

## 2020 Call for Applications

### New Changes and Key Requirements

- TRDRP will only have one grant cycle for the 2019-2020 fiscal year.
- Submission of a letter of intent (LOI) is **required**, including for resubmitted applications, except for the Rapid Response Research to Accelerate Policy Award and the Community-Partnered Participatory Research Award.
- All applications received for the 2020 Call must clearly address tobacco or tobacco-related disease. A focus on the biological effects of nicotine and flavorants is particularly encouraged.
- The names of some awards have been revised.
- A research priority has been added to include other health effects not listed in the other 8 priorities.
- Two new award types have been added: Rapid Response Research to Accelerate Policy, and Community-Partnered Participatory Research Award.
- Applicants are required to determine whether the sex of an animal model or human subject should be considered as a biological variable when designing their experiments.
- Multiple applications from a PI will be accepted if the topics are distinct.
- Applicants are required to follow all instructions and submit ALL required forms to avoid administrative rejection.
- LOIs or Applications may be rejected based on programmatic or administrative review.
- Go to <http://www.trdrp.org> for LOI/Application instructions and information on how to access the application submission system.

\* The 2020 Call for Applications refers to applications that will be awarded in calendar year 2020, although the Call is released in calendar year 2019 and some processes will occur in calendar year 2019.

## 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 the use of tobacco products and mitigates the human and economic costs of tobacco product use in California. In November 2016, California voters passed Proposition 56 — the California Healthcare, Research and Prevention Tobacco Tax Act of 2016 which increased the retail tax on tobacco products by \$2. Under the 2019 call for applications, TRDRP awarded over \$57 million dollars to 28 institutions across California.

## Highlights of the 2020 Call for Applications

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

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

Please see [Appendix A](#) for details.

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

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

New and emerging tobacco products that deliver nicotine in various ways are increasingly being used, especially by adolescents. Similarly, flavored tobacco products are very popular among youth and other priority populations, yet little is known about the effects of these additives when inhaled. TRDRP strongly encourages proposals analyzing the toxicology and health effects of flavorings. In addition, studies on the effects of nicotine itself, especially in animal models and

human subjects, are strongly encouraged. Given the variability of ingredients in e-liquids, it is critical that investigators quantify the actual chemical composition, including nicotine and flavoring chemicals, in the substances being tested.

**RESEARCH AWARDS must directly address tobacco-related health disparities or new and emerging tobacco products.** In an effort to more closely align our most generous awards with the most urgent questions in tobacco control, proposals for the award type Research Awards must focus on tobacco-related health disparities or research on new and emerging tobacco products. Please refer to the Research Award description for eligibility criteria.

**Sex as a biological variable.** Consistent with NIH, we now require applicants proposing experiments with biological endpoints to determine whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments.

As explained in “Applying the new SABV (sex as a biological variable) policy to research and clinical care,” *Physiology & Behavior* 187 (2018) 2–5 “Sex originates from an organism’s sex chromosome complement – XX or XY chromosomes in humans, and is reflected in the reproductive organs. Considering SABV is not the same as looking for sex differences, but it is about exploring the influences of sex as a biological variable and revealing the “data hiding in plain sight.” Applicants can review the paper in *Physiology & Behavior* here: <https://www.sciencedirect.com/science/article/pii/S0031938417302585>

The following points are taken verbatim from the article:

- First, before conducting research, find out whether there are known sex differences in the area of study by adding the terms *sex*, *gender*, *male*, and *female* to your literature search. In addition to PubMed, use the GenderMed database.
- Second, randomize and balance the sexes in the study and control groups. If you are testing a pharmaceutical, consult the FDA snapshot page, which provides information about sex differences in drug metabolism and effects for recently approved drugs.
- Third, if sex differences are suspected, e.g., from the literature search, conduct pilot studies to determine whether powering the study to detect sex differences is warranted.
- Fourth, in the analyses of the data, regardless of whether the study was powered to detect sex differences, disaggregate the data to see if there are differences that are hidden when data from males and females are pooled. Analyze key relationships for males and females separately.

Applicants should clearly state the method that was used to determine whether sex should be used as a biological variable in their study.

**Cannabis use and tobacco-related diseases.** There remains a critical need to understand the intersection of cannabis and tobacco. The biological and population level impact of these products in combination is of particular interest to inform effective health policy. Applications that include cannabis must also be related to tobacco use, tobacco policy, or tobacco-related disease. Please refer to the [TRDRP cannabis research policy](http://trdrp.org/funding-opportunities/cannabis-research-considerations.html) for additional guidance. (trdrp.org/funding-opportunities/cannabis-research-considerations.html)

*NOTE: To avoid conflicts with federal and state regulations, investigators are strongly encouraged to refer to their institutional policy on conducting cannabis research before designing studies involving cannabis. Also, if research using cannabis is proposed applicants*

*are required to describe the status of their Drug Enforcement Agency (DEA) license for the use of a Schedule I drug.*

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

**Letter of Intent (LOI) process.** Submission of an LOI is required for all new and resubmitted applications, with the exception of the Rapid Response Research to Accelerate Policy Award and the Community-Partnered Participatory Research Award. LOIs will be programmatically reviewed by TRDRP staff to verify consistency with the requirements and adherence with TRDRP research priorities as described in this call. Applicants must provide sufficient detail in their LOI abstract and specific aims to allow program staff to assess scientific eligibility at the LOI stage. LOIs will not be invited to submit a full application if they do not comply with the tobacco-related disease research requirement (any award type), or if they do not comply with the “tobacco-related health disparities or new and emerging tobacco products” requirement (**Research Awards** only).

TRDRP encourages applicants to contact TRDRP program officers with questions regarding eligibility requirements before submitting an LOI or application. Once an LOI is approved, the applicant will be notified and the application materials will be made accessible to the applicant.

## KEY DATES

Award Type	All Other Award Types	Rapid Response Research to Accelerate Policy Award	Community Partnered Participatory Research Pilot Award
<i>Call open</i>	Tuesday, October 1, 2019	October 2019	October 2019
<i>LOI submission deadline (approved on a rolling basis)</i>	Thursday, November 14, 2019 12 p.m. PT	N/A	N/A
Due date for new applications and resubmissions	Thursday, January 23, 2020 12 p.m. PT	Thursday, January 23, 2020 12 p.m. PT	Thursday March 5, 2020 12p.m. PT
Applicants notified	June 2020	June 2020	June 2020
Awards start	July 1, 2020	July 1, 2020	July 1, 2020

### To get started:

1. Determine your [eligibility for funding](http://trdrp.org/funding-opportunities/index.html#eligibility). (<http://trdrp.org/funding-opportunities/index.html#eligibility>)
2. Explore our [research priorities](http://trdrp.org/research-priorities/index.html). ([trdrp.org/research-priorities/index.html](http://trdrp.org/research-priorities/index.html)) (All applications must address one or more.)
3. Review the [2020 call for applications award types](http://trdrp.org/funding-opportunities/award-mechanisms/index.html) ([trdrp.org/funding-opportunities/award-mechanisms/index.html](http://trdrp.org/funding-opportunities/award-mechanisms/index.html)) and [dates and deadlines](http://trdrp.org/funding-opportunities/dates-and-deadlines.html). ([trdrp.org/funding-opportunities/dates-and-deadlines.html](http://trdrp.org/funding-opportunities/dates-and-deadlines.html))
4. Familiarize yourself with our [letter of intent and application processes](http://trdrp.org/funding-opportunities/award-processes/index.html). ([trdrp.org/funding-opportunities/award-processes/index.html](http://trdrp.org/funding-opportunities/award-processes/index.html))
5. Contact a [program officer](http://trdrp.org/about/staff.html) ([trdrp.org/about/staff.html](http://trdrp.org/about/staff.html)) with any questions.
6. Use [SmartSimple](http://ucop.smartsimple.com) ([ucop.smartsimple.com](http://ucop.smartsimple.com)) to submit your LOI and application.

