

2022 Call for Applications

New Changes and Key Requirements

- All applications received for the 2022 Call¹ must clearly address tobacco use prevention, tobacco cessation, or tobacco-related disease.
- Submission of a Letter of Intent (LOI) is **required** for all award types. LOIs will be programmatically reviewed to ensure eligibility and applicants will be notified whether they are eligible to submit a full application within 10 days of the LOI deadline. LOIs for Smoke and Vape-Free Scholars Initiative will be reviewed on a rolling basis.
- To help identify research that directly and immediately supports the <u>Endgame Policy Platform</u>, following programmatic review of LOIs, TRDRP will conduct a blinded-review of LOIs submitted for Pilot Awards, Research Awards and New Investigator Awards. See <u>Appendix B</u> for more details
- Guidance for preparing a Community Engagement and Communications Plan has been updated to assist TRDRP-funded researchers in communicating with communities most impacted by commercial tobacco use.
 The goal is to empower members of those communities to influence decisions and policies that promote health equity and reduce negative impacts of tobacco in their communities
- Annual budgetary caps on the Direct Costs for the following awards have been increased: Research Award
 (\$300,000), Pilot Awards (\$250,000), Pilot CPPRA (\$250,000 per Co-PI) and Full CPPRA (\$300,000 per Co-PI).
 See Appendix B and the CPPRA RFP for more details
- Postdoctoral Award applicants may budget an additional \$2,500 for supplies.
- Three new award types have been added: Community-Partnered Participatory Research Full Award, Smoke and Vape Free Scholars Initiative Planning Award, and Smoke and Vape Free Scholars Initiative Program Award. See https://trdrp.org/funding-opportunities/ for more details.
- 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.

¹ **NOTE**: The 2022 Call for Applications refers to applications that will be awarded in calendar year 2022, although the Call is released in calendar year 2021 and some processes will occur in calendar year 2021.

Introduction

The Tobacco-Related Disease Research Program (TRDRP) funds research that spans social, behavioral and biomedical sciences and has the common objective of achieving health equity for all Californians. Despite having one of the lowest smoking rates in the country, smoking prevalence remains high among California populations that are also plagued by the negative effects of structural and social determinants of health. Reducing the negative impact of tobacco use within these "tobacco priority populations²" is a primary goal of TRDRP. To address this goal, culturally-tailored research is needed on the health and behavioral effects of tobacco products and effective cessation strategies, particularly for tobacco priority populations. It is also imperative that research outcomes can be used to inform the policymakers and the general public about the ills of tobacco product use and tobacco industry marketing practices that target specific populations. This is directly aligned with TRDRP's Five Year Strategic Plan, the Tobacco Education and Research Oversite Committee (TEROC) Achieving Health Equity: California's New Plan for Tobacco and the Endgame Policy Platform, which seeks to end the sale and use of all commercial tobacco products in the state by the year 2035.

Highlights of the 2022 Call for Applications

Research priorities.

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

- 1. Research questions in support of the Endgame Policy Platform https://trdrp.org/about/ca-endgame-resources.html
- 2. Social and behavioral prevention and treatment
- 3. State and local tobacco control policy research
- 4. Tobacco related diseases
 - a. Cancer prevention, treatment and biology
 - b. Cardiovascular and cerebrovascular diseases
 - c. Oral diseases and dental health
 - d. Pulmonary biology and lung diseases
 - e. Other tobacco-related health effects
- 5. Environmental exposure and toxicology
- 6. Neuroscience of nicotine addiction and treatment

Please see Appendix A for details.

² Priority populations in California are those that use tobacco at higher rates, experience greater secondhand smoke exposure, are disproportionately targeted by the industry, and/or have higher rates of tobacco-related disease. These include racial and ethnic minority groups, sexual and gender groups, people of low socioeconomic status, rural residents, military personnel and veterans, workers not covered by smoke-free workplace laws, people with behavioral health conditions, people with disabilities, and school-age youth. Applicants may identify additional priority populations by applying the criteria above or using other disparity indicators. (Source: Tobacco Education and Research Oversight Committee. *Achieving Health Equity: Toward a Commercial Tobacco-Free California*, 2021-2022. Sacramento, CA: Tobacco Education and Research Oversight Committee. 2021.)

Tobacco-related disease remains a research focus.

In addition to tobacco policy, treatment, and prevention research, TRDRP is accepting applications that substantially focus on tobacco-related diseases <u>for all award types</u>. 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 product use.
- 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.

Sex as a biological variable.

Consistent with NIH, TRDRP requires 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. 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:

- 1. 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.
- 2. 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.
- 3. 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.
- 4. 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.

The use of inhaled (combusted or aerosolized) cannabis and its influence on tobacco use behavior, including nicotine addiction, remains largely unexplored. Further, the health impacts of the combined use of inhaled cannabis and nicotine products are not well known. Research on the biological and population level impact of the use of inhaled cannabis is needed to inform effective public health policies. For this reason, TRDRP funds research that includes cannabis as it relates to tobacco use, tobacco policy, or tobacco-related disease.

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.

TRDRP encourages applicants to contact TRDRP program officers with questions regarding eligibility requirements before submitting an LOI or application. All LOIs for the 2022 TRDRP Call for Applications will be reviewed after the LOI deadline of August 26, 2021. Applicants will be notified whether they are eligible to submit a full application within 10 days. NOTE: LOIs for the Smoke- and Vape-Free Scholars Initiative will be reviewed on a rolling basis (see SVFSI Call for Applications).

California-Expert Blinded Review of Letters of Intent (LOIs)

TRDRP seeks to fund research that will inform the Endgame Policy Platform, an effort led by the California Tobacco Control Program (CTCP) to build a movement across California that prepares and transitions communities to end the commercial tobacco epidemic for all Californians by 2035. The goal of the campaign is to eradicate the tobacco industry's influence and the harm caused by tobacco products to the health, environment, and economic well-being of California's diverse populations. A critical component of the campaign is its focus on youth and communities disproportionately burdened by commercial tobacco.

