TOBACCO-RELATED DISEASE RESEARCH PROGRAM

2025 Core Call for Applications

New Changes and Key Requirements

- TRDRP's eligibility criteria has been refined. Applications responding to this 2025 Call for Applications proposing research in basic and preclinical science studies of tobacco-related diseases must incorporate nicotine and/or other constituents of commercial tobacco products in order to be deemed "tobacco-related" and eligible for TRDRP funding. Similarly, clinical, translational, or implementation studies must involve human subjects that have a history of commercial tobacco product use. Eligible studies must have outcomes that will inform prevention of initiation of commercial tobacco product use and/or be informative or beneficial for current and prior commercial tobacco product users.
- Submission of a Letter of Intent (LOI) is **required** for all award mechanisms. To improve the efficiency of our peer review and grantmaking practices, letters of intent (LOIs) for studies that are deemed non-responsive to the refined definition of tobacco-relatedness stated above will not be invited to full application. **Although tobacco-relatedness will be the primary criteria, alignment with programmatic goals will also be considered in the decision to invite to full application, i.e. some eligible studies may not be invited to Full Application if the study goals do not strongly align with TRDRP goals.** LOIs resubmitted from the 2024 Cycle will be exempt from this new requirement for eligibility; however, resubmitted Full Applications will be peer-reviewed and scored according to this revised definition of tobacco-relatedness.
- Application materials and review criteria for Predoctoral and Postdoctoral Award mechanisms have been substantially revised to better reflect the programmatic goals of these awards. Applicants are encouraged to carefully review Appendix B and Appendix E for details of the new requirements and discuss them in advance with their mentors.
- For the first time, TRDRP is proud to offer the Maternal Smoking Cessation Initiative Award (MSCI). Please review the Call for Applications by following this link: (https://www.trdrp.org/funding-opportunities/)
- Applicants are required to follow all instructions and submit ALL required forms to avoid administrative rejection. In particular, the current application templates for grant documentation must be used. See SmartSimple to download the latest templates. Applications failing to use the correct templates will be administratively rejected.
- Go to http://www.trdrp.org/funding-opportunities/ for instructions on how to apply and information on how to access the application submission system. Programmatic guidance for completing Core[1] award applications may be found in Appendix E of this Call for Applications. Programmatic guidance for completing applications for the Community-Partnered Participatory Research Awards (CPPRA) and Maternal Smoking Cessation Initiative Award (MSCI) 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 product[2]. TRDRP does not intend to impinge upon the sacred use of traditional or ceremonial tobacco in American Indian communities.

[1] TRDRP Core Awards include Research Award, Pilot Award, New Investigator Award, Postdoctoral Award, and Predoctoral Award.

[2] 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/)

Summary of Changes to the 2025 Call for Applications

Inconsistencies were noted in the original release of the 2025 Call for Applications. To avoid confusion, the following text has been changed or added to the following sections:

- Mentoring plan documentation is no longer being requested for the Predoctoral and Postdoctoral Awards in the 2025 Call for Applications. Prior mention of the mentoring plan has been changed to reference the training plan for the Postdoctoral (p. 24) and Predoctoral (p. 27) Award.
- A component of Criteria 3 for the Predoctoral Award, the Community Engagement plan, was missing from the Predoctoral Award Guidance Table in Appendix E. This information has been added on page 57.

Introduction

The Tobacco-Related Disease Research Program (TRDRP) funds research that spans social, behavioral, and biomedical sciences and has the common objective of achieving positive health equity for all Californians. The program receives funding from multiple sources: the taxes on commercial tobacco products sold in California, settlement funds from a lawsuit between California and the commercial tobacco industry, and individual contributions from private donors.

TRDRP strategic goals are described in the TRDRP Five Year Strategic Plan, and are aligned with the plan of the Tobacco Education and Research Oversite Committee (TEROC) entitled Achieving Health Equity: Breaking the Commercial Tobacco Industry's Cycle of Addiction, Death, and Environmental Degradation, and the CA Endgame Initiative, which seeks to end the sale and use of all commercial tobacco products in the state.

Commercial tobacco product use is on the decline in California and is projected to continue to decline in future years leading to a decline in the funding TRDRP receives to support research. Despite having one of the lowest smoking rates in the country, smoking prevalence remains high among California populations that are also plagued by other negative effects of structural and social determinants of health. These "tobacco priority populations[3]" continue to experience poor health outcomes while largely providing the funding for TRDRP through the taxes they pay for commercial tobacco products. The challenge going forward is to eliminate the disparities in commercial tobacco product use and related diseases despite the reduction in tax-based revenue.

TRDRP now requires basic and preclinical science studies of tobacco-related diseases to incorporate nicotine and/or other constituents of commercial tobacco products in order to be deemed "tobacco-related" and eligible for TRDRP funding. Similarly, clinical, translational, or implementation studies must involve human subjects that have a history of commercial tobacco product use. Eligible studies must have outcomes that will inform prevention of initiation of commercial tobacco product use and/or be informative or beneficial for current and prior commercial tobacco product users.

Further, TRDRP requires investigators to plan how they will disseminate their research findings by communicating with and engaging community members. It is imperative that research outcomes inform the

[3] 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: Breaking the Commercial Tobacco Industry's Cycle of Addiction, Death, and Environmental Degradation, 2023-2024. Sacramento, CA: Tobacco Education and Research Oversight Committee. 2023.)

primary stakeholders – the users of commercial tobacco products. In addition, disseminating TRDRP-funded research results helps inform the design of evidence-based policies at the state and local level in California.

