

2018 Call for Applications Revised January 2018

AMENDED April 2019 –
See page 49-51 for amended language

Call for Application under Cycle 2018-B: New changes and Requirements

- Submission of a letter of intent (LOI) is required even if you are resubmitting an application.
- Predoctoral and Postdoctoral fellowship awards now offer salary ranges and other institutional allowances.
- Follow all instructions and submit ALL required forms to avoid administrative review and rejection.
- Your submitted application may be withdrawn after administrative review.

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. This resulted in a substantial increase in funds available for research. With this influx of new dollars, TRDRP is exploring innovative strategies to maximize the impact of research and keep administrative costs at a minimum. This Call for Applications contains the first phase of programmatic changes from the early stages of an extended strategic planning process.

Highlights of the 2018 award cycle

Cross-cutting emphasis on research to reduce health disparities. TRDRP-funded research has contributed to the steady decline in California smoking rates over three decades. Cigarette smoking and use of other tobacco products, however, remain disproportionately high in many California communities and contribute directly to the high rates of cardiovascular disease, lung and oral disease, cancer and other tobacco-related diseases in those communities. Research also shows that current community education and prevention efforts and state policies do not go far enough to protect these same communities from being targeted by the tobacco industry. In addition to the grave impact on these communities, these health disparities result in increased health care costs and reduced access to care throughout California. All TRDRP research priorities will encourage studies designed to directly address disparities in tobacco use and the diseases that result.

Expanded cancer research priority. In recent years, TRDRP only accepted proposals for cancer research projects that focused on early detection of the disease. In accordance with the broadened scope of biomedical research mandated by Proposition 56, TRDRP has expanded its cancer research priority beyond early detection to include cancer prevention, cancer health disparities, translational

research and basic science. Projects focusing on tobacco-related diseases remain a priority; however, proposals to study any form of cancer now will be accepted.

New research emphases in lung, cerebrovascular and oral disease. Cancer and heart disease are the tobacco-related diseases most known to the public, but tobacco use is linked strongly to other diseases such as COPD, stroke and poor dental health. To encourage more research into these diseases, their relationship to tobacco use and their connection to other tobacco-related diseases, TRDRP has expanded research priorities in these areas.

Cannabis use and tobacco-related diseases. Californians legalized medical marijuana (cannabis) in 1996, and 20 years later legalized cannabis for recreational use. Still, very little is known about the impact of cannabis use. There is a paucity of rigorous peer-reviewed studies on the potential benefits and harms of cannabis use, and it is extremely difficult for lawmakers to create informed meaningful policies regarding cannabis availability and use. TRDRP now is calling specifically for proposals to understand the contribution of cannabis use to, or medical use of cannabis with tobacco-related diseases. Investigators are strongly encouraged to refer to their institutional policy on conducting cannabis research before designing their study to avoid conflicts with federal and state regulations. Please refer to the TRDRP cannabis research policy. (trdrp.org/funding-opportunities/cannabis-research-considerations.html)

New award types to expand the research pipeline. Training individuals to perform robust research is key in the battle against tobacco use and the environmental and medical harms to Californians. TRDRP is implementing new research supplemental and training awards to fill previous gaps in our portfolio and provide funding to train individuals at all stages of the educational pipeline – from high school students to independent investigators.

Expand funding levels and duration of research award types. The total amount and duration of TRDRP awards have declined steadily in recent TRDRP funding cycles because of the decline in tobacco tax revenue. With passage of Proposition 56, TRDRP is now able to increase award levels and years of funding for all research award types.

Additional funding cycle in 2017-18. To facilitate the anticipated increase in the volume of applications, there will be two receipt dates and review cycles for fiscal year July 1, 2017 – June 30, 2018. This will allow TRDRP the administrative structure to maintain a high quality of peer review of all applications.

Tobacco relevance and TRDRP: Relevance of the proposed research to a tobacco-related area remains a focus of the program. TRDRP will internally review the tobacco relevance of all applications and funding decisions may be affected by the programmatic determination of this relevance.

Out of state research support requests: Due to the mandate that Proposition 56 research dollars must be used within California, a closer review of out of state budget justification requests will be implemented in the upcoming cycle. Only a very limited number of projects with out of state components determined to be essential to the study may be funded.

Expedited Letters of Intent (LOI) process. The processes for submitting a LOI to TRDRP and for performing the administrative review are expedited for this cycle. The LOI process will collect limited details about the proposed project for determining adherence to TRDRP research policies and objectives. Once an LOI is submitted and approved, then application materials will be accessible on proposalCENTRAL to begin the application preparation. Submission of an LOI is required under all circumstances.

KEY DATES

IMPORTANT: TRDRP will now accept applications twice a year under the following date cycles

Fiscal Year 2018-2019	2018A	2018B
Call open	Friday, July 7, 2017	Friday, December 15, 2017
LOI submissions invited	July 7 - August 21, 2017 12 p.m. PT	December 15, 2017 – February 8, 2018 12 p.m. PT
Direct access to application materials after LOI acceptance in proposalCENTRAL	Beginning July 17, 2017	Beginning December 15, 2017
Due date for new applications	Monday, September 25, 2017 12 p.m. PT	Wednesday, February 28, 2018 12 p.m. PT
Due date for resubmissions*	Monday, September 25, 2017 12 p.m. PT	Thursday, March 15, 2018 12 p.m. PT
Applicants notified	January 30, 2018	June 1, 2018
Awards start	April 1, 2018	July 1, 2018

*Resubmission Policy: A resubmission is an unfunded application 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 2018B is considered a resubmission if a similar application was submitted and reviewed in either grant cycle 2017 or in grant cycle 2018A. Applicants are still required to inform the intent to resubmit through an LOI submission, and must note such as a resubmission on proposalCENTRAL (please refer to the LOI/Application instructions for the specific award type). All other applications are considered new applications. The application deadline is different for new applications vs. resubmissions (March 15, 2018). Therefore, it is critical that you note your resubmission status during the LOI stage so your full application deadline can be adjusted accordingly.

Other resubmission examples: For grant cycle 2018A, resubmissions will be accepted in either grant cycle 2018B or grant cycle 2019A. For grant cycle 2018B, resubmissions will be accepted in either grant cycle 2019A or grant cycle 2019B.

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.

To get started:

- 1. Determine your eligibility for funding. (trdrp.org/funding-opportunities/index.html#trdrp)
- 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>2018 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 proposalCENTRAL (proposalcentral.altum.com) to submit your LOI and/or proposal.

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 may result in administrative triage of the application.

TRDRP FUNDING POLICIES

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.

A mandate of Proposition 56 funding is that all research dollars must be used within California. Since the bulk of TRDRP research funds are from Proposition 56, the majority of projects funded in the upcoming TRDRP cycles must be performed entirely within California. TRDRP research funding, however, comes from multiple sources, and there is a small amount of funding for projects with out-of-state components. In those cases, part of the work may be done outside California if the need to do so is well-justified.

In accordance with <u>UC policy</u> (policy.ucop.edu/doc/2500500/ReqSubmitProp-Awar), 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 can now resubmit their recently unfunded applications in the two funding cycles immediately following their original submission cycle. Please refer to Key Dates (trdrp.org/funding-opportunities/dates-and-deadlines.html) for the specific resubmission deadline dates. If the application is resubmitted after the two subsequent cycles, it will be considered a new application and the peer-review process will not consider previous critiques.

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, the University 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.