To help identify research that directly and immediately supports the Endgame Policy Platform, TRDRP will conduct a blinded, non-scientific Letter of Intent (LOI) review. LOI materials will be used by TRDRP staff to determine eligibility (e.g. is the proposed research tobacco-related?) and to prepare for the scientific peer review. TRDRP will also ask experts in California tobacco control to review LOI materials to assess the immediate relevance of the proposed work on the Endgame Policy Platform. If the California experts deem the proposed work to be of potential near-term high impact to CA tobacco control efforts, this will be included as a programmatic consideration when making funding decisions.

Please see Appendix B for Details

KEY DATES

	Core ³ and Community-Based Participatory Research Awards	Smoke and Vape Free Scholars Initiative Awards	
Call open	Thursday July 1, 2021	Friday July 16, 2021	
Applicant Webinars (Register at <u>https://trdrp.org/fundi</u> <u>nq-opportunities/</u>)	Core award mechanisms: Thursday, July 22, 10-11am PT Community-Partnered Participatory Research: Tuesday, July 27 10-11am PT	Smoke and Vape Free Scholars Initiative: Tuesday, July 27 2:30-3:30pm PT	
LOI submission deadline	Thursday, August 26, 2021 12 p.m. PT	Reviewed on a rolling basis; no LOIs accepted after August 26, 2021 12 p.m. PT	
Invitation to Full Application Announced	September 2, 2021	Will be granted on a rolling basis	
Due date for new applications and resubmissions	Wednesday, November 10, 2021 12 p.m. PT	Thursday September 30, 2021 12 p.m. PT	
Applicants notified	March 2022	December 2021	
Awards start	Awards start July 1, 2022 N		

To get started:

- 1. Determine your eligibility for funding (Appendix D).
- 2. Explore our research priorities (All applications must address one or more.) Appendix A
- 3. Review the 2022 Call for Applications award types (Appendix B) and KEY DATES.
- 4. Familiarize yourself with our letter of intent and application instructions.
- 5. Register and join an applicant webinar or find the recording on our website:
 - Core award mechanisms Thursday, July 22, 10-11am
 - Smoke and Vape-Free Scholars Initiative Tuesday, July 27 2:30-3:30pm Pacific Time
 - Community-Partnered Participatory Research Tuesday, July 27 10-11am Pacific Time
- 6. Contact a program officer (trdrp.org/about/staff.html) with any questions.
- 7. Use SmartSimple (https://ucop.smartsimple.com) to submit your LOI and application.

Applicants should 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.

³ Core Awards include Research Award, Pilot Award, New Investigator Award, Postdoctoral Award, and Predoctoral Award

2020 Call for Applications: Award Types

See Appendix B for details

Award Types	Purpose of Award	Maximum Award/Year (Direct Cost)	Maximum Award Duration (years)
Research Award	Conduct research based on preliminary data that will achieve or advance work within one or more stated research priorities.	\$300,000	3
Pilot Award	Gather preliminary data or demonstrate proof-of- principle with potential for high impact within one or more stated research priorities.	\$250,000	2
New Investigator Award	Support and enable new investigators to initiate an independent research program with potential for high impact within one or more stated research priorities.	\$200,000	3
Postdoctoral Award	Support postdoctoral research training under a designated mentor to conduct high impact research within one or more stated research priorities.	See Appendix B	3
Predoctoral Award	Support doctoral student research training with a designated mentor within one or more stated research priorities.	See Appendix B	3
Community Partnered Participatory Research <u>Pilot</u> Award	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 health issue of importance to a community in California.	\$500,000 (\$250,000/Co-PI)	2
Community Partnered Participatory Research <u>Full</u> Award	Support an existing, equitable community and academic research partnership to conduct follow-on research that builds on preliminary data, addresses a research question on a tobacco-related health issue of importance to a community in California, and leads to a sustainable tobacco prevention or treatment intervention.	\$600,000 (\$300,000/Co-PI)	3
Smoke and Vape Free Scholars Planning Award	Support California State Universities and California Community Colleges to assemble an administrative and mentoring partnership with a doctorate granting institution, then prepare and submit a Program Award application.	\$25,000	1

Award Types	Purpose of Award	Maximum Award/Year (Direct Cost)	Maximum Award Duration (years)
Smoke and Vape Free Scholars Program Award	Support California State Universities and California Community Colleges, in partnership with doctorate-granting institutions, to develop and administer mentorship & training programs for undergraduate, post-bac and masters-level students from diverse backgrounds to conduct tobacco-related research projects in a mentor's laboratory or team, while also engaging in local tobacco control activities.	See RFP	4
Student Research Supplement ¹	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
Cornelius Hopper Diversity Supplement ²	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. Supplements are funded above the award mechanism cap.	\$20,000/year	2

See <u>Appendix C</u> and <u>Appendix D</u> for details on TRDRP Application and Grant Making Policies and Procedures

TRDRP CONTACTS

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

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Cardiovascular, Cerebrovascular, Pulmonary and Oral Disease

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

Neuroscience of Nicotine Addiction and Environmental Exposure and Toxicology

Deborah Colosi, PhD (510) 587-6140, Deborah.Colosi@ucop.edu

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

Research Grants Program Office (RGPO)

RGPOGrants@ucop.edu (510) 987-9386

APPENDIX A: RESEARCH PRIORITIES

The Tobacco-Related Disease Research Program (TRDRP) funds research that spans social, behavioral and biomedical sciences and has the common objective of achieving health equity for all Californians. Despite having one of the lowest smoking rates in the country, smoking prevalence remains high among California populations that are also plagued by the negative effects of structural and social determinants of health. Reducing the negative impact of tobacco use within these "tobacco priority populations1" is a primary goal of TRDRP. To address this goal, culturally-tailored research is needed on the health and behavioral effects of tobacco products and effective cessation strategies, particularly for tobacco priority populations1. It is also imperative that research outcomes can be used to inform the policymakers and the general public about the ills of tobacco product use and tobacco industry marketing practices that target specific populations. This is directly aligned with TRDRP's Five Year Strategic Plan, the Tobacco Education and Research Oversite Committee (TEROC) Achieving Health Equity: California's New Plan for Tobacco and the Endgame Policy Platform, which seeks to end the sale and use of all commercial tobacco products in the state by the year 2035.