Review the Call for Applications, LOI and Application Instructions, and complete all necessary materials using the appropriate templates and forms. Failure to comply with provided instructions or failure to submit completed forms may result in administrative rejection of the application.

**2020 Call for Applications: Award Types**

See [Appendix B](#) for details

<b>Award Types</b>	<b>Purpose of Award</b>	<b>Maximum Award/Year (Direct Cost)</b>	<b>Maximum Award Duration (up to X years)</b>
<b>Research Award</b>	Conduct research that will address tobacco-related health disparities or new and emerging tobacco products.	\$250,000/year	3
<b>Pilot Award</b>	Gather preliminary data or demonstrate proof-of-principle with potential for high impact within one or more stated research priorities.	\$200,000/year	2
<b>New Investigator Award</b>	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
<b>Postdoctoral Award</b>	Support postdoctoral research training under a designated mentor to conduct high impact research within one or more stated research priorities.	See Appendix B	3
<b>Predocutorial Award</b>	Support doctoral student research training with a designated mentor within one or more stated research priorities.	See Appendix B	3
<b>Rapid Response Research to Accelerate Policy Award</b>	A research and community partnered award with a goal to identify ways local communities can reduce tobacco use and tobacco exposure through local policies.	\$200,000/year	2
<b>Community Partnered Participatory Research Pilot Award</b>	Support development of an equitable community and academic research partnership to conduct pilot research that gathers preliminary data or address a research question on a tobacco-related issue of importance to a community/school in California.	\$200,000/year	2

<b>SUPPLEMENTS TO ACTIVE TRDRP AWARDS</b>			
<b>Student Research Supplement<sup>1</sup></b>	Allow active research training and participation by undergraduate and Master's degree students under the mentorship of a currently-funded TRDRP PI of a non-training award. Supplements are funded above the award mechanism cap.	\$20,000	1
<b>Cornelius Hopper Diversity Supplement<sup>2</sup></b>	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
<b>Dissemination Supplement</b>	Support small scientific conferences and other research dissemination activities for results from TRDRP-funded research.	\$5,000	1

<sup>1</sup>Student Research Supplement applications will be accepted for non-mentored grants such as the Research Award as part of the mentoring PI's annual progress report. Funded supplements are eligible for competitive renewals for up to \$20,000/year through the duration of the parent grant.

<sup>2</sup>Cornelius Hopper Diversity Supplement applications will be accepted for non-mentored grants such as the Research Award as a part of the mentoring PI's annual progress report.

## **TRDRP FUNDING POLICIES AND PROCEDURES**

### **Resubmission Policy**

A resubmission is an unfunded application that was submitted to TRDRP as a new application in the previous year and resubmitted under the current Call for Applications. 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 and must be submitted in the subsequent Call for Applications.

Please note the following exception: applications originally submitted in grant cycle 2019 A, and not resubmitted in grant cycle 2019 B, are eligible for resubmission in response to this 2020 Call for Applications.

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

## Multiple Submissions Policy

Researchers can submit more than one application, provided that the proposed research topics and aims are significantly different for each LOI/application.

## TRDRP Eligibility Criteria

Investigators from California not-for-profit organizations are eligible for TRDRP funding, including but not limited to colleges, universities, hospitals, laboratories, research institutions, local health departments, community-based organizations, voluntary health agencies, health maintenance organizations and tobacco control organizations. The sponsoring institution, in accordance with its own policies and procedures, should designate the principal investigator (PI). The PI must supervise the research project and any trainees directly and in person. U.S. citizenship is not a requirement for eligibility.

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

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

## Applicant Appeal Policy and Procedures

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

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

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

## Submission Process

Submission of a Letter of Intent (LOI) is required to apply for all award types **except** for Community Partnered Participatory Research Pilot Awards, Rapid Response Research to Accelerate Policy Awards, and Award Supplements. The LOI must be submitted electronically. Applicants will have access to the application materials if the LOI is approved, at which time applicants will receive an email notification. LOI submission instructions should be strictly followed as stated.

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

## Review Process and Funding Decisions

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

For more information about the funding process visit the [TRDRP website](https://trdrp.org/funding-opportunities/review-process/index.html) (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:

**Director, TRDRP**

Tracy Richmond McKnight, PhD  
(510) 987-9811, [Tracy.Richmond-McKnight@ucop.edu](mailto:Tracy.Richmond-McKnight@ucop.edu)

**Social Behavioral Sciences and Public Health**

Norval Hickman, PhD, MPH  
(510) 987-9032, [Norval.Hickman@ucop.edu](mailto:Norval.Hickman@ucop.edu)

**Policy Research and Environmental Sciences and Toxicology**

Raymond Boyle, PhD, MPH  
(510) 987-9959, [Raymond.Boyle@ucop.edu](mailto:Raymond.Boyle@ucop.edu)

**Cancer Prevention, Treatment and Biology**

Katherine McKenzie, PhD  
(510) 987-9876, [Katherine.McKenzie@ucop.edu](mailto:Katherine.McKenzie@ucop.edu)

**Biomedical, Cardiovascular and Oral Disease**

Ginny Delaney, PhD  
(510) 587-6292, [Ginny.Delaney@ucop.edu](mailto:Ginny.Delaney@ucop.edu)

**Biomedical, Neuroscience and Lung Disease**

Uta Grieshammer, PhD  
(510) 987-9636, [Uta.Grieshammer@ucop.edu](mailto:Uta.Grieshammer@ucop.edu)

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

**Research Grants Program Office (RGPO)**

[RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu)

(510) 987-9386

# APPENDIX A: RESEARCH PRIORITIES

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

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

## 1. Social and behavioral prevention and treatment

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

**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 among California priority groups. Tobacco-related health disparities (TRHDs) devastate individuals, families, communities and the economy.

### **Social determinants of health**

Multiple complex factors contribute to TRHDs. Research focused on reducing TRHDs should include innovative and creative approaches to measure and mitigate at least one social determinant of health that is associated with tobacco product use, tobacco control policy, or tobacco-related diseases. Understanding and reducing TRHDs requires consideration of intersectional groups and the interaction of individual, interpersonal/social, community/school, institutional, and policy factors across the tobacco use continuum and over the life span. Cultural factors and experiences with discrimination are important to consider when addressing the impact of environment, structural factors, and institutional/government policy on health.