2018-19 TRDRP Grant Award Types

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 achieve or advance work towards achieving high impact within one or more stated research priorities.	\$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 ¹	Support postdoctoral research training under a designated mentor to conduct high impact research within one or more stated research priorities.	\$60,000/year* 100% effort required	3
Predoctoral Research Fellowship Award	Support the mentored research training of predoctoral students for research within one or more stated priorities.	\$30,000/year*	3
Student Research Supplement Award ²	Allow active research training and participation by an undergraduate or graduate student under the mentorship of a currently-funded TRDRP PI of a non-training award. Supplements are above the award mechanism cap.	\$20,000	1
Community Practice- Based Research Planning Award	Supports partnership development among academic researchers and health care practitioners for planning phase health service research that promotes sustainable system change in tobacco cessation efforts at health care clinics.	\$200,000/year	2
Community Practice- Based Research Implementation Award	Supports collaborative health service research that elucidates sustainable systems change factors associated with quality care improvements in tobacco cessation efforts delivered through health clinics serving Medi-Cal beneficiaries	\$500,000/year	3
Cornelius Hopper Diversity Award Supplement ³	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

GRANT TYPES WITH ROLLING DEADLINES⁴			
Mackay California- Pacific Rim Tobacco Policy Scholar Award	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
Special Projects Award	Support small scientific conferences and other research dissemination activities. Provide limited rapid support for early investigation into emerging issues in tobacco control or one or more stated research priorities.	\$5,000	1
Scientific Conference Award	Support in-person scientific conferences that disseminate TRDRP-funded research and convene new emerging issues championed by TRDRP investigators and colleagues	Up to \$50,000/year	2

¹Postdoctoral stipend or salaries are commensurate with the current NIH scale. For example: \$47,484 (Year-0) to \$58,560 (Year-7). Award duration is capped at three years for all awards at the start year of funding. An institutional allowance is allowable upon request.

²Student Research Supplement Award applications will be accepted as a part of the mentoring PI's application under High Impact Research Project Award, High Impact Pilot Research Award, New Investigator Award or Community Practice-Based Research Award grant types only. Decision on awarding supplements will be made after applications have been peer-reviewed and selected for funding by the TRDRP Scientific Advisory Committee (SAC). Funded supplements are eligible for competitive renewals for up to \$20,000/year through the duration of the parent grant.

³Cornelius Hopper Diversity Award Supplement applications will be accepted as a part of the mentoring PI's application.

⁴Applications for the Mackay California-Pacific Rim Tobacco Policy Scholar Award, Special Project Award and Scientific Conference Award may be submitted at any time during the year. Please contact TRDRP staff for details.

^{*} For all allowable costs and caps, please refer to the application instructions and the detailed section within the call on the Predoctoral Research Fellowship Award and the Postdoctoral Fellowship Award.

RESEARCH PRIORITIES

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

- 1. Tobacco-related health disparities
- 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. Tobacco-related health disparities

Purpose: Advance innovative research and collaborations that prevent or reduce tobacco use and the impact of tobacco-related diseases among California's priority groups.

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.

This priority focuses on scientific research aimed at preventing, treating and reducing tobacco use and nicotine dependence and problem cannabis use; multiple health behavior interventions (e.g., obesity and tobacco-related treatments, co-use of cannabis, tobacco, alcohol and/or other substances); embedding tobacco treatments into existing programs (e.g., palliative care programs, cancer treatment or patient-centered medical home health care models); reducing secondhand tobacco and cannabis smoke exposure. Focus also will be on reducing tobacco-related diseases in priority groups and research that promotes a smoke-free life and environment among the following priority groups (alphabetical listing) and other groups with high rates of tobacco use:

- Active military and veterans
- Blue-collar workers
- Children, adolescents and young adults
- Incarcerated and formerly incarcerated individuals
- Individuals with mental illness, including addictive disorders
- Migrant agricultural workers
- People of low socioeconomic status, including the homeless
- People with disabilities
- People with limited education including, high school non-completers
- People with mental illness
- 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)

Researchers may focus on other priority groups as long as they provide rationale to support including other groups disproportionately impacted by tobacco use and tobacco-related diseases.

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.
- Between researchers and local lead agencies (LLAs) funded by the California Tobacco Control Program/CA Department of Public Health (CTCP/CDPH) engaged in local tobacco control programs and local educational agencies (LEAs) funded by the California Department of Education (CDE) engaged in school-based tobacco prevention. Research partnerships should evaluate and strengthen ongoing tobacco control and prevention programs.
- To build capacity and leadership among community-based organizations for scientific research
- To develop the next generation of tobacco control research leaders and advocates.

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 patrons, employees, management, tribal members and tribal leaders.

Social determinants of health

Multiple complex factors contribute to TRHDs. 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. Cultural factors and experiences with discrimination are important to consider when addressing the impact of environment, structural factors and government policy on health. Geospatial research is valuable for characterizing health outcomes in relation to social determinants and informing policies and programs designed to dismantle harmful social determinants of health. There also is an urgent need to address health disparities from an intersectionality theoretical perspective to consider, for example, that people identify with multiple priority groups, each of which could be disproportionately impacted by tobacco use. Intersectionality brings a deeper understanding to TRHD research focused on predictors of tobacco use, prevention and cessation intervention needs and varying outcomes compared to those identifying with one priority group.

Sub-focus areas:

Scientific research with potential to obtain impactful findings in the following areas is considered responsive to priority of reducing TRHDs:

- Optimizing tobacco-related prevention interventions
- Innovative tobacco cessation and cannabis-related interventions
- Harm reduction interventions
- Prevent and reduce child, adolescent and young adult tobacco use and secondhand smoke exposure
- Impacting the social determinants of TRHDs
- Self-reported health effects and contextual factors of new tobacco product and cannabis use

Examples of relevant research topics:

Optimizing tobacco-related prevention interventions

- Theoretical frameworks that support culturally sensitive health communications
- Innovative health messaging strategies and communication toolkits for multiple health behaviors (e.g., messaging that seeks to modify obesity and tobacco-related knowledge, attitudes and behavior)
- Tobacco treatments tailored for and evaluated in comprehensive health care programs (e.g., palliative care programs, cancer treatment or patient-centered medical home health care models)
- Social media and mobile technologies in health communications about tobacco use and other health risk behaviors
- Randomized controlled trials and quasi-experimental studies that compare 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

Innovative tobacco cessation and cannabis-related interventions

- Randomized controlled trials and quasi-experimental studies on culturally sensitive tobacco treatments that address current patterns of use (e.g. interventions that consider poly-tobacco use of cigarettes, e-cigarettes and/or little-flavored cigars; or treatments tailored to light and non-daily smoking)
- Improving access to culturally sensitive tobacco treatments (behavioral and multiple types of pharmacotherapies)
- Interventions that increase and sustain motivation for tobacco abstinence and repeated attempts to quit tobacco;
- Scientific evaluation of community practice-based interventions to expand cessation resources in diverse settings
- Clinical trials of practice-based and evidence-based tobacco treatments in priority groups not typically included in research (e.g., recently incarcerated individuals, rural residents, undocumented immigrants, refugees or people with severe mental illness)
- Multiple health behavior interventions (e.g., obesity, diabetes, illicit substance use or oral health interventions with a tobacco focus)
- Treatments that address tobacco and cannabis co-use issues with and without other substances (e.g., alcohol, prescription opiate misuse);
- Treatments that address problem cannabis use
- Examination of the potential for cannabis to mitigate or worsen opioid dependence and other cannabis co-use issues with other substances
- Health care provider knowledge of medicinal cannabis research and health effects from cannabis use
- Health care provider communication with patients about cannabis treatment for health problems
- Scientific evaluation of culturally sensitive and effective training models to prepare physicians, nurses, pharmacists and allied health professionals to address tobacco and cannabis use in diverse communities

Harm reduction interventions

- Theoretical models of harm reduction that account for TRHDs
- Extent of electronic nicotine delivery systems 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
- Impact of secondhand exposure to smoke and vapor on former smokers, including recent

- auitters
- Health communication development for harm reduction strategies
- End-game strategies and their effect on behavior and social norm change for priority groups