The Tobacco Industry continues to launch new products, for example <u>synthetic nicotine products</u> introduced as recently as 2020. While individual products may experience fluctuations in use over time, overall, new and emerging tobacco products remain remarkably popular, especially among adolescents and some populations that are disproportionately affected by tobacco product use. Yet, the effects of nicotine itself, flavorings, and other additives used in these products are not well understood. TRDRP will continue to fund research analyzing the toxicological, health, and social behavioral effects of these products and their constituents. Studies using cell or animal models, human subjects, and/or Big Data strategies to integrate multiple types of data are all needed to fully understand the effects of these products. To create the base of scientific evidence to effectively end the sale and use of all tobacco products, TRDRP also remains committed to supporting research on prevention and cessation of the use of flavored nicotine products, including menthol, and on effective state and local policies governing the sale of flavored tobacco products.

The use of inhaled (combusted or aerosolized) cannabis and its influence on tobacco use behavior, including nicotine addiction, also remains largely unexplored. Further, the health impacts of the combined use of inhaled cannabis and nicotine products are not well known. Research on the biological and population level impact of the use of inhaled cannabis is needed to inform effective public health policies. For this reason, TRDRP funds research that includes cannabis as it relates to tobacco use, tobacco policy, or tobacco-related disease.

Research into the mechanisms, diagnosis, prevention and treatment of tobacco-related diseases, especially with a focus on disproportionately affected groups, remains critical to help alleviate the suffering caused by tobacco use. Despite the overall decline in cancer death rates, including lung cancer, in the last two decades (see "<u>Trends in Lung Cancer and Cigarette Smoking: California Compared to the Rest of the United States</u>"), disparities in cancer incidence and death rates persist among different demographic groups. Similarly, disparities in diagnosis and mortality exist for other tobacco-related diseases, such as heart disease, stroke, and chronic obstructive pulmonary disease (COPD). TRDRP encourages biomedical research involving tobacco priority populations.

Some of the differences in health outcomes among different demographic groups may be explained by different tobacco use rates, but social and structural determinants of health contribute to disparate health outcomes as well. These disparities underscore the need for impactful research on the effective dissemination of disease prevention strategies and the implementation of evidence-based interventions that can reduce disease burden

in specific cultures and communities that are disproportionately affected by tobacco-related disease. For instance, personal health care decisions, such as whether or how often to see a physician 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 disease surveillance and/or survival in underserved communities. Therefore, TRDRP also supports research that aims to overcome the barriers to implementing system change and design strategies to bring innovative healthcare solutions for tobacco-related diseases and nicotine addiction to all Californians.

All applications must address one or more of TRDRP's nine research priorities, as detailed below.

NOTE: While submission of projects focused on co-use of tobacco with other substances of abuse are welcome, studies that only address non-tobacco substances (e.g. cannabinoids) are not eligible under this Call.

1. Research questions in support of the Endgame Policy Platform

- How does the elimination of flavored tobacco product sales in a community impact retailing in the community overall?
- In jurisdictions that have instituted bans on certain tobacco products: How did retailers' transition from selling tobacco products? How did retailers change inventory to compensate for the loss of tobacco sales, if at all? Which resources from the city were helpful? What would be helpful to support retailers through this transition in other jurisdictions?
- What are the healthcare and environmental cost impacts attributable to state and local tobacco product restriction policies (e.g., reduction in healthcare costs due to treating tobacco-related diseases and concomitant chronic diseases, decreases in second and thirdhand smoke and reductions in tobacco product waste)?

2. Social and behavioral prevention and treatment

TRDRP supports research and collaborations that prevent or reduce tobacco use and the impact of tobacco-related diseases among California's priority groups. California universities and non-profit, community-based organizations with capacity to conduct research in diverse communities are encouraged to address the social, structural, and addictive correlates of tobacco use and related disease, as well as educational and clinical interventions to reduce the deleterious effects from all forms of nicotine delivery systems. Social, behavioral, and public health research that provides evidence to battle nicotine addiction and the predatory marketing of the tobacco industry to diverse communities is needed. Community settings including schools, clinics, community serving organizations, and multi-unit housing are prime collaborators for this research effort.

Examples of relevant research topics:

- Health behavior change interventions that promote cessation of: multiple tobacco product use, flavored tobacco product use, synthetic nicotine products (e.g., nicotine pouches), heated tobacco, tobaccocannabis co-use, and poly-substance use that includes tobacco use
- Development and testing of new theoretical frameworks that advance our understanding of the benefits/limitations of culturally tailored tobacco prevention and treatment interventions compared to interventions targeting the general population with consideration of intersectional identity, culture, and structural determinants of health

- Research that elucidates the role of structural and social determinants of health in shaping the tobacco
 epidemic facing priority populations in California Research that looks into how we can mitigate
 seemingly entrenched disparities and structural determinants of good/poor health behaviors and
 outcomes
- Innovative use of virtual technology to expand the reach of evidence-based tobacco prevention and cessation interventions focused on priority groups and rural areas of California
- Research that broadly develops surveillance tools to track social and behavioral aspects of the retail environment and industry marketing strategies that can worsen tobacco-related health disparities
- Implementation research that can directly inform innovations in health insurance plan coverage of tobacco treatments and improve cessation service integration in health systems. Research that fosters: buy-in among health plans to provide sustainable coverage of evidence-based tobacco treatments, technological innovation that uses machine learning to monitor the prevalence of tobacco-related behaviors and cessation services within and across health plans and health systems, and marketing strategies that lead to a clear communication of a plan's tobacco treatment coverage, costs for the smoker, and which health systems provide access to cessation services. This is particularly important for the Medi-Cal patient population that continues to smoke cigarettes at alarmingly high rates.

3. State and local tobacco control policy research

TRDRP supports critical health policy research needed to inform the state's tobacco control activities and improve the care for Californians with tobacco-related diseases. Research is needed to 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. In particular, research on the potential economic and other impacts of ending the sale and use of commercial tobacco products is needed in support of the *California Endgame Policy Platform*.