### **Collaborations and community engagement**

TRDRP encourages researchers, educators, and academic institutions to collaborate closely with and seek input from nonprofit, community-based organizations, health centers and clinics, schools and other educational settings, tobacco control advocates and programs, American Indian tribal organizations, immigrant service organizations, employment development agencies, post-incarceration service agencies, migrant farmworker support agencies, and policymakers.

Community-based organizations with available infrastructure to manage grant funding are encouraged to apply for TRDRP funding and may play a lead role on a community-academic partnered participatory research project; however, community organizations and their affiliates should participate on a research project to the extent that their capacity and available resources allow. Collaborative research partnerships are needed:

- To address a tobacco-related research question(s) that community members have identified as critically important and that has a negative impact on a priority group in their community

- Between health care practitioners and academic researchers to develop a standard process for addressing tobacco product use that can be employed in clinical settings, and to promote systems level change in cessation-related clinical activities and healthcare policy
- To collect research findings that clarify the extent TRHDs affect a community and inform health protective public policy and tobacco control programming
- To build capacity and leadership among community-based organizations and other nonprofits for scientific research
- To train and prepare the next generation of leaders and advocates in tobacco control research

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

**Sub-focus areas and examples of relevant research topics that apply to California priority groups:**

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

- Impactful health service research that contributes to sustainable systems change in the clinical management of nicotine dependence and sustained coverage of tobacco treatments by health plans
- Examining the benefits and consequences of culturally-tailored tobacco treatments in clinical, school, or other community settings. Pilot tests and validation studies of promising interventions that help e-cigarette users with vaping cessation
- Mechanistic studies that highlight intervention components that contribute to quitting e-cigarettes regardless of product type used
- Health behavior change interventions that promote cessation of multiple tobacco product use, flavored tobacco product use, and tobacco-cannabis co-use
- Development and testing of new theories that support culturally sensitive health communications that consider intersectional identity and cultural factors in tobacco prevention and treatment
- Innovative health messaging strategies and communication toolkits for multiple tobacco product use, flavored tobacco product use, and tobacco-cannabis co-use
- Development and testing the efficacy and effectiveness of social media and mobile technologies in treatments to reduce or eliminate multiple tobacco product use, flavored tobacco use, and tobacco-cannabis co-use
- Scientific evaluations of tobacco prevention and treatment interventions informed by practice-based or community-based knowledge
- Testing evidence-based interventions efficacious for other health issues for similar efficacy or effectiveness in tobacco prevention and treatment interventions and community/school programs

**Harm reduction interventions**

- Testing the extent to which electronic smoking devices result in long-term elimination of combustible tobacco use or substitution
- Tracking health effects among long-term users of electronic smoking devices
- Developing intervention and mechanistic studies focused on sustained nicotine abstinence among successful cigarette quitters
- Examining the benefits and consequences of sustained use of multiple tobacco products
- Characterizing health effects and changes in dependence after long-term nicotine use, or the co-use of cannabis and tobacco products

- Development of a health communication theory or model to accurately inform the public about evidence-based harm reduction interventions

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

- Development of psychometrically rigorous measures that assess utility of youth tobacco prevention activities in and outside of classroom settings
- Scientific evaluations of practice-informed tobacco prevention efforts in diverse school, after school, and non-traditional education settings
- Development of youth-focused health communication strategies that address menthol and flavored tobacco, heated tobacco, pod mod tobacco, or cannabis use
- Community-based studies focused on reducing youth exposure to secondhand tobacco products and cannabis smoke and vapor

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

- Examination of the prevalence and initiation of multiple tobacco product use and tobacco-cannabis co-use among priority groups
- Identifying short- and long-term health effects of tobacco-cannabis co-use
- Development of psychometrically rigorous measures that accurately capture use patterns and dependence from use of electronic smoking devices, heated tobacco, flavored combustible tobacco, and tobacco-cannabis co-use
- Elucidation of social determinants associated with multiple tobacco product use and tobacco-cannabis co-use
- Contributing to a better understanding of cultural and health-related effects of tobacco-cannabis co-use

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

**Purpose:** TRDRP will support research into the causes, early detection, and effective treatment, care, prevention, and potential cures of cancers that the Report of the Surgeon General has identified as being caused by tobacco products. TRDRP will also support projects in which tobacco products or their constituents are integral to the proposed study.

**Background:** Despite the overall decline in cancer death rates in the last two decades (see “Annual Report to the Nation on the Status of Cancer”), disparities in cancer incidence and death rates persist even with greater public knowledge of cancer prevention and recent innovations in cancer screening and treatment. Certain populations, such as African Americans and other racial-ethnic minorities, Californians who live in rural areas or have household incomes below the poverty line and members of the LGBTQ community, 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 cancer prevention strategies and the implementation of evidence-based policy and practice interventions that can reduce the cancer burden in specific cultures and communities that are disproportionately affected by tobacco-related cancer. For instance, personal health care decisions, such as whether or how often to undergo cancer screening or whether to participate in clinical trials, are often influenced by policies governing health care insurance coverage and practice recommendations provided by health care providers. Studies have shown that changes in some current policy and practice recommendations may result in improved cancer surveillance and/or survival in underserved communities. It is therefore important to conduct research with the goal of determining and overcoming

the barriers to implementing system change and designing strategies to bring innovative healthcare solutions for tobacco-related cancers to all Californians.

The persistent high rate of cancer incidence and death among tobacco product users also underscores the need for continued research into the basic mechanisms of how tobacco products drive initiation and malignant progression of cancer and for the development of 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. For the development of therapeutic strategies, TRDRP places emphasis on those that can be implemented in remote, under-resourced clinics or that are targeted to specific cultures and communities that bear a high tobacco-related cancer burden.

An important area of research relates to new and emerging tobacco products. A recent consensus study report by the National Academies of Sciences, Engineering and Medicine concluded that switching from combusted tobacco cigarettes to e-cigarettes reduces exposure to numerous toxicants and carcinogens present in combusted tobacco cigarettes. However, e-cigarettes contain highly variable amounts of potentially toxic substances and there is no available evidence from adequate long-term animal bioassays of e-cigarette aerosol exposures to inform cancer risk. Similarly, it is unknown whether or not e-cigarette use is associated with intermediate cancer endpoints in humans. The continuously changing landscape of electronic nicotine delivery systems poses a particular challenge to understanding their health effects. TRDRP is especially interested in studies that investigate the effects of new and emerging tobacco products, or their individual constituents such as flavorants and nicotine, on cancer risk. In never smokers, what is the harm of e-cigarette use? In smokers who completely switch to e-cigarette use, is there a relative benefit or is there additional harm of e-cigarette use?

