TOBACCO-RELATED DISEASE RESEARCH PROGRAM

2023 Call for Applications

New Changes and Key Requirements

- All applications received for the 2023 Call[1] must clearly address either tobacco use prevention, tobacco cessation, or tobacco-related disease.
- Biomedical studies should focus on diseases that are causally linked to tobacco use or on studies that can discern and reduce tobacco-related health disparities.
- 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.
- Postdoctoral Award annual direct cost caps have been raised to $108,750 to include up to $70,000 stipend support and $38,000 in institutional allowance.
- Predoctoral Award annual direct cost caps have been raised to $95,150 to include up to $40,000 in stipend support, tuition and fee remission up to $50,000 and $4,400 institutional allowance.
- To help identify research that directly and immediately supports the California Endgame Initiative, following programmatic review of LOIs, TRDRP will conduct a blinded-evaluation of LOIs submitted for Pilot Awards, Research Awards and New Investigator Awards. See Appendix B 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/funding-opportunities/ for LOI/Application instructions and information on how to access the application submission system. Programmatic guidance for completing Core[2] award applications may be found in Appendix E of this Call for Applications. Programmatic guidance for completing applications for the Smoke and Vape Free Scholars Initiative and Community-Based Participatory Research Awards may be found in those Calls on our website (https://trdrp.org/funding-opportunities/).

NOTE: The term "tobacco" used in this document refers to all forms of commercial nicotine and tobacco products[3]. TRDRP does not intend to impinge upon the sacred use of traditional or ceremonial tobacco in American Indian communities.

[1] **NOTE**: The 2023 Call for Applications refers to applications that will be awarded in calendar year 2023, although the Call is released in calendar year 2022 and some processes will occur in calendar year 2023.
[2] TRDRP Core Awards include Research Award, Pilot Award, New Investigator Award, Postdoctoral Award, and Predoctoral Award
[3] 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/)

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 populations[4]" is a primary goal of TRDRP. To address this goal, applicants should focus on diseases that are causally linked to tobacco use and on studies that can discern and reduce tobacco-related health disparities. In addition, culturally-tailored research is needed on the health and behavioral effects of tobacco products and effective cessation strategies, particularly for tobacco priority populations. Thirdly, it is imperative that research outcomes can be used to inform policymakers and the general public about the physical harm of tobacco product use and tobacco industry marketing that target specific populations. Communicating evidence-based research helps inform partners to design effective policy interventions. TRDRP requires investigators to plan how they will disseminate their research findings by communicating with and engaging community members. These approaches are directly aligned with TRDRP's own Five Year Strategic Plan, the plan of the Tobacco Education and Research Oversite Committee (TEROC) Achieving Health Equity: California's New Plan for Tobacco and the CA Endgame Initiative, which seeks to end the sale and use of all commercial tobacco products in the state by the year 2035.

Highlights of the 2023 Call for Applications

Research priorities.

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

1. Research questions in support of the CA Endgame Initiative https://trdrp.org/about/ca-endgame-resources.html
2. Social and behavioral studies on tobacco product use prevention and treatment
3. State and local tobacco control policy research
4. Tobacco related diseases
    a. Cancer detection, 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.

[4] 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, 2021-2023*. Sacramento, CA: Tobacco Education and Research Oversight Committee. 2021.)

Eligibility Criteria.

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

1. Projects in which nicotine or other tobacco or vape product constituents are integral to the proposed study.
2. Studies focused on diseases that the Report of the Surgeon General[5] has identified as being causally linked to tobacco or tobacco product use. Note, lung, oral and pharyngeal cancers will be eligible only under one of the following conditions:
    a. Studies focused on lung cancer types that are most closely correlated with tobacco product use, i.e., Small Cell Lung Cancer and/or $EGFR^{WT}$ Non-Small Cell Lung Cancer[6].
    b. Studies focused on Oral Cavity and Pharyngeal Cancer types that are most closely correlated with tobacco product use, i.e., those negative for Human Papilloma Virus (HPV)[7].
3. Observational or laboratory studies (biomedical or behavioral) of co-use of tobacco products with other substances including cannabis. This includes but is not limited to blunts, and THC-nicotine vaping mixtures.
4. Studies of inhaled cannabis use policies and their potential to erode California's smoke-free laws.
5. Health behavior and health policy research focused on tobacco use prevention, cessation strategies, or tobacco product 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.

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[5] Reports of the Surgeon General on the Health Consequences of tobacco product use may be found here: https://www.cdc.gov/tobacco/data_statistics/sgr/index.htm

[6] Non-small-cell lung cancer, Nature Reviews Disease Primers (doi:10.1038/nrdp.2015.9, https://www.nature.com/articles/nrdp201)

[7] Auguste, Aviane et al. "Joint effect of tobacco, alcohol, and oral HPV infection on head and neck cancer risk in the French West Indies." Cancer medicine vol. 9,18 (2020): 6854-6863. doi:10.1002/cam4.3327

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, still requires additional research, especially among tobacco priority populations. 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. Applicable federal rules may include the federal Controlled Substances Act, applicable Drug Enforcement Agency (DEA), and Food and Drug Administration (FDA) policies and regulations. California state rules require researchers to obtain approval from the Research Advisory Panel of California before conducting research in California that involves use of Schedule I or Schedule II controlled substances (see guidance on the RAPC website). Also, if research using cannabis is proposed applicants are required to describe the status of their DDEA registration 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 2023 TRDRP Call for Applications will be reviewed after the LOI deadline of August 18, 2023. Applicants will be notified whether they are eligible to submit a full application within 10 days.

California Expert Blinded Evaluation of Letters of Intent (LOIs)

TRDRP's goal is to achieve a balanced portfolio of near-term impact and longer-term impact research grants. For research of near-term impact, TRDRP seeks to fund research that will inform California tobacco control efforts including the CA Endgame Initiative, 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 addresses the CA Endgame Initiative, TRDRP will invite California Tobacco Control Experts to conduct a blinded review of Letters of Intent (LOI). Applicants will indicate whether their research will have a **high near-term impact** on ending the tobacco product use epidemic in California. For examples, see Endgame Campaign and other California tobacco control goals in Appendix B. If the California experts deem the proposed research to be of potential **high near-term impact** to CA tobacco control efforts, their comments will be included as a programmatic consideration when making funding

decisions. Letters of Intent that indicate a **limited near-term** impact on ending the California tobacco use epidemic, for example, biomedical studies of lung cancer development, will not be reviewed by CA experts. Identifying your application as having **limited near-term** impact will not affect the consideration of your application by peer reviewers. Please see Appendix B for more details.