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

- Updating and modernizing school-based tobacco prevention curricula, as most evidence-based curricula are outdated
- Developing metrics to assess youth tobacco prevention activities that account for variability in intervention modality
- Scientific evaluation of practice-based tobacco prevention interventions conducted in diverse school and after school settings
- Targeted health communications for menthol and flavored tobacco and cannabis prevention, including non-nicotine/non-cannabis electronic cigarettes
- Youth-tailored communication toolkits for new and emerging tobacco products (e.g., "heat-not-burn" tobacco sticks) and cannabis products
- Reducing youth exposure to secondhand tobacco and cannabis smoke and vapor
- Impact of cannabis outlet density and proximity to schools on cannabis-related knowledge, attitudes and behavior
- Elucidating barriers and facilitators to smoking cessation among nicotine dependent youth
- Developing youth leaders in tobacco control and prevention

Impacting the social determinants of TRHDs

- Mechanistic studies to disentangle effects of social determinants of health on tobacco use among priority groups
- Innovative strategies to modify social and physical environments that promote tobacco-free lifestyles
- Extent to which addressing discrimination, stigma, ethnic identity and acculturation benefits tobacco prevention efforts and treatment interventions
- Nuanced interventions for American Indians that differentiate ceremonial tobacco use from commercial tobacco use
- Geospatial research that characterizes impacts of social determinants of health

Self-reported health effects and contextual factors of new tobacco product use and cannabis use

- Development of typologies and theoretical models for problem e-cigarette or cannabis use that define and characterize correlates of problem use for future research
- Theoretical frameworks for problem e-cigarette or cannabis use that take into account the social determinants of health, including cultural factors
- Extent to which heavy cannabis users are similar to or different from heavy tobacco smokers and heavy users of other substances
- Comparing the cannabis use across the lifespan (from youth experimentation to effects of chronic use on the aging brain) to the continuum of nicotine use and dependence
- Examining the health effects of cannabis use in priority populations
- Statistical models to estimate the epidemiological co-occurrence of cannabis use and cardiovascular disease, pulmonary disease and cancer incidence, progression or remission
- Elucidating factors associated with the social determinants of health and cannabis outlet density
- Social and contextual factors that encourage and discourage e-cigarette use and cannabis use across the lifespan
- Trajectories of cannabis use within priority groups (extent to which cannabis use is consistently light, heavy or intermittent as people age)
- Evaluating translational aspects of tobacco control research methods and theoretical models for

- cannabis research
- Comparison of self-reported health effects from secondhand cannabis smoke exposure to secondhand tobacco smoke and nicotine vapor exposure
- Extent to which social normalization of cannabis use re-normalizes tobacco use in California
- Comparative health effects and impairment by mode of cannabis use (smoking, vaping, edibles, dabs, topical application, tinctures/oils, etc.)
- Development of prevention interventions for cannabis use during pregnancy and breastfeeding
- Elucidating relationships between cannabis use and cognitive functioning and mental health (e.g., benefits and harms of cannabis use on PTSD, psychotic disorders, affective and anxiety disorders)

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 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.

In recent years, TRDRP focused its limited funding for cancer research on projects related to early diagnosis of tobacco-related cancers to support studies that could have a direct impact on the prognosis and care for California smokers. With the passage of Proposition 56, TRDRP has a new mandate to fund research on all types of cancers and to expand the range of topics beyond early diagnosis. Specifically, Proposition 56 calls for "research into the causes, early detection, and effective treatment, care, prevention, and potential cures of all types of cancer." Within this broad framework, 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 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 now accept proposals for studies of new agents or methods for treating 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. While TRDRP will continue to prioritize research of cancers that are directly related to tobacco use, studies of all types of cancers will be accepted, particularly since many cancers have similar molecular mechanisms for growth and progression.

Sub-focus areas:

- Cancer prevention
- Cancer policy and practice interventions
- Translational cancer research
- Basic research on cancer initiation and progression

Examples of relevant research topics:

- Evaluation of technology-driven methods for cancer prevention
- 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

3. Cardiovascular and cerebrovascular diseases

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

Background: CVD is a leading cause of one-third of global deaths, according to the World Health Organization's Global Status Report on Noncommunicable Diseases, 2014. In California, the Department of Public Health recent reports that CVD remains the leading cause of death in the state, and over eight million Californians live with the 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 impact is more pronounced in low- and middle-income populations that also see higher rates of tobacco use. The California Health Interview Survey in 2012 found that cardiovascular disease rates were highest among Native Americans and African Americans, two populations also with high rates of tobacco use. Children are vulnerable population to cardiometabolic risk factors because of exposure to tobacco smoke.

The emergence of electronic-cigarettes and other tobacco products that deliver nicotine aerosolized in various solvents raises new critical questions. An American Health Association report reviewed the latest science of this fast-emerging area of tobacco control and the impact of e-cigarettes on public health. Use of these new 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. A new category of tobacco products, called "heat-not-burn" has been touted to reduce risk in global markets. These products must be examined for their claimed characteristics and effects on humans.

TRDRP support for this priority focuses on understanding and identifying functional pathways of normal and diseased cells and molecules. The program will support studies that deepen understanding of proven cellular mechanisms that lead to pathogenesis of cardiovascular and cerebrovascular disorders or diseases, including etiology and mechanisms of tobacco product-induced CVD.

Sub-focus areas:

- Molecular and cellular pathways of initiation and progression of cardiovascular diseases, such as atherosclerosis, hypertension
- 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 metabolism
- Research is needed to understand primary prevention of atrial fibrillation (AF) by evaluating longitudinal risk factors such as tobacco use and how their modification is related to reduce risk of AF.
- 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
- Lifestyle, obesity and dietary factors leading to CVD
- o Effects of initiation of new tobacco and nicotine products on cardiovascular system
- Designing new interventions to prevent cardiovascular disease
- Correlative studies to better understand the shared and causative parameters of heart disease and endodontitis; related oral vasculature, especially in the context of tobacco use

Examples of relevant research topics:

- Mechanisms of atherosclerosis and coronary heart disease, pathophysiology of hypertension
- Innovative treatments to prevent the burden of risk of cardiovascular or cerebrovascular event
- Cerebrovascular studies on vasculature, thrombotic or embolic stroke, ischemia, blood brain barrier and target 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
 - o Identification of toxicants responsible for platelet activation
- Diabetes and the mechanisms by which tobacco toxicants contribute to the development of insulin resistance
- Strategies to reduce the burden of AF by addressing modifiable risk factors such as obesity, hypertension, tobacco and cardiovascular disease
- Studies on and solutions for vulnerable populations that are disproportionately affected by cardiovascular disease due to exposure to tobacco smoke
- Implementation research on utilizing the diagnosis of a myocardial infarction as a teachable moment for patients and families regarding the health impacts of smoking

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 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.

TRDRP support for this priority focuses on understanding and identifying functional pathways of normal and diseased cells and molecules. The program will support studies that deepen understanding of proven cellular mechanisms that lead to pathogenesis of cardiovascular and cerebrovascular disorders or diseases, including etiology and mechanisms of tobacco product-induced CVD.

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.

NOTE: Investigators are strongly encouraged to refer to their institutional policy on conducting cannabis research before designing their study to avoid conflicts with federal and state regulations. Please refer to the TRDRP cannabis research policy. (trdrp.org/funding-opportunities/cannabis-research-considerations.html)

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
- SHS as a Class A carcinogen and that it offers no risk-free exposure level, policies to minimize involuntary exposure to SHS, SHS exposure and health risks in all public settings listed above
- Characterization of biomarkers of exposure from all tobacco products
- Thirdhand smoke, 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
- New product and MRTP use increase, toxicology and risk profiles
- 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 thirdhand smoke research. (trdrp.org/highlights-news-events/thirdhand-smoke-consortium.html). TRDRP invites additional innovative research on thirdhand smoke 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 continuum of nicotine addiction and treatment, with a goal of understanding and reducing tobacco use in populations that consistently have the highest smoking rates.

Background: The starting point along the continuum of nicotine addiction and treatment is the underlying biology of the addiction itself. 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 in many smokers who try to quit, but only 30 to 40 percent successfully quit using these therapies. Although some of the variability in quit rates among smokers can be attributed to variable adherence to treatment, it is still unclear if there is a biological basis underlying the variability. 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. It may also help to identify links between smoking and tobacco-related disorders such as cardiovascular disease, obesity, diabetes and cerebrovascular disease.