#### **Sub-focus areas and examples of relevant research topics:**

##### **Development and dissemination of effective cancer prevention strategies for California populations disproportionately impacted by tobacco-related cancer.**

- Behavioral, clinical and/or pre-clinical studies on preventing tobacco-related cancers
- Studies of effective methods for disseminating existing prevention programs into low income communities
- Develop and assess effectiveness and dissemination approaches for a tobacco-related cancer prevention program designed for Vietnamese males

##### **Implementation of evidence-based health care policy and/or practice changes that show promise for reducing tobacco-related cancer deaths and health disparities in California.**

- Evaluation of emergency room intake procedures and their ability to identify patients at risk for tobacco-related cancer; design and assessment of effective approaches to inform those patients of the benefits of cancer screening
- Evaluation of the quality/effectiveness of information about lung cancer screening and proximity to low-dose computed tomography (CT) services in California's Central Valley
- Development of a combined behavioral and medical health care team approach to increasing the racial and ethnic diversity of clinical trial cohorts

##### **Translational research studies of new detection and treatment strategies for tobacco-related cancers**

- Therapeutic efficacy studies of new biologics in small or large animal models of tobacco-related cancers
- Development of "theranostic" molecular imaging methods for simultaneous diagnosis and treatment of tobacco-related cancer

- Development of effective early detection techniques and precision medicine therapeutic strategies tailored to African-American lung cancer patients
- Studies of innovative patient care strategies to improve response to therapy and/or quality of life for patients with pancreatic cancer
- Palliative care interventions for seriously ill cancer patients and their families in rural areas

**Basic research studies of the molecular genetic mechanisms of tobacco-related cancer initiation, progression and resistance to therapy**

- Characterization of newly discovered genetic or epigenetic alterations in lung cancer
- Molecular studies of the initiation and malignant progression of hepatocellular carcinoma
- Pathways in the development of resistance to PD-1/PD-L1 targeted immunotherapies in tobacco-related cancers
- Evaluation of the effects of e-cigarette use or e-liquid constituents, such as nicotine or flavorants, on disease progression in small cell lung cancer
- The role of tobacco products in the initiation and progression of breast cancer

### **3. Cardiovascular and cerebrovascular diseases**

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

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

Health disparities exist among Californians diagnosed with CVD and CVA. According to the 2012 California Health Interview Survey, Native Americans and African Americans reported substantially higher rates of CVD than other ethnic groups. In addition, Californians with less education and those living in poverty also reported higher rates of cardiovascular disease. As reported in the 2016 “Burden of Cardiovascular Disease in California,” between 2000 and 2014 death from CVD was substantially higher among African Americans and Pacific Islanders as compared to other racial/ethnic groups. Among Californians, strokes occur most frequently among African American and multiracial adults over 65. Between 2000 and 2014, death resulting from stroke was higher among African Americans and Pacific Islanders than other racial/ethnic groups. Research into interventions to reduce CVD and CVA among these and other priority groups is urgently needed.

The emergence of electronic cigarettes and other tobacco products that deliver nicotine aerosolized in various solvents raises urgent new questions. In addition, the iQOS product, recently approved for sale by the FDA, and advertised to “heat-not-burn” tobacco has been reported by the tobacco industry to reduce health risk relative to combustible tobacco products, although these studies have not been corroborated by independent research teams. Use of these new and emerging tobacco products has soared in the last few years, particularly among adolescents, and is expected to overtake the

conventional cigarette market within the next decade. Due to the rapid uptake of these products among young people and the lack of existing regulation of these products, research is vital to understand more about the toxicity profile of these products and their potential for harm. The National Academies of Sciences, Engineering and Medicine recently published a consensus report of the health effects related to the use of e-cigarettes and identifying gaps and opportunities for future research. The report states that “There is *no available evidence* whether or not e-cigarette use is associated with clinical cardiovascular outcomes (coronary heart disease, stroke, and peripheral artery disease) and subclinical atherosclerosis (carotid intima-media thickness and coronary artery calcification).”

TRDRP support for this priority focuses on (1) identifying mechanisms by which e-cigarettes, iQOS, and other new and emerging tobacco products may harm the cells and tissues of the heart and vasculature; (2) human and animal studies of the effects of new and emerging tobacco products on the cardiovascular and cerebrovascular system (3) new interventions to decrease CVD and CVA health disparities among priority groups (see a list of priority groups under **Research Award**).

### **Sub-focus areas and examples of relevant research topics:**

#### **Effects of new and emerging tobacco products on the development of or complications of CVD or CVA**

- How new and emerging tobacco products affect oxidative stress, mitophagy, and endothelial cell function.
- Effect of nicotine, and or e-liquid flavorings on cardiovascular diseases such as:
  - Cardiomyopathy
  - Vascular function/vasoconstriction
  - Inflammatory responses leading to atherosclerosis and thrombosis

#### **Determining the causal link (if any) between atrial fibrillation (AF) and combustible and/or new and emerging tobacco products.**

- Epidemiological studies of combustible tobacco product users to identify causal links to atrial fibrillation.
- Human studies of new and emerging tobacco users to explore the effects of nicotine and flavorings on arrhythmogenic phenotypes.

#### **Population-level studies to assess the cardiovascular and cerebrovascular risk posed by new and emerging tobacco products**

- Studies of biological samples from new and emerging tobacco product users to determine whether subclinical markers of CVD and CVA are altered.
- Genomic studies of new and emerging tobacco users to assess epigenetic changes across the genome.
- Epidemiological studies of new and emerging tobacco product users to identify emerging health issues.

#### **New, culturally appropriate interventions to decrease CVD and CVA health disparities among priority groups**

- Community-based participatory research partnerships that address commercial tobacco-related CVD and CVA health disparities. (see CPPRA pilot grant mechanism guidance on page 39)
- Evaluation of interventions to decrease commercial tobacco-related health disparities in priority populations.

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

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

### Sub-focus areas and examples of relevant research topics:

#### Understanding exposure

- Toxicity levels and markers of exposure to e-cigarette constituents and aerosol
- Toxicology and risk profiles of new tobacco products
- Characterization of biomarkers of exposure from all tobacco products and studies on the persistence of biomarkers of combustible tobacco use in former smokers
- Characterization of biological absorption of e-liquid flavorants

#### Understanding cannabis exposure

- Measuring biomarkers of exposure to cannabis and tobacco
- Measuring different methods of cannabis product use

#### Studies of environmental waste and bioaccumulation

- 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
- Other environmental pollutants contributing to tobacco-related disease

#### Interventions to reduce SHS and THS exposure

- Current local policy approaches to controlling aerosol and tobacco smoke exposure in multi-unit housing, indoor public spaces and other settings such as cars, and hotels
- Policies to minimize involuntary exposure to SHS, secondhand vape aerosol, and the

- associated health risks in all public settings
- THS, pathways of exposure characterization, risk evaluation and toxicology
- Epidemiology of tobacco use and exposure, field measurements and factors of risk assessment

*NOTE: TRDRP currently funds a statewide research consortium on [thirdhand smoke research](https://trdrp.org/highlights-news-events/thirdhand-smoke-consortium.html). (trdrp.org/highlights-news-events/thirdhand-smoke-consortium.html). TRDRP invites additional innovative research on THS under this call. Applicants who plan to pursue THS research are encouraged to conceptualize an approach that may benefit from the existing THS research capacity, infrastructure and methodologies generated through this consortium. Please contact TRDRP staff for additional information.*

## 5. Neuroscience of nicotine addiction and treatment

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

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

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

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

The effects of co-use of nicotine with other substances such as alcohol and cannabinoids is another key area of research, especially in light of the recent legalization of recreational cannabis in California. Adolescents are particularly susceptible to addictions because of the formative stage of their brain development, and they often experiment with multiple substances of abuse, consumed separately or combined in new nicotine delivery devices. It is important, therefore, that we understand the biology and behavioral aspects of co-use of nicotine with other substances of abuse among adolescents.