KEY DATES

Calls open	Friday July 1, 2022
Applicant Webinars (Register at https://trdrp.org/funding-opportunities/)	Community-Partnered Participatory Research: Wednesday July 20 10:30-11:30 am PT Smoke- and Vape-Free Scholars Initiative: Friday July 22 10:30-11:30 am PT Core award mechanisms: Tuesday August 2 10:00-11:00 am PT
LOI submission deadline	Thursday, August 18, 2022 **12 p.m. PT**
Invitation to Full Application Announced	August 25, 2022
Due date for new applications and resubmissions	Thursday October 20, 2022 **12 p.m. PT**
Applicants notified	April 2023
Awards start	July 1, 2023

To get started:

1. Determine your eligibility for funding (Appendix D).
2. Explore our research priorities (All applications must address one or more, see Appendix A).
3. Review the 2023 Call for Applications award types (Appendix B) and KEY DATES.
4. Familiarize yourself with our SmartSimple Applications Submission Instructions and Applicant Guidance and Template Instructions (Appendix E).
5. Register and join an applicant webinar or find the recording on our website:
   - **Community-Partnered Participatory Research** - Wednesday July 20 10:30-11:30 am PT
   - **Smoke and Vape-Free Scholars Initiative** - Friday July 22 10:30-11:30 am PT
   - **Core award mechanisms** - Tuesday August 2 10:00-11:00 am PT
6. Contact a program officer (trdrp.org/about/staff.html) with any question.
7. Use RGPO's SmartSimple system (https://ucop.smartsimple.com) to prepare, submit and track your LOI and application online.

Applicants should review the Call for Applications and SmartSimple Application Submission Instructions, and complete all necessary materials using the appropriate templates and forms. Template instructions may be found in Appendix E of the Core Call for Applications. Failure to comply with provided instructions or failure to submit completed forms may result in administrative rejection of the application.

2023 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 Pilot 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 Full 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 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	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	2
Cornelius Hopper Diversity Supplement	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	2

See Appendix C, Appendix D and Appendix E for application instructions and 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 member:

TRDRP Director
Tracy Richmond McKnight, PhD
(510) 987-9811, Tracy.Richmond-McKnight@ucop.edu

TRDRP Project Analyst
Jennifer Jackson, BS
(510) 987-9888, Jennifer.Jackson@ucop.edu

Program Officers	Social & Behavioral Treatment & Prevention	State & Local Tobacco Control Policy	Tobacco-Related Diseases[8]	Environ-mental Exposure & Toxicology	Neuroscience of Nicotine Addiction & Treatment	Predoctoral/ Postdoctoral Applicants & Grantees	Health Equity	California Commercial Tobacco Endgame Initiative
Norval Hickman, PhD, MPH Norval.Hickman@ucop.edu	✓	✓					✓	
Ginny Delaney, PhD Ginny.Delaney@ucop.edu			✓					
Deborah Colosi, PhD Deborah.Colosi@ucop.edu			✓	✓				
Maggie Kulik, PhD Maggie.Kulik@ucop.edu	✓	✓					✓	✓
Becky Theilmann, PhD Rebecca.Theilmann@ucop.edu			✓		✓	✓		
Marjannie Akintunde, PhD Marjannie.Akintunde@ucop.edu			✓	✓		✓	✓	
Danyetta Anderson, PhD Danyetta.Anderson@ucop.edu	✓		✓				✓	

Inquiries regarding LOI/application forms and instructions should be directed to:
Research Grants Program Office (RGPO)
RGPOGrants@ucop.edu

[8] These include Cancer Treatment & Biology, Cardiovascular & Cerebrovascular Disease, Pulmonary Biology & Lung Disease, Oral Disease and Dental Health, as well as Other Tobacco-Related Health Effects as described in Appendix A.

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 populations[1]" is a primary goal of TRDRP. To address this goal, culturally-tailored research is needed on the health and behavioral effects of tobacco product use and effective cessation strategies, particularly for tobacco priority populations[1]. It is also imperative that research outcomes can be used to inform policymakers and the general public about the ills of tobacco product use and tobacco industry marketing practices that target specific populations. This also includes research on the implementation and evaluation of state and local tobacco control policies. 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 CA Endgame Initiative, 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 synthetic nicotine products 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, still requires additional research, especially among tobacco priority populations. 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 "Trends in Lung Cancer and Cigarette Smoking: California Compared to the Rest of the United States"), 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 are not eligible under this Call.

1. Research questions in support of the *California Endgame Initiative*

- 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 their inventory to compensate for the loss of tobacco sales, if at all? Which resources from the city/county/local jurisdiction were helpful? What would be helpful to support retailers through this transition in other jurisdictions? Which unintended consequences are retailers most concerned about?
- 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)?
- In which instances does cessation support accompany new tobacco prevention and control policies? Does it contribute to the success/failure/acceptance/rejection of these policies?
- Which health communication strategies and message frames best increase the success of prevention efforts and cessation interventions, improve understanding of health impacts of tobacco use or facilitate other tobacco prevention and control messages (e.g., framing around public health benefits, economic benefits, environmental benefits, or social justice) for the different audiences in the state (e.g., the public, incl. tobacco priority populations, policymakers, retailers)?
- How can California tobacco prevention and control efforts be maintained amid declining tax funds due to a decrease in the use of tobacco products?

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. Research from the social, behavioral, and public health sciences that provide evidence to battle nicotine addiction and the predatory marketing of the tobacco industry to diverse communities is needed. Community settings including

schools, clinics, community nonprofit organizations, and multi-unit housing sites are prime collaborators for this research effort.

The program also aims to solicit proposals for research that will have a major impact in identifying, developing, implementing, or testing strategies to prevent, reduce, or eliminate racial or ethnic disparities in tobacco use or tobacco-related morbidity and mortality. It is time for the field to move beyond simple conceptualizations of race and ethnicity, conceptualizing race as a social construct and meaningfully unpacking race and ethnicity using metrics that allow for comparisons across studies, and with an emphasis in integrating experiences related to the commercial, structural, and social inequities that translate to determinants of health for priority populations in California. Research that is embedded in the community's experience and fosters community scientist training focused on tobacco prevention and control will ensure more rapid advances in this impact-driven scientific area. As such, TRDRP continues to solicits projects across the full spectrum of community engagement through Core Award grant types, and has the Community-Partnered Participatory Research Award (CPPRA) grant type to support collaborative community-partnered investigative teams to conduct research projects that address issues prioritized by the community and that reflect lived experiences.