Another space along the continuum is the harm potential of nicotine and other constituents of new tobacco products. Because of the emergence of new nicotine delivery products, such as e-cigarettes and "heat-not-burn" tobacco products (e.g. iQOS) that are particularly popular among youth and young adult, key research is needed understand the long-term effect of nicotine, flavorings and other components of these products on the developing human brain. Research that can inform FDA regulations on new tobacco products are of particular interest.

Further along the continuum, is translating new cessation strategies to the clinic. New strategies using novel biologics, behavior modification techniques or a combination of both are needed combat the persistent cigarette consumption among Californians. One key area of translational research that has yet to be studied definitively among in California is the potential of various nicotine delivery products as cessation aids. E-cigarettes, in particular, have been pushed as potential cessation aids. Definitive human studies, however, are needed to confirm these assertions and establish the methods of administration for effective cessation. With the advent of other purported harm-reduction products on the market, definitive studies on the role they may play in reducing smoking rates are essential.

Although tangential to the nicotine continuum, the co-use of nicotine with other substances such as alcohol and cannabis is another key area of research due to 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 addictive substances such as nicotine, alcohol and cannabis. New nicotine delivery devices often are used to deliver combinations of these substances, as well as flavorings and other constituents. It is important, therefore, that we understand the biological and behavioral aspects of co-use of nicotine and other addictive substances among adolescents.

Sub-focus areas:

- Biological mechanisms of nicotine dependence
- Harm potential of new products
- Treatment and cessation
- Co-use with addictive substances

Examples of potential research topics include:

Multi-parametric risk factors of nicotine addiction and response to treatment

- Biological and behavioral characterization of individual smokers, personalized treatment for smoking 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.)
- Addictive potential of flavorings and other constituents of e-cigarette aerosol
- Randomized controlled trial of e-cigarettes as cessation aids among African American young adults
- Testing the efficacy and side effects of existing cessation drugs in racial/ethnic minority, LGBT and low socioeconomic status groups — sectors typically not fully represented in clinical trials

6. Oral diseases and dental health

Purpose: Support innovative and high impact research that advances understanding of oral diseases and developing approaches to enhance oral health and disease prevention.

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 new TRDRP emphasis will support research on early detection, prevention and treatment of oral diseases and new approaches for dental care. 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. Oral health is an essential part of general health, however, the pathways from tobacco use (combusted or vaporized) to oral disease initiation, progression and prognosis are less clear. We also do not fully understand the impact of e-liquid or e-cigarette aerosol on oral health and disease development. Thus, California-based researchers are invited to explore innovative fronts in oral disease research.

Building the health workforce to address oral diseases strengthens the broad research areas included in this priority. Research that fosters partnerships and leverages existing funding support to conduct effective prevention and treatment interventions for oral diseases in California's diverse communities is 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 oral disease
- Tools and diagnostic methods of early detection of oral diseases
- Oral epithelial dysplasia as a risk for oral cancer; biology and early detection
- Oral microbial biofilms and disease progression
- Basic and applied research in periodontitis and chronic and opportunistic infections of the mouth
- Risk factors for dental caries and issues related to dietary sugars
- Oral disease prevention through community-clinic partnerships
- Innovative research to address disparities in dental health access and oral disease pathogenesis

Examples of relevant research topics:

- Mechanisms of oral biology of mucosal diseases
- Manifestation and systemic inflammations of oral mucosa or periodontal disease
- Salivary dysfunction associated with systemic oral diseases
- Pathophysiology and biomarkers of oral squamous cell carcinoma (SCC)

- 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
- Effects of taxing sugar-sweetened beverages on caries and treatment costs
- Community-based participatory research methods and translational approaches to increase access to culturally sensitive dental care and preventing oral diseases among underserved groups
- Potential causal pathways from substance use to oral diseases and conditions.

7. Pulmonary biology and lung diseases

Purpose: Support innovative, timely and high impact research to better understand basic, translational or clinical sciences related to pulmonary and lung diseases.

Background: Chronic obstructive pulmonary disease (COPD), acute and chronic lower respiratory infections and lung diseases are leading causes of death worldwide. Most COPD is related to cigarette smoking, while 10 to 15 percent of COPD cases occur in individuals who have never smoked. In California, the prevalence rate is 12 percent for chronic lung diseases, namely pediatric and adult asthma and COPD. This creates a large disease and economic burden in the state.

Under this priority, TRDRP supports research that is crucial to understanding the etiology and mechanisms of pulmonary and lung diseases, especially those that are induced by tobacco use or exposure. While all forms of nicotine are known to impair lung function, the use of aerosolized nicotine in new electronic tobacco products and marked uptake of these products need to be studied to respond to rising health consequences in pulmonary lung diseases.

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

Sub-focus areas:

- Mechanistic studies to better define COPD
- Etiology of asthma; basic to advanced research to understand and develop diagnostic approaches, especially for children of disproportionately-affected populations
- Upper respiratory tract inflammation and infections
- Immune system-mediated disorders of lung
- Acute and chronic disease related to new and emerging tobacco products
- Lung development, pre-natal and neonatal lung exposure to tobacco toxins
- Diagnostic and therapeutic approaches to prevention and treatment of lung diseases
- Regional and societal heterogeneity and epidemiological assessments of exposures that are determinants of lung diseases
- Cannabis use or exposure leading to pulmonary health consequences, both in co-use settings of tobacco smoke or alone

Examples of relevant research topics:

- The molecular mechanisms and genetics of underlying differences in COPD susceptibility and progression, including gender differences
- Clinical research focusing on functional status assessment and goal setting for patients with COPD using spirometry tests, as well as tobacco screening and use status
- Airway hypersensitivity and inflammation, such as asthma and emphysema
- Effective and new diagnostic and therapeutic options to treat lung diseases
- Epigenetics of immune-mediated pulmonary diseases

- Inflammatory responses and mechanisms in chronic bronchitis
- Educational prevention on lung health and tobacco use, especially for youth and communities with disparate rates of tobacco use

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 assess, understand and implement science-informed tobacco control polices.

Background: The enactment of five state tobacco control laws in June 2016 and passage of Proposition 56 in November 2016 to increase the state tobacco excise tax were major policy advances to protect Californians from tobacco exposure and reduce morbidity and mortality rates from tobacco-related diseases. These efforts have infused energy and desperately needed resources into California's tobacco control, prevention, education and research efforts.

At the same time, California voters approved Proposition 64, legalizing the recreational use and sale of cannabis, which may increase the prevalence of and public exposure to secondhand cannabis smoke. Further, Philip Morris has announced plans to shift from the combustible tobacco market and aggressively market their iQOS product ("heat-not-burn" tobacco sticks or electronically-heated tobacco) and brand in Europe and Asia as a reduced-risk product. Philip Morris' Modified Risk Tobacco Product application is under review by the U.S. FDA and, if approved, it would permit the iQOS to be sold in the U.S. as a reduced-risk tobacco product.

Tobacco control must prepare to address "heat-not-burn" tobacco because it will hit the U.S. market before independent research assesses its risks and safety. The tobacco industry also shows signs that it may enter the nicotine replacement therapy market with its own line of flavored nicotine lozenges and gum. In this regard, tobacco companies are communicating to the public its plans to pivot toward public health goals for tobacco control, which is similar to their corporate social responsibility activities in the 2000s.