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

**Sub-focus areas and examples of relevant research topics:**

**Biology and behavior of nicotine dependence**

- Multi-parametric risk factors of nicotine addiction and response to treatment in vulnerable populations
- Studies of brain connectivity and interaction between neural pathways utilized by different agonists (e.g., glutamatergic, cholinergic, dopaminergic, etc.) in response to nicotine
- The neurological effects of complete switching from combusted to e-cigarettes in veterans
- Effects of flavorants and other constituents of e-cigarette aerosol on nicotine addiction
- Neuroimaging or other clinical studies of the acute effects of nicotine or flavorants, alone or combined, on human brain structure and function

**Biology and behavior of cessation**

- The mechanistic characterization of biological and behavioral differences between female and male e-cigarette users during withdrawal
- Studies of the side effects of existing cessation drugs in priority populations such as various racial/ethnic, sexual or socioeconomic sectors that are often not fully represented in clinical trials

**Treatments for nicotine addiction – conventional cigarettes and new tobacco products**

- Development and neurological characterization of cessation approaches for e-cigarette-only and dual users
- Development and neurological characterization of personalized treatment approaches for tobacco use disorders in LGBTQ individuals

**Harm potential of new and emerging tobacco products on the developing brain**

- The molecular, cellular and behavioral effects of nicotine, with and without flavorants, on the developing brain

**Biology and behavior of co-use of nicotine with other substances of abuse**

- The study of the impact of other substances of abuse on the molecular, cellular and behavioral effects of nicotine on the developing brain
- Addictive potential of combined nicotine and cannabinoid use in African American youth

NOTE: While submission of projects focused on co-use of tobacco with other substances of abuse are welcome, studies in “Neuroscience of nicotine addiction and treatment” that address non-tobacco substances (e.g. cannabinoids) only are **not** eligible under this Call.

## 6. Oral diseases and dental health

**Purpose:** Support innovative and high impact research that advances the understanding of the effects of combustible and new and emerging tobacco products on dental health and develops approaches to detect, prevent, and treat tobacco-related oral disease.

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

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

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

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

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

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

### **Sub-Focus areas and examples of relevant research topics:**

#### **Tools and cost-effective diagnostic methods of early detection of tobacco-related oral diseases**

- New approaches to make early detection of oral disease more cost effective and accessible.
- Research into interventions to reduce oral cancer incidence and mortality among priority groups

#### **The impact of nicotine and flavored e-liquids on oral health**

- Investigation of causal pathways from new and emerging tobacco product use to oral diseases and conditions
- The effect of nicotine on the oral microbiome, dental caries, periodontitis or tooth loss
- The effect of flavorings on the oral microbiome, dental caries, periodontitis or tooth loss
- Investigations of carcinogenic properties of nicotine and flavorings in oral cancer

### **Evaluation of cessation strategies practiced by dental professionals**

- Motivational interviewing in the detail clinic to encourage commercial tobacco product cessation
- Evaluation of ethnically and culturally sensitive cessation strategies in priority populations.

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

- Pathophysiology and biomarkers of oral squamous cell carcinoma (OSCC)
- How new and emerging tobacco products affect dental caries, periodontitis or tooth loss
- Role of oral microbial entities in oral cancers, inflammatory and degenerative aspects of disease progression
- Potential causal pathways from new and emerging tobacco product use to oral diseases and conditions

## **7. Pulmonary biology and lung diseases**

**Purpose:** Support innovative, timely and high impact research addressing basic, translational or clinical aspects of tobacco-related pulmonary biology and lung diseases. TRDRP will support studies on lung diseases that the Report of the Surgeon General has identified as being caused by tobacco-related products. TRDRP will also support projects in which tobacco-related products or their constituents are integral to the proposed study. Research that can inform FDA regulations on new and emerging tobacco products is of particular interest.

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

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

An important area of research relates to new and emerging tobacco products. A recent consensus study report by the National Academies of Sciences, Engineering and Medicine concluded that switching from combustible tobacco cigarettes to e-cigarettes reduces exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes. However, e-cigarettes contain highly variable amounts of potentially toxic substances and it is not known whether or not e-cigarettes cause respiratory diseases in humans. Recently, there have been reports of an increase in severe pulmonary disease associated with using e-cigarettes, triggering a health advisory from the Center for Disease Control and Prevention (CDC) and the California Department of Public Health (CDPH). The continuously changing landscape of electronic nicotine delivery systems poses a particular challenge to understanding their health effects, and TRDRP is especially interested in studies that investigate the pulmonary effects of new and emerging tobacco products, or their individual constituents such as e-liquid vehicle or flavorants. In never smokers, what is the harm of e-cigarette use? In smokers who completely switch to e-cigarette use, is there a relative benefit or is there additional harm of e-cigarette use? In addition, since some new tobacco products, such as e-cigarettes, deliver nicotine in the absence of well-known toxins present in tobacco smoke, it is of interest to better understand the potential effects of nicotine itself on lung health.

In light of the recent legalization of cannabis in California, it is important to understand its impact on tobacco-related disease. TRDRP invites proposals to study the effects of smoking or vaping cannabis on the initiation and progression of tobacco-related lung diseases and the pulmonary effects caused by co-use of tobacco and cannabis.

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

**Sub-focus areas and examples of relevant research topics:**

**Mechanistic studies to better define the effects of tobacco products and their constituents on lung biology**

- Epigenetic changes in various lung cell types in animals or humans exposed to inhaled e-cigarette aerosol, role of nicotine or flavorants
- Cellular interactions or molecular pathways that drive the inflammatory response in the lungs of hookah users

**Mechanistic studies to better define the etiology and progression of lung diseases caused by tobacco products or their constituents**

- The molecular mechanisms and genetics of differences in COPD susceptibility and progression, including sex differences
- The role of combusted tobacco smoke or new and emerging tobacco products in the development and exacerbation of asthma or idiopathic pulmonary fibrosis
- Big data / data-driven approaches to understand factors contributing to COPD exacerbations in different priority populations

**Development of diagnostic and therapeutic approaches for the prevention and treatment of tobacco-related lung diseases**

- Development of wearable devices to diagnose tobacco-related lung disease and track its progression
- Drug repurposing for the treatment of COPD
- Development of targeted, precision medicine approaches to treating COPD in American Indian / Alaska Natives

**Discovery and understanding of lung disease related to co-use of different tobacco products and co-use of tobacco products with other substances of abuse**

- Inflammatory responses and mechanisms that lead to COPD in response to co-use of tobacco and cannabis
- Characterization of molecular and cellular effects and functional differences in the lungs of combustible cigarette smokers, e-cigarette users and dual users.

**Effects of pre-natal and neonatal exposure to tobacco products or their constituents on lung development and disease**

- Development of an animal model of e-cigarette inhalation during pregnancy and analysis of the effects of nicotine and different flavorants on lung development in offspring

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

## 8. State and local tobacco control policy research

**Purpose:** Advance the ability of state agencies, legislative and regulatory bodies and local governments throughout California to evaluate, understand and implement science-informed tobacco control policy. Reducing tobacco use to low levels will continue to require local community actions. Beverly Hills ban of tobacco sales is an example of a new transition away from commercial tobacco. Policy research will be needed to test new ideas.