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, tobacco-cannabis 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 general population-based interventions with consideration of intersectional issues and structural determinants of health
- Research that elucidates the role of structural, commercial, and social determinants of health in shaping the tobacco epidemic facing priority populations in California – Research that examines strategies to reduce indicators of tobacco-related health disparities and structural determinants of poor mental and physical health
- Innovative use of virtual technologies to expand the reach and access of evidence-based or practice-informed tobacco prevention and cessation interventions focused on priority groups and rural areas of California
- Research that broadly develops surveillance tools to track social, behavioral, and commercial changes of the tobacco retail environment and industry marketing strategies that can worsen tobacco-related health disparities
- Implementation science research that can directly inform innovation in the provision of tobacco prevention and cessation services that addresses health insurance coverage issues and expands access to Californians with lower income levels and/or Medi-Cal enrollees. Development and testing of methods that can translate to the adoption, integration, and routinization of evidence-based practices, interventions, and policies into best practices for health care and public health settings to improve quit attempts, abstinence rates, and reduce the number of new tobacco users entering the market. Machine learning methods and other artificial intelligence technologies that focus on economies of scale in health care systems are essential for a competitive implementation science focused research application.
- Innovations in the measurement of social constructs and typology of study designs available to examine and track changes in tobacco-related health disparity indicators over time. For example, designs that include analysis with sufficient power to stratify by important sociodemographic characteristics

(race/ethnicity, gender, LGBTQ+ identity) and innovations in the measurement of structural determinants and commercial determinants of health are critically needed in the field.

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 *CA Endgame Initiative.* See App A, Sec 1 above.

Examples of relevant research topics:

- Evaluation of state and 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

- 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
- Examination of effective communication approaches to inform policy in support of the CA Endgame Initiative

4. Tobacco-Related Diseases

TRDRP supports innovative, timely and high impact research that addresses basic, translational or clinical aspects of tobacco-related diseases. Research into the mechanisms, diagnosis, prevention and treatment of tobacco-related diseases, with a focus on disproportionately affected groups, is of critical importance to reducing the negative impact of tobacco product use. TRDRP-funded studies must focus on diseases and biomedical mechanisms that are directly related to tobacco use. *See the introductory section on Eligibility Criteria for guidance.* Research that can inform FDA regulations on new and emerging tobacco products is of particular interest.

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

- Behavioral, clinical and/or pre-clinical studies on the carcinogenic potential of new tobacco products
- Epidemiology studies to correlate cotinine or other biomarker levels with cancer risk in tobacco priority populations.
- Genetic/Epigenetic studies to investigate the use of menthol or other flavors that predispose tobacco priority populations to cancer.
- Molecular biology studies identifying polycyclic aromatic hydrocarbons (PAHs) in individuals that co-use cannabis and tobacco
- Use of precision medicine approaches to develop therapeutic strategies for small cell lung cancer. *Note that lung cancer research should focus on diseases that are strongly correlated with tobacco product use, i.e. small cell lung cancer (SCLS) and wild-type EGFR non-small cell lung cancer (NSCLC).*

- 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 users of new and emerging tobacco products to determine whether subclinical markers of CVD and cerebrovascular accident (CVA) are altered.
- Interrogation of longitudinal health 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 or stroke risk.
- 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 or cerebrovascular 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. Note*: Research on Oral Cavity and Pharyngeal Cancers should focus on diseases that are strongly correlated with tobacco product use (i.e. Human Papilloma Virus-negative cancers)*
- 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 e-cigarette 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
- Impact of tobacco product use on the general lung health of youth or other tobacco priority populations

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.
- Devise strategies to mitigate exposure to tobacco product(s) and Tobacco Product Waste (TPW).
- Identify tobacco products, SHS, THS and TPW chemical exposure levels, chemical composition of dust and aerosol particle composition and chemical interactions using technologies and model systems, and identify biomarkers to distinguish tobacco product use, and cannabis product co-use.
- Enable prediction of human health effects of tobacco products by identifying causal links of dose-response toxicity assessments on human biological pathways and conduct validation studies using primary human cell models.
- 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.
- Evaluate the impact of environmental endpoints of TPW including metabolites and microplastics on the environment and ecosystems such as soil, aquatic systems, waste management systems and storm drains.
- Determine the environmental burden of E-cigarettes product waste components such as batteries, and metallic components.

NOTE: TRDRP currently funds a statewide consortium on thirdhand smoke (THS) research which includes the University of California San Francisco (UCSF) Tobacco Biomarkers Laboratory. (trdrp.org/highlights-news-events/thirdhand-smoke-consortium.html). This laboratory is directed by Peyton Jacob, PhD and Neal Benowitz, MD in the Clinical Pharmacology Program, Department of Medicine at UCSF. Investigators in the Clinical Pharmacology Program conduct studies on the pharmacology and toxicology of tobacco use including development of new biomarkers and analytical methods. The UCSF Tobacco Biomarkers Laboratory collaborates with other investigators to analyze samples on a recharge basis and they welcome collaborations with TRDRP applicants. Tobacco product toxicants that can be detected and quantified include 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
- Neuroimaging studies to identify brain changes and biomarkers associated with nicotine addiction
- Studies to investigate the long-term impacts of nicotine addiction in association with cognitive abilities across the lifespan

APPENDIX B: DETAILS ON GRANT AWARD TYPES

California Expert Blinded Evaluation of Letters of Intent (LOIs)

Impact Question on Letter of Intent (LOI)

Eligibility to apply to this Call for Applications begins at the Letter of Intent (LOI) stage. 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. Beginning at the LOI stage, TRDRP also works to build a balanced portfolio of near-term impact and longer-term (possibly higher payoff) impact research grants. For research of near-term impact, TRDRP seeks to fund research that will inform California tobacco control efforts including the CA Endgame Initiative, 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.