The tobacco control policy landscape continues to change rapidly in the U.S. and globally. While California is poised to further reduce tobacco smoking on the heels of recently enacted legislation, the industry will continue to:

- attract youth and adults to nicotine addiction with menthol tobacco and little-flavored cigars/cigarillos sold and taxed at a lower rate than cigarettes;
- sell combustible tobacco products to the poor, individuals with mental illness and people of
 color in the U.S., and in low- and middle-income countries, demonstrating complete disregard
 for the disproportionate impact of tobacco use and tobacco-related diseases for certain groups;
- manipulate trade agreements to benefit their financial interests and to discourage protective public health laws at the local, state, national and global level; and
- change their brand image by revising their corporate social responsibility campaign with the
 "heat-not-burn" tobacco and other electronically heated tobacco products at the center, in the
 hopes that the public will be convinced of their intention to pivot toward public health goals;
 however, the message will likely be framed as protecting public health from tobacco-related
 diseases through reduced-risk tobacco products.

The complexity of this new era of tobacco control policy work will require timely dissemination of impactful research findings to California policymakers and stakeholders at local, state and national levels and globally. Training needs to be accelerated to expand capacity in the tobacco control workforce in California and to prepare the next generation of leaders in the field. We encourage policy researchers to scientifically evaluate community programs and school based tobacco activities through collaboration with Local Lead Agencies (LLAs) funded by the California Tobacco Control Program/ CA Department of Public Health (CTCP/CDPH) and Local Educational Agencies (LEAs) funded by the

California Department of Education (CDE). The following policy-related research topics are considered responsive to this priority.

Sub-focus areas:

- Downstream effects from California's changing tobacco control policy landscape
- Research on training to expand tobacco control capacity and leadership
- Menthol and flavored tobacco regulation
- Countering tobacco industry marketing and corporate social responsibility efforts
- Reducing tobacco product waste and protecting the environment through policymaking
- Protecting youth from tobacco and cannabis exposure
- Tobacco policy interactions with cannabis policy
- Impact of federal and global tobacco control policy on California policymaking
- Tobacco industry influence

Examples of relevant research topics:

Downstream effects from California's changing 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
- Facilitators and barriers to implementation and enforcement of smoke and tobacco free school campuses
- Progress toward closing loopholes in smoke-free workplace laws
- Changes to the tobacco and vapor retail environment in response to recent California laws
- Policy impacts on narrowing or widening health disparities
- Evaluation of methods to achieve community college tobacco-free policies
- Geospatial research to characterize policy effects and health outcomes
- Economic modeling to characterize pre- and post- policy effects from new California laws on tobacco prevalence, youth access, tobacco-related diseases and tobacco-related health care expenditures
- Extent to which end-game strategies can reduce tobacco-related disparities
- Analysis of intended and unintended consequences from implementation of end-game strategies
- Extent to which Proposition 64 is associated with cannabis use, problem cannabis use and cannabis-related health and legal issues
- Economic impact of recreational and medical cannabis use

Research on training to expand tobacco control capacity and leadership

- Theoretical models and curricula for training community members and researchers in policy advocacy
- Multidisciplinary leadership development programs in tobacco control that focus on translational science to inform policy
- Building relationships with community organizations that serve priority groups in California to strengthen tobacco policy
- Building relationships with American Indian tribal leadership and community-based organizations (Researchers 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 patrons, employees, management, tribal members and tribal leaders)

Menthol and flavored tobacco regulation

- Research to support local ordinances regulating menthol cigarettes and flavored tobacco (e.g., little cigars, cigarillos and e-juices)
- 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
- Preparing municipalities for industry litigation threats and organizing tobacco retailers against menthol and flavored tobacco regulation

Countering tobacco industry marketing and corporate social responsibility efforts

- Evaluating strategies to counter the tobacco industry's pressure on American Indian tribal leadership and policies related to commercial tobacco use in American Indian gaming casinos
- Establishing groundwork for future tobacco control policy change through coordination with American Indian tribes and trusted organizations serving this priority group
- Evaluation of community efforts to counter tobacco industry marketing campaigns
- Characterizing the direction of new and emerging tobacco industry corporate social responsibility efforts
- Analyzing tobacco industry documents and other sources to reveal their intention to pivot and align with public health's tobacco control goals and manipulation of public perception of tobacco companies

Reducing tobacco product waste and protecting the environment through policymaking

- Policy development to address the impact of tobacco butt and electronic cigarette waste on the environment
- Policies to prevent leaching of tobacco chemical waste products into waterways, soil and coastal areas
- Fire risk from cigarette butts
- Theoretical models and policy experiments to hold the tobacco industry and e-cigarette industry accountable for product waste
- Communication strategies to inform the public of the impact of tobacco waste on the environment

Protecting youth from tobacco and cannabis exposure

- Evaluating changes in youth tobacco and cannabis use, perceptions of new and emerging product, and access to tobacco/cannabis products to inform local and state policy development
- Evaluating youth exposure to cannabis smoke; knowledge, attitudes and behaviors associated with edible cannabis and flavored cannabis derived oils and concentrates to inform counter marketing strategies and policy development
- Youth perceptions of vaporized cannabis and cannabinoids
- Developing and evaluating counter marketing approaches for flavored cigarillos and cannabis
- Strategies to support local and state laws requiring childproof packaging of e-juices/e-liquids and cannabis products
- Discouraging marketing and packaging that attracts youth at the point of sale

Tobacco policy interactions with cannabis policy

- Reconciling conflicts between local multi-unit housing (MUH) smoke free policies and adult recreational cannabis smoking in MUH
- Impacts from secondhand cannabis smoke and vapor exposure
- Helping local governments align indoor tobacco smoke free laws with cannabis smoking regulation
- Extent to which cannabis marketing and policies on possession and use renormalize tobacco/nicotine use and smoking

Correlates of tobacco and cannabis outlet density

Impact of federal and global tobacco control policy on California policymaking

- Evaluating changes in federal regulation of tobacco and nicotine products and weakening or strengthening of national tobacco laws
- Evaluating the extent to which trade agreements between California and/or U.S. with other nations strengthens or weakens tobacco control laws
- Characterizing tobacco industry manipulation and strategies to weaken local, state, federal and international tobacco control policymaking

Tobacco industry influence

- Industry manipulation of non-profit organization
- Industry lobbying impact on tobacco control policymaking in California
- Industry's influence in public and private schools; civic, cultural and advocacy organizations; and the hospitality industry
- Product promotions targeting rural smokers, low-income residents and individuals with mental illness
- Elucidating mechanisms used by industry to fund consultants, front groups and powerful individuals who advocate for industry interests
- Evaluating the extent to which the continuum of risk theory is a vehicle to build evidence for policies supported by the industry and/or the tobacco control community, including harm reduction advocates and scientists

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.

- Maximum award amount per year: \$250,000 (direct)
- 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:** Maximum \$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 research 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 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?
- 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: Assess whether the budget request is appropriate for the project, whether there is scientific or budgetary overlap and whether 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)
- 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)
 - Travel to TRDRP conference: Maximum \$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.

Award requirements:

- Applicants must have a PI-status at the sponsoring institution.
- Awardees are required to commit at least 10 percent of their research 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

^{**}Any item costing \$5,000 or more

future, including specific funding sources and award types?

• 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)

- **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 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?

Other considerations

- Budget: Assess whether the budget request is appropriate for the project, whether there is scientific or budgetary overlap and whether 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)
- 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)
 - o Travel to TRDRP conference: Maximum \$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.

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 research effort each year to activities supported by this award.
- Candidate should have no more than five years since completing formal postdoctoral training, or since the doctoral degree if no postdoctoral training.
- 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?
- 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

^{**}Any item costing \$5,000 or more

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?
- 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)?

Criteria-3 (20 percent scoring weight)

- 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?
- **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

- 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 award amount per year: Up to \$60,000 in stipend
- Maximum duration: 3 consecutive years
- Allowable direct costs: Stipend, tuition & fees, and Institution allowance
 - Stipend: Postdoctoral stipend or salaries will be commensurate with current NIH scale and experience. Refer to the Stipend Table below.
 - 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:

We expect that fellows will pursue their research training full time, defined as devoting at least 40 hours per week to research training activities. Beyond full-time training, TRDRP recognizes that fellows may engage in part-time employment incidental to their training. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part-time research, teaching, or clinical employment so long as those activities do not interfere with, or lengthen, the duration of their TRDRP training. Federal funds may only be used for stipend supplementation when specifically authorized under the terms of the program from which funds are derived and only with express permission of both funding agencies.