**Background:** The tobacco control policy landscape continues to change rapidly in response to the introduction of new and novel products. New policy research ideas should examine the retail industry, tobacco industry marketing, flavorants, cannabis use, and youth interest in new products. The tobacco industry spends billions of dollars marketing tobacco products through the retail environment and these channels are important to efforts to reduce youth tobacco product access. There is an opportunity for community partnerships to focus on evidence-based policy adoption.

In 2020, we have added a new award type: Rapid Response Research to Accelerate Policy. This two-year grant supports teams of researchers working in partnership with advocates, community members, policymakers and other decision makers to identify emerging local tobacco policy issues, conduct research on these issues, and disseminate the research results in a timely way. The research conducted under this award mechanism can be descriptive, analytical, or address causal relationships among new or existing policies and should focus on informing policies that reduce tobacco-related health disparities. Further details are provided in Appendix B.

### Sub-focus areas and examples of relevant research topics:

#### Retail, Marketing and youth Initiation

- Countering tobacco industry marketing and corporate social responsibility efforts
- Protecting youth from tobacco and cannabis marketing
- Tobacco control policy interactions with cannabis control policy
- Testing methods of retail stores tobacco sales reduction

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

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

#### Menthol and flavored tobacco regulation

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

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

- Advancing mobile health interventions for tobacco treatment and healthcare policy
- Studies that examine basic minimum income as a cessation mechanism
- Studies of tobacco treatment in locations such as pharmacies
- Testing enhanced smoking cessation treatment in healthcare settings
- Research to understand cut-down-to-quit as a treatment for smoking

## 9. Other tobacco-related health effects

**Purpose:** TRDRP supports research projects on diseases not included in TRDRP priority areas 1-8, as long as the disease has been identified as being causally associated with tobacco smoking in the Report of the Surgeon General or if tobacco-related products or their constituents are integral to the proposed study.

## APPENDIX B: DETAILS ON GRANT AWARD TYPES

### 1. Research 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 promising preliminary or supporting data. Proposals should reflect a clear progression beyond the earliest phases of the work. Research Award applications should not be exploratory in nature or lacking strong supporting data.

In an effort to more closely align funding with the most urgent questions in tobacco control, Research Awards must focus on **tobacco-related health disparities or research on new and emerging tobacco products**.

Eligibility criteria:

1. Research on reducing tobacco-related health disparities in priority groups and research that promotes a smoke-free life and environment among the following priority groups<sup>1</sup> (alphabetical listing) and other groups with high rates of tobacco use:
  - Current members of the military and veterans
  - Individuals employed in blue-collar jobs, agriculture, and the service industry
  - School-aged youth and young adults
  - Incarcerated and formerly incarcerated individuals
  - Individuals with mental illness, including substance use disorders
  - People of low socioeconomic status, including the homeless
  - People with disabilities
  - People with limited education including, high school non-completers
  - Pregnant and breastfeeding women
  - Racial/ethnic minorities (e.g., African Americans, American Indians and Alaska Natives, Asian Americans, Latinos, Native Hawaiians and other Pacific Islanders, and individuals identifying with multiple racial groups)
  - Rural residents
  - Sexual/gender minorities (e.g., Lesbian, Gay, Bisexual, Transgender people)

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

2. Research on new and emerging tobacco products including electronic nicotine delivery devices (e-cigarettes, heat not burn devices), nicotine gels, hookah (water pipe tobacco), atomizers, vaping tanks and mods, dissolvable tobaccos, and other new smokeless tobacco (e.g. snus).

Researchers may focus on other new and emerging tobacco products as long as they provide an explanation of the tobacco product they propose to study.

### Research Award overview:

- **Must clearly address tobacco-related health disparities or new and emerging tobacco products**
- **Maximum award amount per year:** \$250,000 (direct costs)
- **Maximum duration:** 3 years
- **Allowable direct costs:** Salaries, fringe benefits, supplies, publishing, sub-contracts\*, equipment (costing more than \$5,000), travel
- **Travel:**
  - **Project-related travel:** As needed (must be fully justified)
  - **Travel to TRDRP conference:** \$750 (mandatory)
  - **Scientific conference travel:** Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30 percent, or 26 percent for projects conducted off-campus.

\*All out-of-state sub-contracts, collaborations, and expenditures 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 effort each year to activities supported by this award
- U.S. citizenship is not a requirement

### Review criteria:

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

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

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

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or

preventative interventions that drive the field of tobacco-related research or any of the stated research priorities?

- **Research plan:** Are the conceptual framework, design (including composition of study population and strength of recruitment plan), methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Has the applicant adequately considered whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments? 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 go beyond the research community and include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project.
- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, the adequacy of plans to include subjects of both genders, all racial and ethnic groups (and subgroups) and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of human subjects 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. Pilot 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 for future impact are two key components of this award, with the ultimate goal of providing initial support for research with a strong rationale, resulting in the leverage of funding from other funding agencies.

- **Maximum award amount per year:** \$200,000 (direct costs)
- **Maximum duration:** 2 years
- **Allowable direct costs:** Salaries, fringe benefits, supplies, publishing, sub-contracts\*, equipment (costing more than \$5,000), travel
- **Travel:**
  - **Project-related travel:** As needed (must be fully justified)
  - **Travel to TRDRP conference:** \$750 (mandatory)
  - **Scientific conference travel:** Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30 percent, or 26 percent for projects conducted off-campus

\*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 effort each year to activities supported by this award
- U.S. citizenship is not a requirement

### Review criteria:

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

- **Responsiveness to intent of the award type:** Is the study pilot or exploratory in nature? Does the study represent a new research trajectory that is not currently funded from other sources? Does the applicant describe how the pilot study will lead to an expanded research effort in the future, including specific funding sources and award types?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?
- **Innovation:** Does the research propose new paradigms, challenge existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies, adaptations of existing methods or technologies to new uses or with understudied populations? Does the proposed research represent more than an incremental advance upon published data? For example, does the project challenge existing interventions, clinical practice or policy; address an innovative hypothesis or critical barrier to progress in the field?

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

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field of tobacco-related research or any of the stated research priorities?
- **Research plan:** Are the conceptual framework, design (including composition of study population and strength of recruitment plan), methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Has the applicant adequately considered whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments? Does the applicant acknowledge potential problem areas and consider alternative strategies?
- **Near-term leveraging potential:** When the TRDRP-funded studies under a Pilot 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? How likely can the applicant leverage funding from other sources to further develop this area of research within two to three years after initial funding?

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

- **Investigators:** Are the investigators appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support?
- **Community engagement and communication plan:** Does the applicant propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing about the nature and significance of the research outcomes. To what extent does the dissemination of relevant results of funded research go beyond the research community and include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project
- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed
- **Inclusion of women, minorities and children in research:** If human subjects are involved, the adequacy of plans to include subjects of both genders, all racial and ethnic groups (and subgroups) and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of human subjects will be evaluated.
- **Care and use of vertebrate animals in research:** If vertebrate animals are involved in the project, plans for their care and use will be assessed.