Examples of relevant research topics:

- Evaluation of local tobacco regulations and their impacts on public health and the local economy such as:
 - regulation of menthol cigarettes and other flavored tobacco products
 - intended and unintended consequences of state and local tobacco laws
 - changes to the tobacco and vapor retail environment in response to recent laws
 - strategies to build support for minimum price and unit packaging
- Evaluations of how cannabis control policy interacts with and potentially undermines tobacco control
 policy
- Characterizing evidence-informed policy approaches that support stronger local smoke-free ordinances and protect youth from tobacco and cannabis marketing

4. Tobacco-Related Diseases

TRDRP supports innovative, timely and high impact research that addresses basic, translational or clinical aspects of tobacco-related diseases. See the introductory section on <u>Tobacco-Related Disease Research</u> for a list of eligibility criteria. Research such as the health effects of nicotine, and or e-liquid flavorings, that can inform FDA regulations on new and emerging tobacco products is of particular interest.

a. Cancer prevention, treatment and biology example research topics:

- Behavioral, clinical and/or pre-clinical studies on the carcinogenic potential of cannabis and/or new tobacco products
- Therapeutic efficacy studies of new biologics in small or large animal models of tobacco-related cancers
- Development of effective early lung cancer detection techniques tailored to a specific priority population
- Use of precision medicine approaches to the development of therapeutic strategies for tobaccorelated cancers
- Palliative care interventions for seriously ill cancer patients and their families in rural areas

b. Cardiovascular (CVD) and cerebrovascular diseases example research topics:

- Studies of biological samples from new and emerging tobacco product users to determine whether subclinical markers of CVD and cerebrovascular accident (CVA) are altered.
- Interrogation of longitudinal studies of priority populations such as the Jackson Heart Study to better understand the intersection of social determinants of health, tobacco use and heart disease.
- The intersection of the effects of tobacco product use with chronic stressors such as structural racism and other social determinants of health on cardiovascular health.
- The extent to which interventions that promote positive psychosocial assets (optimism, resilience, purpose in life) may mitigate the negative effects of discrimination and promote both tobacco cessation and improved cardiovascular health

c. Oral diseases and dental health example research topic:

- Innovative, cost effective and accessible approaches to early detection of oral disease.
- Research into interventions to reduce oral cancer incidence and mortality among tobacco priority populations
- Motivational interviewing in the dental clinic to encourage commercial tobacco product cessation
- The effect of new and emerging tobacco products on tobacco-related conditions such as dental caries, periodontitis or tooth loss

d. Pulmonary biology and lung diseases example research topics:

- Molecular changes in various lung cell culture models or in animals or humans exposed to inhaled ecigarette smoke and aerosol, role of nicotine or flavorants
- Cellular interactions or molecular pathways that drive the inflammatory response in the lungs of tobacco users
- The mechanisms (molecular, genetic, social) that drive differences in COPD susceptibility and progression
- The role of combusted tobacco smoke or new and emerging tobacco products in the development and exacerbation of asthma or idiopathic pulmonary fibrosis

e. Other research topics pertaining to tobacco-related health effects:

- Eye diseases including, but not limited to, age-related macular degeneration, cataracts, diabetic retinopathy, dry eye, glaucoma, and uveitis;
- Type 2 diabetes and associated serious health complications, such as poor blood flow leading to amputation and peripheral neuropathy; and
- Communicable diseases, such as influenza and COVID-19.

5. Environmental Exposure and Toxicology

TRDRP will support innovative and high impact projects that use environmental research and health communication strategies to prevent exposure to all tobacco products, secondhand (SHS) and thirdhand (THS) smoke, chemical residue interactions, and tobacco waste product bioaccumulation in vulnerable communities. TRDRP will continue to support toxicology studies of new and emerging tobacco products alone or in combination with cannabis.

Examples of relevant research topics:

- Integrate approaches to prevent environmental exposure to all tobacco products, SHS and THS with implementation of tobacco cessation in multi-unit housing, all indoor public spaces or other settings
- Characterize the health impact and risk factors of environmental exposure to all tobacco products, SHS
 and THS including identification of chemical composition and interactions, dose-response threshold
 levels for toxicity, biomarkers of use, and dual tobacco and cannabis product use
- Devise strategies to mitigate exposure to tobacco toxicants
- Conduct epidemiologically based exposure research to identify and characterize the tobacco control needs of vulnerable populations and communities
- Identify innovative methodologies to assess and reduce the environmental and economic impact of the production, sale and use of tobacco products and new product waste and bioaccumulation

NOTE: TRDRP currently funds a statewide research consortium on thirdhand smoke research. (trdrp.org/highlights-news-events/thirdhand-smoke-consortium.html). The Thirdhand Smoke Consortium invites all TRDRP applicants in California to use the UCSF Tobacco Biomarkers Laboratory for measures of nicotine and metabolites, carcinogen biomarkers, thirdhand smoke components, tobacco specific nitrosamines and various smoke toxicants. The following link describes the various assays and costs: https://cancer.ucsf.edu/research/cores/tobacco-biomarkers.

6. Neuroscience of nicotine addiction and treatment

TRDRP supports innovative research that addresses the biology of nicotine addiction and treatment, with a goal of understanding and reducing commercial tobacco product use in populations that consistently have the highest smoking rates.

Examples of relevant research topics:

- The molecular, cellular and behavioral effects of nicotine, with and without flavorants, on the developing brain
- Development of therapeutic strategies for nicotine-addicted youth and young adults
- Effects of flavorants and other constituents of vape product aerosol on nicotine addiction
- Addictive potential of combined nicotine and cannabinoid use in specific priority populations
- Studies of brain connectivity and interaction between neural pathways utilized by different agonists (e.g., glutamatergic, cholinergic, dopaminergic, etc.) in response to nicotine

APPENDIX B: DETAILS ON GRANT AWARD TYPES

California-Expert Blinded Review of Letters of Intent (LOIs) - New for 2022 Call

NOTE: The term "tobacco" used in this document refers to all forms of commercial nicotine and tobacco products⁴. TRDRP does not intend to impinge upon the sacred use of traditional or ceremonial tobacco in American Indian communities.

Impact Question on LOI

TRDRP seeks to fund research that will inform the *Endgame Policy Platform*, an effort to build a movement across California that prepares and transitions communities to end the commercial tobacco epidemic for all Californians by 2035. The goal of the campaign is to eradicate the tobacco industry's influence and the harm caused by tobacco products to the health, environment, and economic well-being of California's diverse populations. A critical component of the campaign is its focus on youth and communities disproportionately burdened by commercial tobacco.