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 will be commensurate with current NIH scale and experience.
 For example: \$47,484 (Year-0) to \$58,560 (Year-7). Award duration is capped at three years for all awards at the start year of the award year funding.

TRDRP STIPEND GUIDELINES AND CAPS FOR POSTODOCTORAL FELLOWSHIPS

Career Level	Years of	Actual Stipend for	Projected Stipend for
Caleel Level	Experience	FY 2016	FY 2017
Postdoctoral	0	\$43,692	\$47,484
	1	\$45,444	\$47,844

2	\$47,268	\$48,216
3	\$49,152	\$50,316
4	\$51,120	\$52,140
5	\$53,160	\$54,228
6	\$55,296	\$56,400
7 or More	\$57,504	\$58,560

- A 100 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 (separate from the project of a mentor).
- 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 a detailed mentoring plan that is prepared in consultation with the applicant.
- U.S. citizenship is not a requirement.

Review criteria:

Criteria-1 (30 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?

Criteria-2 (50 percent scoring weight)

- **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?
- 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?

Criteria-3 (20 percent scoring weight)

- **Mentor's qualifications and commitment:** Based on the advisor and the department, as demonstrated by 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?

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 Research Fellowship Award

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

Upon consideration of our annual direct cost caps for our Predoctoral Fellowship Award and in alignment with NIH standards, TRDRP will allow fellowship applicants to submit applications in excess of the previously announced direct cost budgetary caps, effective immediately:

- Maximum award amount per year: \$30,000 in stipend
- Maximum duration: 3 consecutive years
- Allowable direct costs: Stipend, tuition & fees, and Institution allowance
 - 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 (separate from the project of a mentor).
- 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 a detailed mentoring plan that is prepared in consultation with the applicant.
- U.S. citizenship is not a requirement.

Review criteria:

Criteria-1 (30 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? Are the applicant's academic record and research experience of high
quality? Does the applicant have the potential to develop into an independent and productive
researcher? Does the applicant demonstrate commitment to a research career in the future?
Letters of support are available that strongly support the applicants' career and plan?

Criteria-2 (50 percent scoring weight)

- **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?
- 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?

Criteria-3 (20 percent scoring weight)

- Mentor's qualifications and commitment: Based on the advisor and the department, as
 demonstrated by 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

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: Foster 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.

Applicant PIs are encouraged to consider participation by undergraduate and early-level graduate students under their mentorship of a currently funded TRDRP PI of a High Impact Pilot award or High Impact Research award. Additional supplement requests are above the award cap and are available for all PI applicants that are applying for any non-mentoring grant types, such as the High Impact Research Project Award, High Impact Pilot Research Award, New Investigator Award or Community Practice-Based Research Awards. 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, domestic travel
- Equipment: Not allowed as part of this supplemental funding
- Travel:
 - o **Project-related travel:** As needed (must be fully justified)
 - Travel to TRDRP conference: Maximum \$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: 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. The submitting PI applicant for the above grant type will submit a supplement application on proposalCENTRAL (at the same time the new TRDRP research application is submitted) using the following requirements.
 - 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.

- 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.
- Candidate biosketch.

7. Community Practice-Based Research Planning Award

Purpose: Supports partnership development among academic and healthcare practitioner researchers to conduct health service research focused on health systems change in the delivery, access, cost effectiveness, and quality of tobacco interventions for Medi-Cal beneficiaries. This grant type supports a collaborative health service research team that aims to collect clinically-relevant metrics and elucidate mechanisms and outcomes associated with improvements to evidence-based tobacco cessation treatments targeting smokers representing California's diverse Medi-Cal patient population. Research partnerships are intended to continue beyond the life of the planning grant and research findings are expected to generalize across clinical services and regions in California.

- Maximum award amount per year: \$200,000 (direct cost cap)
- Maximum duration: 2 years
- Allowable direct costs: Salaries, fringe benefits, supplies, sub-contracts*, equipment**, travel
- Travel:
 - Project-related travel: As needed (must be fully justified).
 - Consortium meetings: Travel and related meeting expenses (at least one annual meeting is mandatory)
 - Scientific conference travel: Up to \$2,000 per year may be applied to attend scientific meetings. If both the Principal Investigator (PI) and Co-Investigator (Co-I) wish to each attend a scientific meeting in the U.S., up to \$4,000 per year may be budgeted.
- 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

Budget: TRDRP will issue award funds as one grant to a lead institution or organization, which must support the administrative component and have the capacity for fiscal management of grant funds, including subcontracts to support consortium activities. The majority of funds for the administrative component are not intended to support the ground up development of a shared electronic health records database, but a small portion of funds may be used to support the addition of tobacco-specific enhancements such as improved assessment methods and referral tracking measures for inclusion in an existing electronic health records system. The administrative component is expected to be affiliated with the lead institution or organization.

Award requirements:

- The lead applicant must have a PI-status at the sponsoring institution.
- The lead applicant PI is required to commit at least 10 percent of their research effort each year to activities supported by this award.
- One signature health service research project is required to be conducted in all recruited clinical sites, and additional projects are highly encouraged
- Collection of quality improvement metrics that elucidate patient, provider, and organizational

- factors associated with delivery of and access to tobacco interventions for Medi-Cal enrollees
- Community clinical practice sites eligible to participate in a research consortium must provide healthcare services to at least 50% Medi-Cal beneficiaries based on annual patient census data
- An administrative component is required that provides oversight, evaluation, and infrastructure support for consortium research and dissemination activities
- 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 planning phase of health service research will lead to an expanded research effort in the future, including specific funding sources and award types?
- 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 proposed health service research project(s) challenge existing interventions, clinical practice or policy; address an innovative hypothesis or critical barrier to progress in the implementation of evidence-based tobacco treatments?

Criteria-2 (40% scoring weight)

• Research Plan: Are the conceptual or clinical framework, design (including composition of study population and strength of recruitment plan), methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project and the nature of the grant type? Does the applicant clearly describe relationships to be examined? Does the applicant acknowledge potential problem areas and consider alternative strategies? Are the sample sizes identified adequate to answer the proposed research question(s)? Is there a power analysis and is it appropriate to the study design? If an intervention is proposed, are the variables and relationships to be examined clearly identified and testable? Is it appropriate for the research team to collect patient-level data and are methods adequately described for collecting patient-level data? Will the administrative component provide adequate infrastructure to support all research activities and communications between consortium members? Is the functional capacity of the administrative component clearly described?

Criteria-3 (30% Scoring weight)

- Collaboration: Are procedures identified to establish or strengthen a collaborative partnership between clinical practitioners and academic researchers? Does the team have the potential to include additional collaborative investigators and clinics in the consortium? Does the research process apply the knowledge of clinic staff, for example, including care coordinators, case managers, and patients including their families, as well as other stakeholders relevant to the success of consortium aims and goals? Are measures included to assess the health of the partnership? Will the proposed collaborative relationship and communication pathways empower healthcare sites to pilot and implement quality improvements and practice changes in how tobacco use is addressed? Are researchers, practitioners, and other stakeholders prepared to work together for an extended period of time?
- Investigators: Are investigators appropriately trained and well-suited to carry out the work? Is
 the work proposed appropriate to the experience level of the PI, Co-I, and other researchers?
 Does the investigative team bring complementary and integrated expertise to the project (if

applicable)? Do the investigators demonstrate access to the population (i.e., low-income patients with high rates of tobacco use and low utilization of tobacco cessation treatments)?

- **Environment**: Do the scientific and clinical environments in which the work will be done contribute to the probability of success? Does the proposed research benefit from unique features of the scientific and clinical environments, or participant 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 community groups about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results from funded research include channels and tools targeting clinicians, patients and patient advocates, public health practitioners (e.g., county health departments), health insurance companies including managed care plans, tobacco control advocates, policymakers, or the general public?