To help identify research that directly and immediately supports the CA Endgame Initiative, TRDRP will invite California Tobacco Control Experts to conduct a blinded evaluation of Letters of Intent (LOI). Applicants will indicate whether they believe their research will have a **high near-term impact** on ending the tobacco product use epidemic in California, for examples see Endgame Campaign and Other California Tobacco Control Goals. If the California experts deem the proposed work to be of potential **high near-term impact** to CA tobacco control efforts, their comments will be included as a programmatic consideration when making funding decisions. Letters of Intent that indicate a **limited near-term impact** on ending the California tobacco use epidemic, for example biomedical studies of lung cancer development, will not be evaluated by CA experts. Identifying your application as having **limited near-term impact** will not detrimentally affect the consideration of your application by peer reviewers.

Instructions to Applicants:

Please describe how your proposed research, if selected for funding and completed, would inform the specific activities aimed at ending the tobacco use epidemic in California, i.e., having a **high near-term impact**. If your work would not directly inform these efforts, please enter N/A. Identifying your application as having **limited near-term impact** in this way will not detrimentally affect the consideration of your application by peer reviewers.

Endgame 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 (and state) 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.

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-commercial 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 Experts

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

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

For LOIs deemed to have a high near-term impact, please describe how you would use the information generated by this research in your work as a CA tobacco control expert.

- **High Near-Term Impact** – This project would directly contribute to current policies or practices being actively pursued by California tobacco control organizations. Please describe how you would use the information generated by this research in your work as a CA tobacco control expert.
- **Limited Near-Term Impact** – This project could indirectly impact current or future CA tobacco control efforts, or is basic research that may lead to future treatments or lessening the burden of tobacco-related disease. Identifying an application as having **limited near-term impact** will not affect the consideration of the application by peer reviewers.

Research Award

Purpose: Conduct next phase/fully developed research based on promising preliminary or formative data gathered through prior pilot research. High 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. LOIs may also be evaluated by California tobacco control experts to identify projects with potential high near-term impact on ending commercial tobacco

use and health consequences thereof for all Californians. CA Experts will be blinded to applicant name and institution. (See Appendix B)

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:**
  - **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 25 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 is 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 preliminary data address one or more TRDRP research priorities and demonstrate that the study is 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? See Appendix A for a detailed description of TRDRP Research Priorities.
- **Innovation:** Does the research adapt existing methods or technologies to new uses or with understudied populations, 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? 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?

- **Approach:** 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 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:** Is the budget request for the project appropriate? Is there scientific or budgetary overlap with other active awards? If out-of-state contracts or collaborations are included in the budget, how essential are they to successful completion of the project?
- **Protection of human subjects from research risk:** If human subjects are involved, will protections from research risk relating to their participation in the proposed research be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate 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? Are plans for the recruitment and retention of human subjects adequate.
- **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 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. LOIs may also be evaluated by California tobacco control experts to identify projects with potential high near-term impact on ending commercial tobacco

use and health consequences thereof for all Californians. CA Experts 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 25 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, 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 applicant provide information on how the study will gather preliminary data that addresses one or more TRDRP research priorities and demonstrates proof-of-principle to support the feasibility of a new paradigm or research hypothesis? 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? See Appendix A for a detailed description of TRDRP Research Priorities.
- **Innovation:** Does the research adapt existing methods or technologies to new uses or with understudied populations, 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? 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; or 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?

- **Approach:** 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, will it be likely that their results will constitute a larger R01-level or P01-level study with high probability of funding from another agency such as the NIH? How likely can the applicant leverage funding from other sources to further develop this area of research within two to three years after initial funding?

Criteria-3 (20 percent scoring weight)

- **Investigators:** Are the investigators appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the 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 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:** Is the budget request for the project appropriate? Is there scientific or budgetary overlap with other active awards? If out-of-state contracts or collaborations are included in the budget, how essential are they to successful completion of the project?
- **Protection of human subjects from research risk:** If human subjects are involved, will protections from research risk relating to their participation in the proposed research be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate 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? Are plans for the recruitment and retention of human subjects adequate.
- **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 the focus areas covered under TRDRP research priorities. New investigators may use this award to generate pilot data for future funding or they may use it to for an established line of research that is already supported by preliminary evidence.

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. LOIs may also be evaluated by California tobacco control experts to identify projects with potential high near-term impact on ending commercial tobacco use and health consequences thereof for all Californians. CA Experts 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:**
  - **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; TRDRP conference to be allocated in year 1 of the budget)
- **Indirect costs:** Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 30 percent, or 25 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 is extremely limited and TRDRP does not encourage such expenses.

Award requirements:

- TRDRP New Investigator Award applicants must have PI-status at the sponsoring institution at the time of award start date.
- Please note that the New Investigator awards offered by the NIH are different from those offered by TRDRP. TRDRP New Investigator Awards are not mentored awards and require an independent PI status at the sponsoring institution. Applicants who do not currently have PI status are required to submit a letter from their Department Chair stating that the applicant will be granted PI status by the award start date.
- Awardees are required to commit at least 50 percent effort to activities supported by this award for the first year. Awardees may reduce effort in years 2 and 3 pending successful milestone completion.
- 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 (e.g., 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:** Does the applicant describe how the study is pilot research or exploratory in nature (e.g., will it gather preliminary data or demonstrate proof of principle to support the feasibility of a new paradigm or hypothesis)? Will the study yield data that may be leveraged for future research support? Does the applicant describe how the study will lead to an expanded research effort in the future, including specific funding sources and award types? Does the applicant describe how the project will address one or more TRDRP research priorities? See Appendix A for a detailed description of TRDRP Research Priorities.
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease?
- **Innovation:** Does the research adapt existing methods or technologies to new uses or with understudied populations, 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? 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 research priorities?
- **Approach:** 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 have the necessary training and experience to carry out the proposed research? 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 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:** Is the budget request for the project appropriate? Is there scientific or budgetary overlap with other active awards? If out-of-state contracts or collaborations are included in the budget, how essential are they to successful completion of the project?
- **Protection of human subjects from research risk:** If human subjects are involved, will protections from research risk relating to their participation in the proposed research be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate 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? Are plans for the recruitment and retention of human subjects adequate.
- **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 $70,000
- **Maximum duration:** 3 consecutive years
- **Allowable direct costs:**
    - **Stipend:** Postdoctoral stipend must adhere to NIH experience scale or the rates set by their institution with institutional documentation of the alternate payment scale
    - **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, courses and educational materials, project related travel, and travel to scientific meetings. TRDRP will cover up to **$38,000** 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 (e.g., 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)