### 3. New Investigator Award

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

- **Maximum award amount per year:** \$200,000 (direct costs)
- **Maximum duration:** 3 years
- **Allowable direct costs:** Salaries, fringe benefits, supplies, publishing, sub-contracts\*, equipment (costing more than \$5,000), travel
- **Travel:**
  - **Project-related travel:** As needed (must be fully justified)
  - **Travel to TRDRP conference:** \$750 (mandatory)
  - **Scientific conference travel:** Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30 percent, or 26 percent for projects conducted off-campus.

\*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 PI-status at the sponsoring institution at the time of award start date.
- Please note that the New Investigator awards offered by the NIH are different from those offered by TRDRP. TRDRP New Investigator Awards are not mentored awards and require an independent PI status at the sponsoring institution. Applicants who do not currently have PI status are required to submit a letter from their Department Chair stating that the applicant will be granted PI status by the award start date.
- Awardees are required to commit at least 50 percent of their effort each year to activities supported by this award
- At the time of award start date, no more than five years should have elapsed since an applicant completed formal postdoctoral training, or since the doctoral degree if no postdoctoral training. Some applicants may have lapses in their research or research training, or may have periods of less than full-time effort. TRDRP will consider requests to extend the new investigator eligibility period for reasons that may include but are not limited to: medical conditions, disability, family care responsibilities, clinical training, natural disasters, or active duty military service. These exceptions will be determined on a case-by-case basis at the sole discretion of TRDRP. Please briefly describe the reason for the requested extension and the number of months for the requested extension in your Letter of Intent.
- If a New Investigator Award application is resubmitted, the eligibility period is based on the award state date of this Call for Applications.
- **Applicant must enter the end date of last postdoctoral training, as listed in their Biographical Sketch.**
- U.S. citizenship is not a requirement

## Review criteria:

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

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

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

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice? What will be the effect of these studies on the concepts, methods, technologies, treatments, services or preventative interventions that drive the field of tobacco-related research or any of the 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? Has the applicant adequately considered whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments? Does the applicant acknowledge potential problem areas and consider alternative strategies?
- **Near-term leveraging potential:** When the TRDRP-funded studies under a New Investigator Award are completed, is there compelling promise and high likelihood that their results will constitute a larger R01-level or P01-level study with high probability of funding from another agency such as the NIH? With TRDRP funding of the proposal, can the applicant leverage funding from other sources to further develop this area of research within two to three years after initial funding?

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

- **New Investigator status and research team:** Does the PI applicant strongly fit the criteria for the New Investigators Award? Is the research team appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support?

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

#### Other considerations

- **Budget:** Appropriateness of the budget request for the project, scientific or budgetary overlap and degree to which out-of-state contracts or collaborations are essential for the project.
- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, the adequacy of plans to include subjects of both genders, all racial and ethnic groups (and subgroups) and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of human subjects 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 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 TRDRP research priorities.

- **Maximum stipend amount per year:** Up to \$60,000
- **Maximum duration:** 3 consecutive years
- **Allowable direct costs include:** Stipend, tuition & fees, institution allowance, publishing, and travel to TRDRP conference
  - **Stipend:** Postdoctoral stipend must adhere to NIH experience scale or the rates set by their institution with institutional documentation of the alternate payment scale
  - **Tuition and Fees:** Postdoctoral Trainees will be provided 60% of tuition and fee costs, up to \$16,000 per year. If funded, TRDRP will request documentation of the institution's tuition and fees structure.
  - **Institution Allowance:** The applicant may request an institutional allowance to help defray the cost of 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 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 Postdoctoral Awards are not provided as a condition of employment with either TRDRP or the sponsoring institution, institutions may not seek funds, or charge individual awards, for costs that normally would be associated with employee benefits (FICA, workman's compensation, life insurance, union dues, and unemployment insurance).

#### **Requirements:**

- A minimum 75 percent time commitment on the part of the postdoctoral trainee is required
- The candidate must be recognized by the applicant institution as a postdoctoral trainee no later than the award start date.
- The application must be prepared and submitted by the trainee and must outline an original research project (distinct from the project of a mentor, whether funded by TRDRP or another source). Feedback on the application by mentors or others is highly recommended.
- A letter of support from the mentor and a minimum of two additional references are required. Letters should address the candidate's training, potential and the commitment of the mentor and the department to the candidate's career development. In addition, the mentor must provide their biosketch and a detailed mentoring plan that is prepared in consultation with the applicant.
- The mentoring plan should be unique to the applicant and tailored to address the specific needs of the applicant.
- U.S. citizenship is not a requirement

#### **Review criteria:**

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

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

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

- **Mentor's qualifications and commitment:** Based on the advisor and the department, as demonstrated by the mentor's biosketch, letters of support and training plan, the quality of the training resources and environment.
- **Environment:** Does the institutional environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support and commitment?
- **Community engagement and communication plan:** Does the trainee 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 go beyond the research community and include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public?

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

- **Research plan:** Are the conceptual framework, design (including composition of study population and strength of recruitment plan), methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Has the applicant adequately considered whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments? Does the applicant acknowledge potential problem areas and consider alternative strategies? Will the proposed research training experience significantly contribute to the development of the candidate's career potential as a researcher in the proposed area?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?

### Other considerations

- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk of 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 human subjects 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 Award

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

- **Maximum stipend amount per year:** Up to \$30,000
- **Maximum duration:** 3 consecutive years
- **Allowable direct costs include:** Stipend, tuition & fees, institution allowance, publishing, and travel to TRDRP conference
  - **Stipend:** Up to \$30,000 a year
  - **Tuition and Fees:** Predoctoral students will be provided 60% of tuition and fee costs, up to \$16,000 per year. Students enrolled in formally combined, dual degree training will be provided 60% of tuition and fee costs, or up to \$21,000 per year. If funded, TRDRP will request documentation of the institution's tuition and fees structure.
  - **Institution Allowance:** The applicant may request an institutional allowance to help defray the cost of expenses such as health insurance, medical liability or other special insurance, research supplies, equipment, books and travel to scientific meetings and other project-related travel. These costs will be covered up to **\$4,200** per year. 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 predoctoral awards are not provided as a condition of employment with either TRDRP or the sponsoring institution, institutions may not seek funds, or charge individual awards, for costs that normally would be associated with employee benefits (FICA, workman's compensation, life insurance, union dues, and unemployment insurance).

**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 application submission.
- The application must be prepared and submitted by the student and must outline an original research project (distinct from the project of a mentor, whether funded by TRDRP or another source). Feedback on the application by mentors or others is recommended.
- A letter of support from the mentor and a minimum of two additional references are required. Letters should address the candidate's training, potential, and the commitment of the mentor and department to the candidate's career development. In addition, the mentor must provide their biosketch and a detailed mentoring plan that is prepared in consultation with the applicant.
- U.S. citizenship is not a requirement.

**Review criteria:**

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

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

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

- **Mentor's qualifications and commitment:** Based on the advisor and the department, as demonstrated by the advisor's biosketch, the letters of support and training plan, the quality of the training resources and environment.
- **Environment:** Does the institutional environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support and commitment?