Other Considerations

- **Budget:** Assess whether the budget request is appropriate for the project(s), whether there is scientific or budgetary overlap and whether out-of-state contracts or collaborations are essential for the project(s).
- 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. If the research plan proposes to include patient or client health information as data, efforts to be compliant with the Health Insurance Portability and Accountability Act (HIPAA) and all state and federal laws in the collection and management of participant data should be described.
- Inclusion of Women, Minorities, and Children in Research: If human subjects are involved, the adequacy of plans to include subjects of all genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.
- Care and Use of Vertebrate Animals in Research: If vertebrate animals are involved in the project, plans for their care and use will be assessed.

The Community Practice-Based Research Planning Award is **fully described** in an uploaded document. Read more (http://trdrp.org/files/mechanisms/trdrp-community-practice-based-research-planning-award-mechanism.pdf)

8. Community Practice-Based Research Implementation Award

Purpose: Supports collaborative health service research that elucidates sustainable systems change factors associated with quality care improvements in tobacco cessation efforts delivered through health clinics serving Medi-Cal beneficiaries. This implementation science grant type is intended to fund collaborative research consortia comprised of a lead academic researcher and a lead healthcare practitioner with input from health providers, clinic staff, healthcare administrators, patients, and patient advocates to conduct fully developed research projects that improve the delivery, access, cost effectiveness, and quality of tobacco treatments for California's diverse Medi-Cal patient population. Reports and recommendations that speak to best practices for improving the delivery of and access to evidence-based tobacco treatments are expected throughout the funding timeline and by the culmination of the award period. Findings are expected to generalize and be sustainable across clinical

services, California region, and diverse patient populations.

- Maximum award amount per year: \$500,000 (direct cost cap)
- 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).
 - Consortium meetings: Travel and related meeting expenses (at least one annual meeting is mandatory)
 - Scientific conference travel: Up to \$2,000 per year may be applied to attend scientific meetings. If both the Principal Investigator (PI) and Co-Investigator (Co-I) wish to each attend a scientific meeting in the U.S., up to \$4,000 per year may be budgeted.
- 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

Budget: TRDRP will issue award funds as one grant to a lead institution or organization, which must support the administrative component and have the capacity for fiscal management of grant funds, including subcontracts to support consortium activities. The majority of funds for the administrative component are not intended to support the ground up development of a shared electronic health records database, but a small portion of funds may be used to support the addition tobacco-specific enhancements such as improved assessment methods and referral tracking measures for inclusion in an existing electronic health records system. The administrative component is expected to be affiliated with the lead institution or organization.

Award requirements:

- The lead applicant must have a PI-status at the sponsoring institution
- The lead academic researcher and healthcare practitioner researcher are both required to commit at least 20% of their research effort each year to activities supported by this award
- One signature health service research project is required to be conducted in all recruited clinical sites, and additional projects are highly encouraged
- Collection of quality improvement metrics that elucidate patient, provider, and organizational factors associated with delivery of and access to tobacco interventions for Medi-Cal enrollees
- Community clinical practice sites eligible to participate in a research consortium must provide healthcare services to at least 50% Medi-Cal beneficiaries based on annual patient census data
- An administrative component is required that provides oversight, evaluation and infrastructure support for consortium research and dissemination activities
- Opportunities to support pilot health service research projects conducted by graduate students, post-doctoral fellows, and other emerging investigators
- U.S. citizenship is not a requirement

Review Criteria

Criteria-1 (30% scoring weight)

• Responsiveness to Intent of the Award Type: Does the application propose activities aimed at forming a consortium of publicly funded clinics serving predominantly low income smokers to conduct tobacco cessation service research? Is the signature research project fully developed

rather than pilot or exploratory? Does the study build upon work performed as part of prior pilot work? Does the applicant research team propose research projects with potential to impact systems change in healthcare? Does the applicant describe how the implementation research effort will lead to the consortium's ability to inform best practices for addressing tobacco use in clinical settings serving California's Medi-Cal patient population with potential to sustain efforts beyond the funding period?

- Potential for the Proposed Work to Inform Practice and Policy: To what extent could the proposed research be expected to contribute to a clear, short-term and long-term impact on the health services field related to tobacco cessation efforts, as well as on system level policies and practices aimed at advancing tobacco treatments for the Medi-Cal patient population who are tobacco users? To what extent does the implementation phase of funding contribute to actionable policy recommendations that could be adopted by managed care health plans or the California Department of Healthcare Services for statewide efforts to address Medi-Cal beneficiaries' tobacco use?
- Innovation: Does the research propose new paradigms, challenge existing paradigms, or is 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 for new uses or with understudied populations? Does the proposed research represent more than an incremental advance upon published data? For example, do the proposed projects challenge existing paradigms, interventions, clinical practice, or policy; address an innovative hypothesis or critical barrier to progress in the field?

Criteria-2 (40% scoring weight)

Research Plan: Are the conceptual or clinical framework, design (including composition of study population and strength of recruitment plan), methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project and the nature of the grant type? Does the applicant report non-duplicated annual patient census data for each clinic they propose to include in the research project(s)? Do proposed clinics provide healthcare services to at least 50% Medi-Cal beneficiaries based on annual patient census data? Does the applicant clearly describe relationships to be examined? Does the applicant acknowledge potential problem areas and consider alternative strategies? Are the sample sizes identified adequate to answer proposed research question(s)? Is there a power analysis and is it appropriate to the study design? If an intervention is proposed, are the variables and relationships to be examined clearly identified and testable? Is it appropriate for the research team to collect patient-level data and are methods adequately described for collecting patientlevel data? Are milestones well-defined with quantifiable measures that are appropriate for assessing the success of the implementation phase award? Will the administrative component provide adequate infrastructure to support all research activities and communications between consortium members? Is the functional capacity of the administrative component clearly described?

Criteria-3 (30% Scoring weight)

• Collaboration: Are procedures identified to establish or strengthen a collaborative partnership between clinical practitioners and academic researchers? Does the team have the potential to include additional collaborative investigators and clinics in the consortium? Does the research process apply the knowledge of clinic staff, for example, including care coordinators, case managers, and patients including their families, as well as other stakeholders relevant to the success of consortium aims and goals? Are measures included to assess the health of the partnership? Will the proposed collaborative relationship and communication pathways empower healthcare sites to pilot and implement quality improvement and practice changes in

how tobacco use is addressed? Are researchers, practitioners, and other stakeholders prepared to work together for an extended period of time?

- **Investigators**: Are investigators appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the PI, Co-I and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)? Do the investigators demonstrate access to the population (i.e., low-income patients with high rates of tobacco use and low utilization of tobacco cessation treatments)?
- **Environment**: Do the scientific and clinical environments in which the work will be done contribute to the probability of success? Does the proposed research benefit from unique features of the scientific and clinical environments, or participant 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 community groups about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results from funded research include channels and tools targeting clinicians, patients and patient advocates, public health practitioners (e.g., county health departments), health insurance companies including managed care plans, tobacco control advocates, policymakers, or the general public?

Other Considerations

- **Budget:** Assess whether the budget request is appropriate for the project(s), whether there is scientific or budgetary overlap and whether out-of-state contracts or collaborations are essential for the project(s).
- 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. If the research plan proposes to include patient or client health information as data, efforts to be compliant with the Health Insurance Portability and Accountability Act (HIPAA) and all state and federal laws in the collection and management of participant data should be described.
- Inclusion of Women, Minorities, and Children in Research: If human subjects are involved, the adequacy of plans to include subjects of all genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.
- Care and Use of Vertebrate Animals in Research: If vertebrate animals are involved in the project, plans for their care and use will be assessed.