To help identify research that directly and immediately supports the *Endgame Policy Platform*, TRDRP will conduct a blinded, non-scientific Letter of Intent (LOI) review. While LOI materials will be used by TRDRP staff to determine eligibility (e.g. is the proposed research tobacco-related?) and to prepare for the scientific peer review, TRDRP will also ask experts in California tobacco control to review LOI materials to assess the immediate relevance of the proposed work on the *Endgame Policy Platform*. If they deem the proposed work to be of potential near-term high impact to CA tobacco control efforts, this will be included as a programmatic consideration when making funding decisions. *Your answer to this Impact Question will be a key focus of their review.* If you believe that your proposed research would be of immediate relevance to efforts aimed at ending the commercial tobacco epidemic for all Californians, particularly for youth and communities disproportionately burdened by commercial tobacco, please describe how the proposed research would support one or more of the following *Campaign* and other California tobacco control goals:

- 1. Countering the tobacco industry's influence and tactics that are aimed to ensure easy availability of their products. Examples of goals include:
 - a. Reducing tobacco retail licensing
 - b. implementing local flavor bans;
 - c. reducing economic impacts of tobacco sales restrictions on small businesses;
 - d. avoiding unintended consequences of tobacco-free policies, such as criminalization or discriminatory enforcement
 - e. deglamorizing tobacco use especially in social and entertainment media;
 - f. preventing marijuana use from undercutting past and future tobacco control progress.

⁴ Commercial tobacco is mass-produced and sold for profit by companies for recreational and habitual use in cigarettes, smokeless tobacco, pipe tobacco, cigars, hookahs, and other products. (Source: https://keepitsacred.itcmi.org/)

- 2. Countering the structural, political, and social factors that lead to health disparities, and that promote and sustain tobacco use and disease in California. Examples of goals include:
 - a. Identifying incentives and disincentives to reduce the tobacco industry's influences;
 - b. promoting anti-tobacco social norm change without impinging upon the sacred use of tobacco;
 - c. integrating tobacco-free living elements into community planning, economic development, and redevelopment;
 - d. reducing exposure to secondhand smoke/aerosol, tobacco smoke/aerosol residue (thirdhand smoke), and tobacco product waste.
- 3. Providing evidence-based tobacco use prevention and cessation strategies for California's diverse schools and communities. Examples of goals include:
 - a. Reducing the availability of tobacco products;
 - b. providing culturally, linguistically, and age-appropriate cessation services;
 - c. ensuring access to cessation pharmacotherapy and behavioral counseling particularly for youth and communities disproportionately burdened by commercial tobacco;
 - d. achieving Medi-Cal reimbursement of all forms of cessation treatment.

Evaluation instructions for CA Impact reviewers

The California tobacco control experts will be given the following instructions when evaluating the LOIs.

Please answer the question: If this study is funded, completed and data is produced, what impact will it have on ending the commercial tobacco epidemic for all Californians or other current tobacco control efforts in the State?

The goal of this assessment is to identify applications whose potential for impact is so high that it warrants programmatic consideration for funding even if moderate or fixable scientific flaws are identified during scientific merit review ('high near-term impact').

In making your assessment, consider the stated goals of the Local Lead Agency Campaign to End Commercial Tobacco and other California tobacco control organizations in their effort to end the commercial tobacco epidemic for all. Research that is likely to benefit youth and/or communities that are disproportionately burdened by commercial tobacco is of particular interest to TRDRP.

Evaluation Choices for Impact Question

- High Near-Term Impact This project is directly relevant to current policies or practices being actively
 pursued by California tobacco control organizations. [should be reserved for rare cases; requires written
 comment by reviewer]
- **Limited Near-Term Impact** This project could indirectly impact current or future CA tobacco control efforts, or basic research that may lead to future treatments or lessening the burden of tobacco-related disease. [this is not a negative; TRDRP expects that most applications will fall in this category]

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.

Eligibility: Any tobacco related topic may be submitted under the Research Award mechanism.

Letter of Intent Requirement: A letter of Intent is required for the Research Award mechanism. It will be used to assess the application eligibility requirement of tobacco-relatedness. It will also be reviewed by California tobacco control experts to identify projects with potential to specifically impact ending commercial tobacco use and health consequences for all Californians. These reviewers will be blinded to applicant name and institution.

Research Award overview:

- Maximum award amount per year: \$300,000 (direct costs)
- Maximum duration: 3 years
- **Allowable direct costs:** Salaries, fringe benefits, supplies, publishing, sub-contracts*, equipment (costing more than \$5,000), travel
- Travel:
 - o **Project-related travel:** As needed (must be fully justified)
 - Travel to TRDRP conference: \$750 (mandatory)
 - Scientific conference travel: Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 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, 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.

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.

Eligibility: Any tobacco related topic may be submitted under the Pilot Award mechanism.

Letter of Intent Requirement: A Letter of Intent is required for the Pilot Award mechanism. It will be used to assess the application eligibility requirement of tobacco-relatedness. It will also be reviewed by California-based tobacco control experts to identify projects that have California-specific impact on ending commercial tobacco use and health consequences for all. These reviewers will be blinded to applicant name and institution.

Overview:

- Maximum award amount per year: \$250,000 (direct costs)
- Maximum duration: 2 years
- **Allowable direct costs:** Salaries, fringe benefits, supplies, publishing, sub-contracts*, equipment (costing more than \$5,000), and 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

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

^{*}All out-of-state sub-contracts and collaborations must be well-justified. Please note that funding is extremely limited for out-of-state expenses, and TRDRP does not encourage such expenses.

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 P01level 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.

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.

Eligibility: Any tobacco related topic may be submitted under the New Investigator Award mechanism.

Letter of Intent Requirement: A letter of Intent is required for the New Investigator Award mechanism. It will be used to assess the application eligibility requirement of tobacco-relatedness. It will also be reviewed by California-based tobacco control experts to identify projects that have California-specific impact on ending commercial tobacco use and health consequences for all. These reviewers will be blinded to applicant name and institution.

Award Overview:

- 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:
 - o **Project-related travel:** As needed (must be fully justified)
 - Travel to TRDRP conference: \$750 (mandatory)
 - Scientific conference travel: Up to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP conference)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30 percent, or 26 percent for projects conducted off-campus.

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 effort to activities supported by this award for the first year. Awardees may reduce effort in years 2 and 3 pending successful milestone completion.

^{*}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.

- 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 (eg pandemics), 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 start date of this Call for Applications.
- Applicant must enter the end date of their 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.