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

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

- **Research plan:** Are the conceptual framework, design (including composition of study population and strength of recruitment plan), methods and analyses adequately developed, well-integrated and appropriate to the aims of the project? Has the applicant adequately considered whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments? Does the applicant acknowledge potential problem areas and consider alternative strategies? Will the proposed research training experience significantly contribute to the development of the candidate’s career potential as a researcher in the proposed area?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?

### Other considerations

- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk of 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 human subjects 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. Rapid Response Research to Accelerate Policy Award

**Purpose:** Although California is a leader in local efforts to advance tobacco control policy, some communities are further ahead in developing these policies. This award mechanism will bridge this gap and generate ideas for local tobacco control policy. The goal is to identify ways local communities can reduce tobacco use and tobacco exposure through local policies.

**\*\*\*Important Note: Applicant teams are required to review and respond to a separate RFA for this grant type that will be available in late October 2019\*\*\***

## 7. Pilot Community-Partnered Participatory Research Award (Pilot CPPRA)

**Purpose:** This award supports a two-year, pilot research grant to build equitable and sustainable partnerships in order to plan and conduct meaningful research that will impact community- and school-level tobacco use and inform evidence-based prevention and treatment programs and interventions or

contribute to practice changes in clinics and schools. This grant type has multiple requirements, including a collaborative, equitable research partnership comprised of a Community Co-PI and Academic Co-PI to gather preliminary data or demonstrate proof-of-concept for a tobacco-related research question of importance to the community of interest and that advances science. There must be a clearly stated intention to sustain the community-academic partnership; plans to apply for follow-on funding after the pilot phase grant expires; plans to eventually develop a research-informed, community-forward prevention or treatment intervention; or contribute to tobacco-related practice or program enhancement in communities, schools, or clinics.

**\*\*\*Important Note: Applicant teams are required to review and respond to a separate RFA for this grant type that will be available in late October 2019\*\*\***

## AWARD SUPPLEMENTS

Grantees of active TRDRP awards are eligible to apply for Award Supplements. Application materials are provided upon request from [RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu), and applications are reviewed by TRDRP staff.

### Student Research Supplement

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

**Mentor eligibility:**

- Recipients of non-mentored TRDRP grants, such as Research Awards, are eligible to apply for a Student Research Supplement.
- Principal Investigators of Postdoctoral and Predoctoral Awards are **not** eligible to apply for a Student Research Supplement.

**Student eligibility:**

- Undergraduate and master's students are eligible for a Student Research Supplement
- Students enrolled in a predoctoral degree program are **not** eligible for this supplement and should apply for the Predoctoral Award.

**Supplement details:**

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

### Supplement submission procedure:

- To be considered for funding, an application for a Student Research Supplement must be submitted as part of a scientific progress report for an active non-mentored TRDRP grant. Investigators must have at least one year remaining on their TRDRP parent award to ensure the best conditions and results for prospective trainees.
- Please contact the Contracts and Grants team at the UCOP Research Grants Program Office for application materials by emailing [RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu).
- At the time of submitting your annual scientific progress report, **please contact your program officer via email**, letting them know you are including a supplement application in your progress report.

## Cornelius Hopper Diversity Supplement

**Purpose:** The Cornelius Hopper Diversity Supplements are intended for trainees and California residents from underrepresented communities and/or those who wish to pursue careers in one or more stated TRDRP research priorities focused on underserved communities. The Supplement should support their initial entry into the field of tobacco-related research or within the stated TRDRP research priorities.

Principal investigators with an active TRDRP grant should encourage trainees from socioeconomic, cultural, ethnic, racial, linguistic and geographic backgrounds who are not well-represented in the tobacco control research 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.

### Mentor eligibility:

- Recipients of non-mentored TRDRP grants, such as Research Awards, are eligible to apply for a Cornelius Hopper Diversity Supplement.
- Principal Investigators of Postdoctoral and Predoctoral Awards are **not** eligible to apply for a Cornelius Hopper Diversity Supplement.

### Candidate eligibility:

- Undergraduate students, master's students and graduate students are eligible for a Cornelius Hopper Diversity Supplement.
- Individuals who are working in the tobacco control field or proposed research area but do not have experience in research, community members, school personnel or students are eligible for a Cornelius Hopper Diversity Supplement.
- Individuals who have earned a doctoral degree (e.g. Ph.D., M.D., J.D. ) are **not** eligible to be supported by this Supplement.

### Supplement details:

- **Maximum supplement amount per year:** \$20,000 (direct cost)
- **Maximum duration:** 2 years
- **Allowable direct costs:** Salary and benefits, tuition, enrollment fees for the trainee, supplies, domestic travel
- **Equipment:** Not allowed as part of this supplemental funding
- **Supplies and Travel:**

- **Project-related travel:** As needed (must be fully justified)
- **Travel to TRDRP conference:** \$750 (mandatory)
- **Scientific conference travel:** Up to \$2,000 per year (excluding TRDRP Conference)
- **Supplies:** Up to \$2,200 (must be fully justified)
- **Indirect costs:** Not allowed

#### Supplement submission procedure:

- To be considered for funding, an application for a Cornelius Hopper Diversity Award Supplement must be submitted as part of a scientific progress report for an active, non-mentored TRDRP grant.
- Investigators must have at least one year remaining on their TRDRP parent award to ensure the best conditions and results for prospective trainees.
- Please contact the Contracts and Grants team at the UCOP Research Grants Program Office for application materials by emailing [RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu).
- At the time of submitting your annual scientific progress report, **please contact your program officer via email**, letting them know you are including a supplement application in your progress report.

## Dissemination Supplement

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

#### Eligibility:

- Recipients of all TRDRP grants are eligible to apply for a Dissemination Supplement.

In order to qualify for funding, the planned activities must be directly related to your research funded by TRDRP. Requests for publication costs must be accompanied by documentation of manuscript acceptance from a peer-reviewed journal. The dissemination activity must take place primarily in California and/or involve California investigators and include, where applicable, discussants and speakers funded by TRDRP. The cost associated with an online broadcast or archiving of an in-person conference (i.e., webcast or webinar) that includes TRDRP-funded research findings is eligible for support under this Dissemination Supplement.

#### Supplement details:

- **Maximum supplement amount:** \$5,000 (direct cost)
- **Allowable direct costs:** publication costs, meeting-related expenses.
- **Equipment:** Not allowed as part of this supplemental funding
- **Supplies and Travel:**
  - **Travel:** No cap, all travel-related costs must be fully justified. Some travel accommodations might not be allowed due to UCOP Travel Policy
  - **Supplies:** must be fully justified
- **Indirect costs:** Not allowed

#### Supplement submission procedure:

- To be considered for funding, an application for a Dissemination Supplement must be submitted

as part of a scientific progress report for an active TRDRP grant.

- **Please contact a TRDRP program officer regarding the appropriateness of your proposal prior to submission.**
- Please contact the Contracts and Grants team at the UCOP Research Grants Program Office for application materials by emailing [RGPOGrants@ucop.edu](mailto:RGPOGrants@ucop.edu).
- At the time of submitting your annual scientific progress report, **please contact your program officer via email**, letting them know you are including a supplement application in your progress report.