible)
- Contingency plans for future conferences dependent upon, for example, the outcome of the first year's conference or developments in the field
- Conference support: Did the applicant describe resources available to them through their host institution that would be used to support the conference(s) and that speak to the potential success of the institution to support a meeting of TRDRP-funded researchers? Individuals should describe other funding and resources that will be used as leverage to expand the scope and reach of the TRDRP-funded conference(s).

#### Criteria-2 (30 percent scoring weight)

Community engagement: Community engagement is encouraged, if it is appropriate to the
scientific topics to be presented and discussed at the conference. Applicants are encouraged to
include community input and residents, if appropriate, on the conference organizing committee,
as conference invitees, and in the interpretation and dissemination of research findings in
presentations. Community advocates, local lead agency representatives engaged in community
tobacco control program and school-based tobacco prevention educators may be invited to
participate and present if it fits with the scope of the scientific content.

Program officers may be consulted to assist with recruitment efforts and may recommend involvement of scientists, policy makers, community-based organizations and community advocates.

• **Significance:** Does this conference address an important problem? If the aims of the application are achieved, how will scientific knowledge, policy, and clinical practice or community programs be advanced? What will be the effect of these endeavors on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field?

- Innovation: Does the conference employ novel approaches or methods to fulfill its purpose?
   Does the conference draw together appropriate experts who may otherwise not have an opportunity to meet?
- **Approach:** Are the format and agenda for the conference appropriate for achieving the goals and objectives? Is the conference timely for the subject matter? For applications designating one PI and multiple co-investigators, is the leadership plan approach, including the designated roles and responsibilities, governance and organizational structure consistent with and justified by the topics of the conference and the expertise of each of the investigators?

#### Criteria-3 (20 percent scoring weight)

- Investigator(s): Is the PI well-suited for organizing and fulfilling the goals and objectives of this conference? Are the qualifications and past performance of the PI appropriate, and are they well-suited for their described roles in the conference? Are the key personnel and selected speakers appropriate and well-suited for their described roles in the conference? Is the necessary expertise involved for a successful conference meeting(s)?
- **Environment:** Is the conference site appropriate? Does the applicant organization have the ability to contribute to the probability of success? Do the proposed meetings, exhibits, interactions, etc., take advantage of unique features of the environment or employ useful collaborative arrangements? Is institutional support evident?

#### **Contacts**

Applicants are required to contact a <u>TRDRP program officer</u> (trdrp.org/about/staff.html) to discuss their conference plan prior to submitting an application for this mechanism.