- **Approach:** 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, will protections from research risk relating to their participation in the proposed research be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate 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? Are plans for the recruitment and retention of human subjects adequate.
- **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 $40,000
- **Maximum duration:** 3 consecutive years
- **Allowable direct costs:**
  - **Stipend:** Predoctoral 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:** Predoctoral students may budget for full tuition and fee costs up to $50,000, consistent with relevant collective bargaining agreements. Documentation of the institution's tuition and fees structure should be included in the budget justification.
  - **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, courses and educational materials, project related travel, and travel to scientific

meetings. These costs will be covered up to **$4,400** 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:** 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)

- **Approach:** 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, will protections from research risk relating to their participation in the proposed research be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate 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? Are plans for the recruitment and retention of human subjects adequate.
- **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 are explained 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)
    - **Community Co-PI budget max**: $250,000 per year
    - **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**:
    - **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 25 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 is 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: Detailed review criteria are described in the CPPRA RFA.

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)
    - **Community Co-PI budget max**: $300,000 per year
    - **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**:
    - **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 25 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 is 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: Detailed review criteria are described in the CPPRA RFA.

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.

Maximum award amount offered: 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 25 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 type 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/.

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 **not** eligible to apply for a Cornelius Hopper Diversity Supplement.

Trainee eligibility:

- Undergraduate and master's degree candidates 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, as well as community members, school personnel or students are eligible for a Cornelius Hopper Diversity Supplement.
- Individuals enrolled in a doctoral degree program or who have earned a doctoral degree (e.g. Ph.D., M.D., J.D.) are **not** eligible to be supported by this Supplement.

Supplement details:

- **Maximum supplement amount per year:** $20,000 (direct cost)
- **Maximum duration:** 2 years
- **Allowable direct costs:** Salary and benefits, tuition, enrollment fees for the trainee, supplies, domestic travel
- **Equipment:** Not allowed as part of this supplemental funding
- **Supplies and Travel:**
  - **Project-related travel:** As needed (must be fully justified)
  - **Travel to TRDRP conference:** $750 (mandatory)
  - **Scientific conference travel:** Up to $2,000 per year (excluding TRDRP Conference)
  - **Supplies:** Up to $2,200 (must be fully justified)
- **Indirect costs:** Not allowed

Supplement submission procedure:

To be considered for funding, an application for a Cornelius Hopper Diversity Award Supplement must be submitted as part of a scientific progress report for an active, non-mentored TRDRP grant. CPPRA grantees may be subject to special submission conditions.

Investigators must have at least one year remaining on their TRDRP parent award to ensure the best conditions and results for prospective trainees.

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

Student Research Supplement

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

Mentor eligibility:

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

Trainee eligibility:

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

Supplement details:

- **Maximum supplement amount per year:** $20,000 (direct cost)
- **Maximum duration:** 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:

To be considered for funding, an application for a Student Research Award Supplement must be submitted as part of a scientific progress report for an active, non-mentored TRDRP grant.

Investigators must have at least one year remaining on their TRDRP parent award to ensure the best conditions and results for prospective trainees.

Please see https://trdrp.org/funding-opportunities/award-mechanisms/student-research-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:

- NIH Guidelines: https://grants.nih.gov/faqs#/person-months.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 receive full tuition and fee remission (up to $50,000) and compensation in line with the relevant collective bargaining agreement. Stipends may not exceed $40,000 per project year. Stipend may be budgeted as salary (and included in the MTDC cost calculation) if the institution pays these expenses through a personnel line item. Tuition remission will be considered compensation and should not offset other financial aid. Undergraduate stipends and tuition and fee remission will be considered on a case-by-case basis.

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

Travel – TRDRP Meeting: 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 TRDRP-organized meeting during the first year of the grant. All applicants, including fellowship applicants, should budget a one-time $750 expense under year 1 in a travel budget line labeled: "Travel - TRDRP Meeting".

Travel - Project Related: 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.

Travel - Scientific Meetings: 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

Indirect cost policy: Indirect costs are NOT allowed for Postdoctoral Fellowship Awards, Predoctoral Fellowship Awards, Student Research Supplement Awards, or Cornelius Hopper Diversity Award Supplements. 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 (25% 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 25% 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 18, 2022 deadline and applicants will be notified whether they are eligible to submit a full application on August 25, 2022.

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

Review Process and Funding Decisions

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

For more information about the funding process visit the TRDRP website (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. 2022) and resubmitted under the current Call for Applications (i.e. 2023). 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.

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.

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 online in 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 research project funded by one of the programs in the UC Research Grant Program Office (RGPO), such as TRDRP, 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 UC Publication Management System, 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

APPENDIX E. APPLICANT GUIDANCE AND TEMPLATE INSTRUCTIONS FOR CORE AWARDS

The purpose of this appendix is to assist applicants in preparing application materials and addressing reviewer evaluation criteria (see 2023 Call Appendix B for each award type's review criteria). Applicants must read and follow all submission and application instructions in this document, LOI and Application Submission Instructions as well as the 2023 Call for Applications.

Instructions for completing Templates in SmartSimple

Research Plan

(Required for Research, Pilot, New Investigator, Postdoctoral and Predoctoral Award Applicants)

The following are recommended as headings in the research plan that will assist applicants in communicating clearly with peer reviewers

1. **Revision Statement (IF APPLICABLE):** The revision statement should summarize any substantial additions, deletions, and changes that have been made. It should also include responses to critiques to the previous submission. Limit to 2 pages for resubmission; if this is a new application, do not include this section
2. **Specific Aims:** List the broad, long-term objectives and what the specific research in this proposal is intended to accomplish. State the hypotheses to be tested.
3. **Significance**: Briefly describe the state of your field and describe the gaps that the proposed project is intended to fill. Describe your long-term research plans. Provide an account of preliminary studies pertinent to the proposal or supporting scientific evidence for a Pilot Award or New Investigator Award.
4. **Responsiveness and Innovation:** Describe how the proposed research addresses one or more of the TRDRP research priorities. (Please see Appendix A of the 2023 Call for Applications for details). Describe how the proposed research represents more than an incremental advance upon published data. Describe how the research is innovative for instance,
    a. adapts existing methods or technologies to new uses or to serve understudied populations,
    b. proposes new paradigms, challenge existing paradigms or
    c. is otherwise highly creative in one or more of the following ways: the concept or question, research methods, or technologies.
5. **Near-term Leveraging Potential:** *For a Pilot or New Investigator Applicants*, when the TRDRP-funded studies are completed, describe how the results could be leveraged into a larger R01-level or P01-level study from TRDRP or another agency such as the NIH. Describe how leverage funding from other sources would be used to further develop this area of research within two to three years after initial funding.
6. **Approach**: Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Include how the data will be collected, analyzed, and interpreted. Describe any new methods and their advantage over existing methodologies. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Describe the inclusion of human subjects or the use of animal models, if applicable. For experiments with biological endpoints, please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Any substantial collaboration

with individuals not included in the budget should be described and documented and a letter from each collaborator should be uploaded to the Appendix.