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.

Eligibility: Any tobacco related topic may be submitted under the Postdoctoral Award mechanism.

Letter of Intent Requirement: A Letter of Intent is required for the Postdoctoral Award mechanism. It will be used to assess the application eligibility requirement of tobacco-relatedness.

Award Overview:

- Maximum stipend amount per year: Up to \$60,000
- Maximum duration: 3 consecutive years
- Allowable direct costs:
 - o **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.
 - o **Supplies and Expenses:** Up to \$2,500 per year (must be fully justified).
 - o **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. TRDRP will cover up to **\$8,850** per year for these costs. 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 (eg 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 the mentor should participate in the preparation by providing guidance and feedback. The application must describe an original research project. The project should not have identical aims with an application or grant of the mentor, whether funded by TRDRP or another source.
- A letter of support from the mentor and a minimum of two additional references are required. Letters should address the candidate's training, potential and the commitment of the mentor and the department to the candidate's career development.
- The mentor must provide a 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?
- Mentoring 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.

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.

Eligibility: Any tobacco related topic may be submitted under the Predoctoral Award mechanism.

Letter of Intent Requirement: A Letter of Intent is required for the Predoctoral Award mechanism. It will be used to assess the application eligibility requirement of tobacco-relatedness.

Award Overview:

• Maximum stipend amount per year: Up to \$30,000

• Maximum duration: 3 consecutive years

Allowable direct costs:

o **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.
- o **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 (e.g. 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. The mentor should participate in the preparation by providing guidance and feedback. The application must describe an original research project. The project should not have identical aims with an application or grant of the mentor, whether funded by TRDRP or another funder.

- 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.
- The mentor must provide a 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.

Pilot Community-Partnered Participatory Research Award (Pilot CPPRA)

Please Note: the CPPRA grant type has a separate Request for Applications (RFA), which must be read and adhered to by applicant teams. The separate RFA can be found on TRDRP's website under Funding Opportunities

Purpose: The **Pilot CPPRA** provides up to **2-years** of support for the initial phase of a project, including testing the acceptability and feasibility of methods, strengthening collaborative relationships, developing tools and methods for a later intervention, collecting preliminary data, and demonstrating proof-of-principle of a new paradigm or research hypothesis. The ultimate goal of the Pilot CPPRA is to provide initial support for partnered research with a strong rationale and potential to inform a prevention or cessation intervention in the future.

Eligibility: There are multiple eligibility criteria required for this grant type, which is explicated in the standalone Pilot CPPRA RFA.

Letter of Intent Requirement: A Letter of Intent (LOI) is required for this grant type. See page 10 of CPPRA RFA and the TRDRP LOI instructions.

- Maximum award amount per year: \$500,000 per year (Direct Costs)
 - o Community Co-PI budget max: \$250,000 per year
 - o Academic Co-PI budget max: \$250,000 per year
- Maximum duration: 2 years
- Allowable direct costs: Salaries, trainee/internship costs, fringe benefits, supplies, participant incentives, subcontracts*, equipment (costing more than \$5,000), travel, publishing costs and other dissemination activities
- Travel:
 - o **Project-related travel**: As needed in each Co-PI budget (must be fully justified)
 - Travel to TRDRP conference (Mandatory): \$750 for the Community Co-PI; \$750 for the Academic Co-PI
 - Scientific conference travel: maximum of \$2,000 per year for the Community Co-PI; maximum of \$2,000 per year for the Academic Co-PI
- **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: The nuanced requirements for the CPPRA grant type and expectations for Community and Academic Co-PIs are explicated in the standalone CPPRA RFA.

Review criteria: The broad review categories are provided here; detailed review criteria are explicated in the CPPRA RFA.

Criteria Set-1 (40 percent scoring weight) "RESEARCH"

- Statement of Goals, Research Questions, and Specific Aims
- Background, Significance, and Relevance to a Tobacco-Related Area
- Research Plan: Research Design, Conceptual Framework, and Data Analysis Plan

Criteria Set-2 (40% scoring weight) "PARTNERSHIP"

- Partnership Collaboration Plan and Team Communication Process
- Potential for the Proposed Work to Benefit the Community and Lead to an Intervention
- Community Engagement and Capacity Building
- Dissemination Approaches and Sustainability Plan
- Statement of Future Goals

Criteria Set-3 (20% scoring weight) "RESOURCES"

- Investigative Team
- Environment, Facilities, and Resource Availability
- Community Assets

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.

For more details, read the Community-Partnered Participatory Research Award Request for Applications https://trdrp.org/funding-opportunities/.

Full Community Partnered Participatory Research Award (Full CPPRA)

Please Note: the CPPRA grant type has a separate Request for Applications (RFA), which must be read and adhered to by applicant teams. The separate RFA can be found on TRDRP's website under Funding Opportunities

Purpose: The **Full CPPRA** provides up to **3-years** of support to develop, evaluate, test, or examine a community tobacco prevention intervention or treatment intervention, building on pilot or preliminary data, focused on tobacco-related research issues of importance to the community that is the focus of the project.

Eligibility: The multiple eligibility criteria for this grant type are outlined in the standalone CPPRA RFA.

Letter of Intent Requirement: A Letter of Intent (LOI) is required for this grant type. See page 10 of CPPRA RFA and TRDRP LOI instructions

- Maximum award amount per year: \$600,000 per year (Direct Costs)
 - o **Community Co-PI budget max**: \$300,000 per year
 - o **Academic Co-PI budget max**: \$300,000 per year
- Maximum duration: 3 years
- Allowable direct costs: Salaries, trainee/internship costs, fringe benefits, supplies, participant incentives, subcontracts*, equipment (costing more than \$5,000), travel, publishing costs and other dissemination activities
- Travel:
 - o **Project-related travel**: As needed in each Co-PI budget (must be fully justified)
 - Travel to TRDRP conference (Mandatory): \$750 for the Community Co-PI; \$750 for the Academic Co-PI
 - Scientific conference travel: maximum of \$2,000 per year for the Community Co-PI; maximum of \$2,000 per year for the Academic Co-PI
- **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: The nuanced requirements for the CPPRA grant type and expectations for Community and Academic Co-PIs are described in detail in the standalone CPPRA RFA.