The Community Practice-Based Research Implementation Award is fully described in an uploaded document. Read more (http://trdrp.org/files/mechanisms/trdrp-community-practice-based-research-implementation-award-mechanism.pdf)

9. Cornelius Hopper Diversity Award Supplement

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

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

- Maximum supplement amount per year: \$20,000 (direct cost)
- Maximum duration: 2 years
- Allowable direct costs: Salaries, fringe benefits, tuition, enrollment fees for the trainee, domestic travel
- Equipment: Not allowed as part of this supplemental funding
- Travel:
 - Project-related travel: As needed (must be fully justified)
 - Travel to TRDRP conference: Maximum \$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)
- 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. For example, undergraduate students, graduate students who have not advanced to candidacy, or individuals who are working in the tobacco control field or proposed research area but do not have experience in research. Individuals who are eligible for TRDRP fellowships and other career development awards are encouraged to apply through those award types rather than applying for the Hopper Diversity Supplement.
- Investigators must have at least one year remaining on their TRDRP award to ensure the best conditions and results for prospective trainees. Therefore, Hopper Diversity Supplement applications must be submitted as part of an initial application or as part of an annual scientific progress report.
- The Hopper Diversity Supplement is available to principal investigators of any TRDRP award except for Postdoctoral Awards, Predoctoral Awards and Mackay Policy Scholar Awards.
- Eligible trainees may be undergraduate students, graduate students, community members, school personnel or health sciences students, working under the mentorship of a currently funded TRDRP mentor.
- 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.

10. 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., 15 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); 50 percent of award amount can be spent out of state)
- **Maximum duration:** 3 years
- Allowable direct costs: Salaries and salary off-criteria,
- Scholar research expenses: \$25,000
- Training/mentoring expenses: \$40,000
- Travel:
 - o **Travel to TRDRP conference:** Maximum \$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)
- Out of state expenses: Limited to 25 percent of total award budget
- **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 15 years post completion of his/her terminal research degree or 15
 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 at the time of submission. 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.
- At least 75 percent of the scholar's training and research must be based in California.
- 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
 - Frame a policy position or positions
 - 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
 - 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)
 - Government office placement (e.g., state legislature; finance or health agencies/ministries)
 - Policy and research seminars
 - Leadership training (e.g., Bloomberg)
 - Media training (e.g., Stanford-NBC News, World Lung Foundation)
 - 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

- 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?

11. Special Projects

Support can be requested to support dissemination of findings from TRDRP-funded research or to allow tobacco investigators to evaluate, in a timely manner, new and breaking trends in tobacco control or tobacco-related disease research. In order to qualify for funding, the planned activities must be directly related to one or more of TRDRP's research priorities. The activity must 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 Special Projects award type. Proposals may be submitted at any time and should be submitted on proposalCENTRAL. Applications for Special Project Awards will go through a separate review process. Special Project 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.

12. 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 support 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, equipment*, travel, honoraria all conference costs subject to TRDRP approval based on programmatic budget policies
- Indirect costs: Not allowed

*Any item costing \$5,000 or more

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)
- o 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 dissemination of 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 through proposalCENTRAL, 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 Special Projects award type.

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:

- Conference topic(s), objectives and goals
- 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
- Resource sharing plan: 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, 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.

SUBMISSION PROCESS

Submission of a Letter of Intent (LOI) is required to apply for all research awards except for Special Projects, Cornelius Hopper Diversity Award Supplements, and Student Research Supplements. The LOI must be submitted through proposalCENTRAL (with the exception of the Conference Award – in this case the Program Officer will provide potential applicants with an LOI template to be completed via email). Applicants will have access to the application template web pages if the LOI is approved, at which time applicants will receive an email notification. In order to be considered for a programmatic review, a LOI must be submitted using the template available on proposalCENTRAL (with the exception of the conference award) and must address all sections listed there-in. LOI submission instructions should be strictly followed as stated.

For technical help with proposalCENTRAL, please email pcsupport@altum.com or call 800-875-2562 (Toll-free U.S. and Canada). proposalCENTRAL customer support is available Monday to Friday, 8:30 a.m. to 5 p.m. (EST).

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 review the applications for tobacco relatedness. They will first consider funding scientifically meritorious tobacco-related research applications, and then prioritize scientifically meritorious applications that address the expanded priorities areas described in this Call for Applications.

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

Health Policy Research

Tyler Martz, DrPH, MPH (510) 987-0965, Tyler.Martz@ucop.edu

Cancer Prevention, Treatment and Biology

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

Jessica Wu, PhD (510) 987-0329, <u>Jessica.Wu@ucop.edu</u>

Biomedical and Environmental Sciences

Anwer Mujeeb, MSc, PhD (510) 287-3340, <u>Anwer.Mujeeb@ucop.edu</u>

Biomedical and Clinical Sciences

Nicholas Anthis, DPhil (510) 987-0358, Nicholas.anthis@ucop.edu

Biomedical Sciences

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

Clinical Sciences and Epidemiology

Laura Packel, PhD, MPH (510) 987-9858, <u>Laura.Packel@ucop.edu</u>

Neuroscience and Biomedical Sciences

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

MARCH 2019 AMENDMENT

Maximum Award/Year (Direct Cost)	Maximum Award Duration (up to X years)
\$250,000/year	3
\$200,000/year	2
\$200,000/year	3
\$60,000/year* 100% effort required	3
\$30,000/year*	3
\$20,000	1
\$200,000/year	2
\$500,000/year	3
\$20,000/year	2
	#200,000/year \$200,000/year \$200,000/year \$60,000/year* 100% effort required \$20,000 \$200,000/year \$200,000/year

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 award amount per year: Up to \$60,000 in stipend
- Maximum duration: 3 consecutive years
- Allowable direct costs: Stipend, tuition & fees, and Institution allowance
 - Stipend: Postdoctoral stipend or salaries will be commensurate with current NIH scale and experience. Refer to the Stipend Table below.
 Postdoctoral stipend must adhere to the rates set by their institution with institutional documentation of the 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:

• We expect that fellows will pursue their research training full time, defined as devoting at least 40 hours per week to research training activities. Beyond full-time training, TRDRP recognizes that fellows may engage in part-time employment incidental to their training. Fellows and trainees may spend on average, an additional 25% of their time (e.g., 10 hours per week) in part-time research, teaching, or clinical employment so long as those activities do not interfere with, or lengthen, the duration of their TRDRP training. Federal funds may only be used for stipend supplementation when specifically authorized under the terms of the program from which funds are derived and only with express permission of both funding agencies. Fellows may reduce effort on the grant to a minimum of 75% after the first year upon submission of justification of reduction in time and an updated budget. Unexpended stipends may be rebudgeted into Institutional Allowance and/or Tuition and Fees with written permission of TRDRP Program Officer or Program Director. No limits apply to these categories during re-budgeting.

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 will be commensurate with current NIH scale and experience.
 For example: \$47,484 (Year-0) to \$58,560 (Year-7). Postdoctoral stipend or salaries must
 adhere to the rates set by their institution with institutional documentation of the payment scale.
 Award duration is capped at three years for all awards at the start year of the award year
 funding.

TRDRP STIPEND GUIDELINES AND CAPS FOR POSTODOCTORAL FELLOWSHIPS

Career Level	Years of Experience	Actual Stipend for FY 2016	Projected Stipend for FY 2017
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Postdoctoral Postdoctoral	0	\$43,692	\$47,484
	4	\$45,444	\$47,844
	2	\$47,268	\$48,216
	3	\$49,152	\$50,316
	4	\$51,120	\$52,140
	5	\$53,160	\$54,228
	6	\$55,296	\$56,400
-	7 or More	\$ 57,504	\$58,560

- A 100 percent time commitment on the part of the postdoctoral fellow is required for the first year of the TRDRP fellowship. Fellow may reduce effort to minimum 75% in the second and third years of award, upon approval by TRDRP Program Officer or Director.
- 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 (separate from the project of a mentor).
- 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 a detailed mentoring plan that is prepared in consultation with the applicant.
- U.S. citizenship is not a requirement.