7. **Literature Cited (No Page Limit for this Section)**: If desired, you may choose to start this section on a new page. List relevant references. Each reference must include the title, names of all authors, book or journal, volume number, page numbers, and year of publication. The references should be limited to relevant and current literature. Be concise and select only those literature references pertinent to the proposed research.

Facilities

(Required for Research, Pilot, New Investigator, Postdoctoral and Predoctoral Award Applicants)

Briefly describe the facilities and resources (e.g., laboratory space, core facilities, major equipment, access to populations, statistical resources, animal care, and clinical resources for research awards or administrative space and equipment) that are needed and are available for successfully carrying out the proposed research. Make sure all of the research needs described in the research plan are addressed in this section. Describe resources to be supplied by subcontractors and those that are external to the institution.

Community Engagement Plan

(Required for Research, Pilot, New Investigator, Postdoctoral and Predoctoral Award Applicants)

TRDRP's vision is to eliminate commercial tobacco use and tobacco-related diseases and improve the health and well-being of all Californians. One important step toward achieving this vision is for TRDRP-funded researchers to communicate with communities most impacted by commercial tobacco use, so that members of those communities are themselves empowered to influence decisions and policies that promote health equity and reduce negative impacts of tobacco in their communities.

Examples of community engagement activities include:

1. Educate the public about the health consequences of tobacco product use, tobacco related disease, and/or the social determinants of health
2. Participate and foster the participation of research team members in programs focused on
    a. Supporting trainees from backgrounds that are underrepresented in STEM[9];
    b. Supporting the reduction of tobacco-related health disparities for all Californians;
    c. Supporting state and local efforts to end the tobacco epidemic for all;

[9]The National Science Foundation (NSF) definition of STEM fields includes mathematics, natural sciences, engineering, computer and information sciences, and the social and behavioral sciences – psychology, economics, sociology, and political science (National Science Foundation, Division of Science Resources Statistics, 2009) Source: https://www.apa.org/pubs/info/reports/stem-discipline

3. Seek, create and distribute materials, based on your research interests, for use by California public health, educational, or community organizations.

Describe how the research team will employ their scientific and research expertise to engage with groups and individuals in the public (i.e., non-experts in your field) throughout the period of the award. Do not limit your community engagement activities to disseminating the results of completed TRDRP-funded research. Funds to support these activities may be included in the project budget.

Be sure to include physically distanced, contact-free, or virtual options to account for the current uncertainty around future public health restrictions.

Career Development Plan

(Required for Postdoctoral and Predoctoral Award Applicants)

In consultation with your mentor, draft a document that summarizes:

(i) your research and educational background,
(ii) how you became interested in your chosen research area
(iii) your long-term plans for a research career, and
(iv) how you envision the current project contributing to your development into an independent researcher in this field.

Mentoring Plan

(Required for Postdoctoral and Predoctoral Award Applicants)

The mentor, in consultation with the postdoctoral or predoctoral applicant, must construct a detailed, well-rounded training and mentoring plan.

This plan should include, but not be limited to, the following:

(i) counseling on how to advance one's career in the proposed research field.
(ii) scientific research methods and writing;
(iii) effective collaboration and presentation skills;
(iv) community engagement; and how to disseminate research in a manner readily understandable by non-scientists.

Explain what additional experiences will be planned to supplement the trainee's knowledge of their research field. Describe the 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.

Mentor Training Experience

(Required for Postdoctoral and Predoctoral Award Applicants)

The mentor should provide a list of doctoral candidates or postdoctoral fellows successfully trained, their current position(s)/status (if known), and whether they are working in a tobacco-related area of research.

Vertebrate Animal Subjects

This form is required for all applications. If your research does not involve vertebrate animals, simply check the box to acknowledge receipt and completion of this form.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendation.

Human Subjects Accrual

This form is required for all applications. If your research does not involve human subjects, simply check the box to acknowledge receipt and completion of this form.

1. Provide a detailed description of the proposed involvement of human subjects in the work outlined in the Research Plan.
2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the University of California and TRDRP that research involving human subjects must include males, females, and members of racially/ ethnically diverse groups in study populations. Applicants must describe how these groups will be included as research participants and identify the criteria for inclusion or exclusion of any subpopulation. If this requirement is not satisfied, the rationale must be clearly explained and justified. For example, adequate inclusion of certain groups as subjects in research studies may be impossible or inappropriate with respect to the purpose of the research, due to the health of the subjects, or for other legitimate scientific reasons. Summarize the gender and racial/ethnic composition of

the subject population. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, human in vitro fertilization, prisoners or other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated.

3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent. State if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

5. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

6. Describe the procedures for protecting against or minimizing any potential risks, including risks to confidentiality, and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects of the subjects. Also, where appropriate, describe provisions for monitoring collected data to ensure the safety of subjects.

7. Discuss why the risks, if any, are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of knowledge that may reasonably be expected to result. If a test article (such as an investigational new drug, device or biologic) is involved, name the test article and state whether the IND has been obtained.

Additional Documentation of Assurances for Human Subjects: In the Appendix, if available at the time of submission, include official documentation of approval by the IRBs of all participating institutions, showing the title of this application, the Principal Investigator's name, and the inclusive approval dates; do not include supporting protocols. Approvals obtained under a different title, investigator, or organization are not acceptable, unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to TRDRP as soon as possible, but no later than six months after the award start date. Funds will not be released until all assurances are received by TRDRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, approvals from the IRBs of each will be required.