Review criteria: The broad review categories are provided here; detailed review criteria are explicated in the CPPRA RFA.

Criteria Set-1 (40 percent scoring weight) "RESEARCH"

- Statement of Goals, Research Questions, and Specific Aims
- Background, Significance, and Relevance to a Tobacco-Related Area
- Research Plan: Research Design, Conceptual Framework, and Data Analysis Plan

Criteria Set-2 (40% scoring weight) "PARTNERSHIP"

- Partnership Collaboration Plan and Team Communication Process
- Potential for the Proposed Work to Benefit the Community and Lead to an Intervention
- Community Engagement and Capacity Building
- Dissemination Approaches and Sustainability Plan
- Statement of Future Goals

Criteria Set-3 (20% scoring weight) "RESOURCES"

- Investigative Team
- Environment, Facilities, and Resource Availability
- Community Assets

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.

For more details read the Community-Partnered Participatory Research Award Request for Applications https://trdrp.org/funding-opportunities/.

Smoke and Vape Free Scholars Initiative (SVFSI)

Please Note: the SVFSI grant type has a separate Request for Applications (RFA), which must be read and adhered to by applicant teams. The separate RFA can be found on TRDRP's website under Funding Opportunities

Purpose: This award will help develop a pipeline of dedicated tobacco control researchers and advocates. Funded awards will support mentorship and training activities that include enabling undergraduate, post-bac and masters-level students from diverse backgrounds to conduct tobacco-related research projects in a mentor's laboratory or team, while also engaging in local tobacco control activities and participating in other educational activities.

Eligibility: The multiple eligibility criteria for this grant type are described in detail in the standalone SVFSI RFA.

Letter of Intent Requirement: A Letter of Intent (LOI) is required for this grant type. LOIs for the Smoke- and Vape-Free Scholars Initiative will be reviewed on a rolling basis.

Maximum award amount offered:

- Planning Awards: \$25,000 total direct costs for 1 year
- Program Awards: \$1,050,000 total direct costs for 4 years
- **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 is extremely limited for out-of-state expenses. TRDRP does not encourage such expenses.

Award requirements: The nuanced requirements for the SVFSI grant types and expectations for training teams are described in detail in the standalone SVFSI RFA.

For more details read the Smoke and Vape Free Scholars Initiative Call for Applications https://trdrp.org/funding-opportunities/.

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 <u>not</u> eligible to apply for a Student Research Supplement.

Trainee eligibility:

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

Supplement details:

- Maximum supplement amount per year: \$20,000 (direct cost)
- Maximum duration: 2 years
- **Allowable direct costs:** Salaries, fringe benefits, tuition, enrollment fees for the trainee, 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:

Please see https://trdrp.org/funding-opportunities/award-mechanisms/student-research-supplement.html for detailed instructions.

Cornelius Hopper Diversity Award Supplement

Purpose: The Cornelius Hopper Diversity Supplements are intended to support trainees and California residents from underrepresented communities and/or those who wish to pursue careers in research 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 <u>not</u> eligible to apply for a Cornelius Hopper Diversity Supplement.

Trainee eligibility:

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

Supplement submission procedure:

Please see https://trdrp.org/funding-opportunities/award-mechanisms/cornelius-hopper-diversity-supplement.html for detailed instructions.

APPENDIX C: COST AND EXPENSE GUIDELINES

Personnel

- The Budget Summary line item for Personnel should reflect the total cost of all individuals identified as supported by the grant and their level of effort. In the personnel section of the application, be sure to name all individuals to be supported by the grant and provide their percent effort (months devoted to the project). All paid individuals must also be listed on the budget.
- Follow the NIH Guidelines and Calculation scheme for determining Months Devoted to Project, available at the links below:
 - o NIH Guidelines: http://grants.nih.gov/grants/policy/person months fags.htm
 - NIH Calculation Scheme:
 http://grants.nih.gov/grants/policy/person months conversion chart.xls
- When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income (e.g., clinical or consulting incomes). TRDRP does not enforce a salary cap, as long as the overall budget adheres to the costs & expenses guidelines and the amount requested stays within the allowable costs.

Student Tuition Fees, Graduate Student Stipends

• For non-fellowship awards: Graduate students may be paid as personnel and may also receive tuition remission. Tuition remission, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition listed in this category) may not exceed \$30,000 per project year. A maximum of \$16,000 per year is allowed for the combined costs of tuition/enrollment fee remission, fringe benefits, and health insurance. Stipend may be budgeted as salary (and included in the MTDC cost calculation) if the institution pays these expenses through a personnel line item.

Other Project Expenses

- Include expected costs for supplies and other research expenses not itemized elsewhere.
- Pooled expenses may be allowed as a direct cost at the discretion of the Program with certification of the following: 1) the project will be directly supported by the pooled expenses, 2) the pooled expenses have been specifically excluded from the indirect cost rate negotiation, and 3) the pooled expenses have been allocated consistently over time within the organization. Please explain any requested pooled expense requests in the budget justification.

Equipment (Unit Cost over \$5,000)

• For all Awards, each requested equipment item must be >\$5,000 and explained in the budget justification.

Travel

- <u>Travel TRDRP Meeting</u>: TRDRP may organize an event requiring your travel to the Oakland area within the funded grant period. Funds up to \$750 should be set aside for attending the Research Grants Program Office (RGPO) Meeting during the first year of the grant. All other applicants, including fellowship applicants, should budget a one-time \$750 expense under year 1 in a travel budget line labeled: "Travel TRDRP Meeting".
- <u>Travel Project Related</u>: Project-related travel expenses are allowable only for travel directly related to the execution of the proposed research activities. Label such expenses as "Travel Project Related." These expenses must be fully justified in the budget justification.
- <u>Travel Scientific Meetings</u>: Scientific conference travel is limited to \$2,000 per year (excluding a mandatory allocation of \$750 in one year of the project for travel to the TRDRP Conference under Travel RGPO Meeting). The same limit applies to Fellowship recipients. Label such expenses as "Travel-Scientific Meetings" and explain in budget justification.

Service Contracts and Consultants

Both categories require additional description (Budget Justification).