Research Award – Applicant Instructions			
Research Award- Review Criteria (Percent Scoring Weight)		**Where in the app to address**	**Guidance**
Criteria 1 (30%)	Responsiveness to the Intent of the Award Mechanism	Research Plan	Describe the preliminary data, how it addresses one or more TRDRP research priorities, and demonstrate the study is fully developed rather than pilot or exploratory in nature. Explain how the study builds upon work performed as part of prior pilot work. Explain how the specific aims expand and/or advance the scope of the prior study. 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	Research Plan	Describe how the application focuses on tobacco use prevention, treatment, regulation, or tobacco-related disease. See Appendix A for a detailed description of TRDRP Research Priorities.
	Innovation	Research Plan	Describe how the research adapts existing methods or technologies to new uses or with understudied populations, proposes new paradigms, challenges existing paradigms, or is otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies. Describe how the proposed research represents more than an incremental advance upon published data. For example, explain how the project challenges existing interventions, clinical practice, or policy; or addresses an innovative hypothesis or critical barrier to progress in the field.
Criteria 2 (50 %)	Significance	Research Plan	Explain an important problem your proposed study and hypothesis addresses. Describe the scientific impact expected upon completion of the proposed specific aims; how the research will advance scientific knowledge or clinical practice by specifically identifying the gaps that the project is intended to fill. Describe 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 TRDRP's research priorities.
	Approach	Research Plan	Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Include how the data will be collected, analyzed, and interpreted. Describe how the conceptual framework, design (including composition of study population and strength of recruitment plan), methods, and analyses have been developed, and appropriately integrated to the aims of the project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Describe any new methods and their advantage over existing methodologies.

Research Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
			If applicable, describe whether the sex of an animal model or human subject will be considered a biological variable in designing the experiments. For experiments with biological endpoints, please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. Explain any potential problem areas and consideration for alternative strategies. The milestones listed in the Milestones Form should be explicitly described here. Any substantial collaboration with individuals not included in the budget should be described and documented with a letter from each collaborator uploaded to the Appendix.
Criteria 3 (20 %)	Investigators	Biosketches; Letters of Support	State how the investigators are appropriately trained and well-suited to carry out this work. Describe how the project proposed is appropriate to the experience level of the PI and other researchers. Explain how the investigative team brings complementary and integrated expertise to the project, if applicable.
	Environment	Facilities	Describe how the scientific environment in which the work will be done contributes to the probability of success. Explain how the proposed studies benefit from unique features of the scientific environment, the subject populations, or employ useful collaborative arrangements. Include evidence of institutional support and whether the project leverages institutional resources.
	Community Engagement	Community Engagement Plan	Describe the 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. Describe to what extent 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.

Pilot Award – Applicant Instructions

Pilot Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
Criteria 1 (30 %)	Responsiveness to Intent of the Award Mechanism	Research Plan	Provide information on how the study will gather preliminary data that addresses one or more TRDRP research priorities and demonstrates proof-of-principle to support the feasibility of a new paradigm or research hypothesis. Describe how the study represents a new research trajectory that is not currently funded from other sources. Describe how completion of this pilot study will lead to an expanded research effort in the future, including specific funding sources and award mechanisms.
	Tobacco-Relatedness	Research Plan	Describe how the application focuses on tobacco prevention, treatment, regulation, or tobacco-related disease. See Appendix A for a detailed description of TRDRP Research Priorities.
	Innovation	Research Plan	Describe how the research adapts existing methods or technologies to new uses or with understudied populations, proposes new paradigms, challenges existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods, or technologies. Describe how the proposed research represents more than an incremental advance upon published data. For example, explain how the project challenges existing interventions, clinical practice, or policy; or addresses an innovative hypothesis or critical barrier to progress in the field.
Criteria 2 (50%)	Significance	Research Plan	Describe the proposal background and critically evaluate the existing knowledge. Explain how the proposed study addresses an important problem. Describe the impact when the aims of the application are achieved, and how will they will advance scientific knowledge or clinical practice.
	Approach	Research Plan	Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Include how the data will be collected, analyzed, and interpreted. Describe how the conceptual framework, design (including composition of study population and strength of recruitment plan), methods, and analyses have been developed, and appropriately integrated to the aims of the project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. If applicable, describe whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments. For experiments with biological endpoints, please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. The milestones listed in the Milestones Form should be explicitly described here. Any substantial

Pilot Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
			collaboration with individuals not included in the budget should be described and documented with a letter from each collaborator uploaded to the Appendix.
	Near-Term Leveraging Potential	Research Plan	When the TRDRP-funded studies under a Pilot Award are completed, describe how the results could be leveraged into a larger R01-level or P01-level study from TRDRP or another agency such as the NIH. Describe how leverage funding from other sources would be used to further develop this area of research within two to three years after initial funding. Note: Any potential for near-term leverage should also be addressed under a separate heading.
Criteria 3 (20%)	Investigator	Biosketches, Letters of Support	State how the investigators are trained to carry out this work. Explain how the work proposed is appropriate to the experience level of the PI and other researchers. Describe how the investigative team brings complementary and integrated expertise to the project, if applicable.
	Environment	Facilities	Describe how the scientific environment in which the work will be done contributes to the probability of success. Explain how the proposed studies benefit from unique features of the scientific environment, or subject populations, or employs collaborative arrangements. Provide evidence of institutional support, as appropriate.
	Community Engagement	Community Engagement Plan	Describe the 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. Describe to what extent 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.

New Investigator Award – Applicant Instructions

New Investigator- Review Criteria (Percent scoring weight)		Where in the app to address	Guidance
Criteria 1 (30%)	Responsiveness to Intent of the Award Mechanisms	Research Plan	Describe the pilot nature of the research (e.g., will it gather preliminary data or demonstrate proof of principle to support the feasibility of a new paradigm or hypothesis). Describe how the study will yield preliminary data that may be leveraged for future research funding. Describe how the study will lead to an expanded research effort in the future, including specific funding sources and award mechanisms. Describe how the project will address one or more TRDRP research priorities (See Appendix A for a detailed description of TRDRP Research Priorities).
	Tobacco-Relatedness	Research Plan	Describe how the application focuses on tobacco prevention, treatment, regulation, or tobacco-related disease.
	Innovation	Research Plan	Describe how the research adapts existing methods or technologies to new uses or with understudied populations, proposes new paradigms, challenges existing paradigms or is it otherwise highly creative in one or more of the following ways: the concept or question, research methods, or technologies. Describe how the proposed research represents more than an incremental advance upon published data. For example, explain how the project challenge existing interventions, clinical practice, or policy; address an innovative hypothesis or critical barrier to progress in the field.
Criteria 2 (50%)	Significance	Research Plan	Explain an important problem your proposed study and hypothesis addresses. Describe the scientific impact expected upon completion of the proposed specific aims; how the research will advance scientific knowledge or clinical practice. Describe 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 TRDRP's research priorities.
	Approach	Research Plan	Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Include how the data will be collected, analyzed, and interpreted. Describe how the conceptual framework, design (including composition of study population and strength of recruitment plan), methods, and analyses have been developed, and appropriately integrated to the aims of the project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. If applicable, describe whether the sex of an animal model or human subject should be considered a biological variable in designing their experiments. For experiments with biological endpoints,

New Investigator- Review Criteria (Percent scoring weight)		Where in the app to address	Guidance
			please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. The milestones listed in the Milestones field should be explicitly described here. Any substantial collaboration with individuals not included in the budget should be described and documented with a letter from each collaborator uploaded to the Appendix.
	Near-term Leveraging Potential	Research Plan	When the TRDRP-funded studies under a New Investigator Award are completed, describe how the results could be leveraged into a larger R01-level or P01-level study from TRDRP or another agency such as the NIH. Describe how leverage funding from other sources would be used to further develop this area of research within two to three years after initial funding. Note: Any potential for near-term leverage should also be addressed under separate heading.
Criteria 3 (20%)	New Investigator Status and Research Team	Biosketches, letters of support.	State how the investigators are trained to carry out this work. Explain how the work proposed is appropriate to the experience level of the PI and other researchers. Describe how the investigative team brings complementary and integrated expertise to the project, if applicable.
	Environment	Facilities, Letters of Recommendation	Describe how the scientific environment in which the work will be done contributes to the probability of success. Explain how the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ collaborative arrangements. Provide evidence of institutional support, as appropriate.
	Community Engagement	Community Engagement Plan	Describe the 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. Describe to what extent 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.

Postdoctoral Award – Applicant Instructions

Postdoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Postdoctoral Award Guidance
Criteria 1 (50 %)	Qualification of the Applicant	Biosketch; Career Development Plan; Letters of Reference	Describe the applicant's academic background and research training. Explain 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	Mentoring Plan	Describe ancillary activities that will enhance the training of the applicant as an independent researcher. Explain what additional experiences will be planned to supplement the trainee's knowledge of their research field. Describe the didactic or interactive activities planned for increasing the trainee's knowledge base in tobacco research and control or any of the stated TRDRP research priorities.
Criteria 2 (25%)	Mentor's Qualifications and Commitment	Mentor's Biosketch, Mentoring Plan, Mentor Training Experience	Demonstrate the mentor's qualifications through descriptions of the mentor, the department, the mentor's biosketch, letters of support and training plan as well as the quality of the training resources and environment.
	Environment	Facilities; Letters of Reference	Describe how the scientific environment in which the work will be done contributes to the probability of success. Describe how the proposed studies benefit from unique features of the scientific environment, or subject populations, or employs collaborative arrangements. Provide evidence of institutional support, as appropriate.
	Community Engagement	Community Engagement Plan	Describe the 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. Describe to what extent 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.

Postdoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Postdoctoral Award Guidance
Criteria 3 (25%)	Approach	Research Plan	Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Describe how the conceptual framework, design (including composition of study population and strength of recruitment plan), methods, and analyses have been developed, and appropriately integrated to the aims of the project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Describe how the proposed research training experience significantly contributes to the development of the candidate's career potential as a researcher in the proposed area. If applicable, describe whether the sex of an animal model or human subject will be considered a biological variable in designing the experiments. For experiments with biological endpoints, please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. The milestones listed in the Milestones Form must be explicitly described here. Any substantial collaboration with individuals not included in the budget should be described and documented with a letter from each collaborator uploaded to the Appendix.
	Tobacco-Relatedness	Research Plan	Describe how the application focuses on tobacco prevention, treatment, regulation, or tobacco-related disease.

Predoctoral Award – Applicant Instructions

Predoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
Criteria 1 (50%)	Qualifications of the Applicant	Biosketch, Letters of Reference, Career Development Plan	Describe the applicant's academic background and research training. Explain 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	Mentoring Plan, Career Development Plan, Letters of Reference	Describe the training environment and any ancillary activities that will enhance the training of the applicant as an independent researcher. Explain any additional experiences that will supplement the trainee's knowledge of their research field. Describe 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%)	Mentor's Qualifications and Commitment	Mentor's Biosketch, Mentoring Plan, Mentor Training Experience	Demonstrate the mentor's qualifications through descriptions of the mentor, the department, the mentor's biosketch, letters of support and training plan as well as the quality of the training resources and environment.
	Environment	Facilities; Letters of Reference	Describe how the institutional environment in which the work will be done will contribute to the probability of success of the applicant. Explain how the proposed studies benefits from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements. Provide evidence of institutional support and commitment, as appropriate.
	Community Engagement	Community Engagement Plan	Describe the 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. Describe to what extent the dissemination of relevant results of funded research include channels and tools targeting clinicians, public health practitioners, advocates, policymakers and the general public.

Predoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
Criteria 3 (25%)	Approach	Research Plan	Describe the research design and the methods to be used to accomplish the specific aims and milestones of the project. Include how the data will be collected, analyzed, and interpreted. Describe how the conceptual framework, design (including composition of study population and strength of recruitment plan), methods, and analyses have been developed, and are appropriately integrated to the aims of the project. Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims. Describe how the proposed research training experience will significantly contribute to the development of the candidate's career potential as a researcher in the proposed area. If applicable, describe whether the sex of an animal model or human subject will be considered a biological variable in designing the experiments. For experiments with biological endpoints, please clearly state the method used to determine whether the sex of an animal model or human subject should be considered a biological variable in designing experiments. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised. The milestones listed in the Milestones Form must be explicitly described here. Explain any potential problem areas and consider alternative strategies. The milestones listed in the Milestones Form must be explicitly described here as well as any substantial collaboration with individuals.
	Tobacco-Relatedness	Research Plan	Describe how the application focuses on tobacco prevention, treatment, regulation, or tobacco-related disease.