Subcontracts

- Detailed contractual budgets must be included as a subcontractor budget in the database, and letters of
 collaboration from each subcontract must be included in the Appendix. A subcontract is not allowed to
 have another subcontract.
- In the case of University of California applicants, subcontracts need to be categorized and broken out as one of two types, University of California-to-University of California (UC to UC) sub agreements or transfers; or, Other. A subcontract is not allowed to have another subcontract. Requires additional description (Budget Justification).

INDIRECT (F&A) COSTS

- <u>Indirect cost policy</u>: Indirect costs are NOT allowed for Postdoctoral Fellowship Awards, Predoctoral Fellowship Awards, Student Research Supplement Awards, Cornelius Hopper Diversity Award Supplements, Dissemination Projects, or Scientific Conference Awards. For other awards, Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC (26% for off-campus projects).
- Modified Total Direct Costs (MTDC) include salaries and wages, fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract) to an outside institution. MTDC does not include (indirect costs are not allowed on): capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, equipment purchases more than \$5,000 per item, the portion of each sub grant and subcontract in excess of the first \$25,000, and the total cost of any subcontract from one UC to another UC campus. On a non-fellowship award, you may apply indirect costs to graduate student salary (under salary only, not as stipend) but not to tuition & fees.
- For all eligible projects that allow grantees to recover the full amount of their federally negotiated indirect cost rate agreement, grantees must also accept the full federally recognized F&A rate for all award subcontractors (except for subcontracts to another UC institution, where F&A is not allowed). If

a grantee or subcontractor does not have a federally negotiated F&A rate at the time of the proposal submission, the grantee and/or subcontractor may estimate what the federally negotiated rate will be at the time of award and include this rate in the proposed budget, or may request a "De Minimis" F&A rate of 10% MTDC. A higher indirect rate that has been accepted for state or local government contract or other California grantmaker contract may be approved at the discretion of the Program Director and the Research Grants Program Office Executive Director.

• Indirect Costs on Subcontracts

- The award recipient institution will pay indirect costs to the subcontractor.
- For non-UC subcontracted partners, TRDRP will allow full F&A of the Modified Total Direct Cost (MTDC), as defined above.
- F&A costs are not allowed for one UC institution's management of a subcontract to another UC institution.

The amount of the subcontracted partner's F&A costs can be added to the direct costs cap of any award type. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.

APPENDIX D: OTHER APPLICATION-RELATED POLICIES, PRE & POST AWARD REQUIREMENTS

Submission Process

Submission of a Letter of Intent (LOI) is required to apply for all award types. The LOI must be submitted electronically. LOI submission instructions should be strictly followed as stated. LOIs will be programmatically reviewed to ensure eligibility after the August 26, 2021 deadline and applicants will be notified whether they are eligible to submit a full application on September 2, 2021.

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 <u>TRDRP website</u> (trdrp.org/funding-opportunities/review-process/index.html).

Resubmission Policy

A resubmission is an unfunded application that was submitted to TRDRP as a new application in the previous cycle (i.e. 2020) and resubmitted under the current Call for Applications (i.e. 2022). 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. *Note the different resubmission criteria in the CPPRA RFP* (https://trdrp.org/funding-opportunities/).

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.

Condition of Award for UC Faculty on payroll at a non-UC entity

In accord with University of California policy, investigators who are University employees and who receive any part of their salary through the University must submit grant proposals through their campus contracts and grants office ("Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University", Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the investigator is employed.

Human Material and Animal Subjects

Approvals for use of human material and animal research subjects are not required at the time of application. Applicants are encouraged to apply to the appropriate board or committee as soon as possible in order to expedite the start of the project, and you must do so before or within 21 days of notification that an award has been offered. This deadline may be negotiable depending on the circumstances of the proposal. If all reasonable efforts are not made to obtain appropriate approvals in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects.

Appeals of Funding Decisions:

An appeal regarding the funding decision of a grant application may be made only on the basis of an alleged error in, or deviation from, a stated procedure (e.g., undeclared reviewer conflict of interest or mishandling of an application). The period open for the appeal process is within 30 days of receipt of the application evaluation from the Program office. Before submitting appeals, applicants are encouraged to talk about their concerns informally with the appropriate program officer or the TRDRP program director.

Final decisions on application funding appeals will be made by the vice president of Research and Innovation, University of California, Office of the President. Applicants who disagree with the scientific review evaluation are invited to submit revised applications in a subsequent grant cycle with a detailed response to the review.

The full appeals policy can be found in the online the University of California, Office of the President, "RGPO Grant Administration Manual – Section 5: Dispute Resolution":

https://www.ucop.edu/research-grants-program/ files/documents/srp forms/srp gam.pdf

Pre-Funding Requirements

Upon request, awardees must supply the following information or documents:

- 1. Supply approved indirect (F&A) rate agreements as of the grant's start date and any derived budget calculations.
- 2. Supply any missing application forms or materials, including detailed budgets and justifications for any subcontract(s).
- 3. IRB or IACUC applications or approvals pertaining to the award.
- 4. Resolution of any scientific overlap issues with other grants or pending applications.
- 5. Resolution of any Review Committee and Program recommendations, including specific aims, award budget, or duration.
- 6. Modify the title and lay abstract, if requested.

Publications Acknowledgement and Open Access

All scientific publications and other products from a RGPO-funded research project must acknowledge the funding support from UC Office of the President, with reference to TRDRP and the assigned grant ID number.

RGPO is committed to disseminating research as widely as possible to promote the public benefit. All publications based on funding received from RGPO are subject to the University's Open Access Policy which went into effect on April 22, 2014. To assist the RGPO in disseminating and archiving the articles, the grantee institution and all researchers on the grant will deposit an electronic copy of all publications in eScholarship, UC's open access repository promptly after publication. Notwithstanding the above, this policy does not in any way prescribe or limit the venue of publication. The full policy is available here:

https://www.ucop.edu/research-grants-program/grant-administration/rgpo-open-access-policy.html

Grant Management Procedures and Policies

All TRDRP grant recipients must abide by other pre- and post-award requirements pertaining to Cost Share, Indirect Cost Rates, Monitoring & Payment of Subcontracts, Conflict of Interest, Disclosure of Violations, Return of Interest, Equipment and Residual Supplies, Records Retention, Open Access, and Reporting as outlined in the Grants Administration Manual (GAM) available at the link below:

http://www.ucop.edu/research-grants-program/ files/documents/srp forms/srp gam.pdf