Research priorities.

All applications must address one or more of TRDRP's research priorities. Please see Appendix A for details.

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
7. Maternal and Fetal Impacts of Smoking

Scientific Eligibility Criteria. *New Criteria for 2025*

A significant change has been made to the TRDRP definition of "tobacco-relatedness", which is an important, scorable review criterion for a research study to be deemed eligible for TRDRP funding. The change will largely impact the eligibility of biomedical science research applications, so please read carefully if your field of interest lies in this area. Eligible studies include:

1. Basic and preclinical science studies of tobacco-related diseases that incorporate nicotine and/or other constituents of commercial tobacco products.
2. Clinical, translational, or implementation studies that involve human subjects with a history of commercial tobacco product use. Such studies should also produce outcomes that will inform the prevention of initiation of commercial tobacco product use and/or be informative or beneficial for current and prior commercial tobacco product users.
3. Health behavior and health policy research focused on tobacco use prevention, cessation strategies, or tobacco product regulation.
4. Studies of inhaled cannabis use policies and their potential to erode California's smoke-free laws.
5. Observational or laboratory studies (biomedical or behavioral) of co-use of tobacco products with other substances including cannabis.

Please note that studies focused on tobacco-related diseases that do not incorporate nicotine and/or other constituents of commercial tobacco products are not responsive to this Call for Applications. Letters of Intent (LOIs) that are not responsive to this Call for Applications will not be invited to submit a Full Application. LOIs resubmitted from the 2024 Cycle will be exempt from this new requirement for eligibility; however, resubmitted Full Applications will be peer-reviewed and scored according to this revised definition of tobacco-relatedness.

Sex as a biological variable.

Consistent with the practices of the National Institutes of Health (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 should review the following paper to make that determination: https://www.sciencedirect.com/science/article/pii/S0031938417302585

The following points are taken verbatim from the article:

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

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

Cannabis use and tobacco-related diseases.

The use of inhaled (combusted or aerosolized) cannabis and its influence on tobacco use behavior, including nicotine addiction, 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 DEA 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 staff with questions regarding eligibility requirements before submitting an LOI or application. All LOIs for the 2025 TRDRP Call for Applications will be reviewed after the LOI deadline of Thursday, August 22, 2024 at 12:00 NOON Pacific Time (PT). Applicants will be notified whether they are eligible to submit a full application by Monday, September 9, 2024.

Please note that to improve the efficiency of our peer review and grantmaking practices, TRDRP reserves the right to limit the number of letters of intent (LOIs) that will be invited to full application. The LOI review will be performed by TRDRP Scientific Staff and studies that are deemed non-responsive to the refined definition of tobacco-relatedness described above will not be invited to full application. **Although tobacco-relatedness will be the primary criteria, alignment with programmatic goals will also be considered in the decision to invite to full application, i.e. some eligible studies may not be invited to full application if the study goals do not strongly align with TRDRP goals.** LOIs resubmitted from the 2024 Cycle will be exempt from this new requirement for eligibility; however, resubmitted Full Applications will be peer-reviewed and scored according to this revised definition of tobacco-relatedness.

KEY DATES

Calls open	Monday, July 1, 2024
Applicant Webinars (Register at https://trdrp.org/funding-opportunities/)	Community-Partnered Participatory Research Award (CPPRA): Tuesday, July 16, 2024 10 a.m. to 11 a.m. PT Core Award Mechanisms: Tuesday, July 23, 2024 10 a.m. to 11 a.m. PT Maternal Smoking Cessation Initiative Tuesday, August 6, 2024 10 a.m. to 11 a.m. PT
LOI submission deadline	Thursday, August 22, 2024, **12 p.m. (noon) PT**
Invitation to Full Application Announced	Monday, September 9, 2024
Due date for new applications and resubmissions	Wednesday, October 30, 2024, **12 p.m. (noon) PT**
Applicants notified	April 2025
Awards start	July 1, 2025

To get started:

1. Determine your eligibility for funding (Scientific Eligibility Criteria; Appendix D).
2. Explore our research priorities (All applications must address one or more, see Appendix A).
3. Review the five award mechanisms (Appendix B) and the KEY DATES.
4. Familiarize yourself with our SmartSimple 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 Award (CPPRA)** - Tuesday, July 16, 2024 at 10 a.m. to 11 a.m. PT (https://UCOP.zoom.us/meeting/register/tJckcumurTMuHtaiYJwz0Vx1y8F3K9u6jUBP)
   - **Core Award Mechanisms** - Tuesday, July 23, 2024 at 10 a.m. to 11 a.m. PT (https://UCOP.zoom.us/meeting/register/tJcpc-6vpzsjHdNle2bac601CtXyM3p8TbN3)
   - **Maternal Smoking Cessation Initiative Award (MSCI) -** Tuesday, August 6, 2024 at 10 a.m. to 11 a.m. PT (https://UCOP.zoom.us/meeting/register/tJYoceugrzspGNY3pGYBr29O_6ylp7lQmfzr)
6. Contact a TRDRP Program Officer (trdrp.org/about/staff.html) if you have questions.
7. Use RGPO's SmartSimple system (https://rgpogrants.ucop.edu) to prepare, submit and track your LOI and application online.

Applicants should review the Call for Applications and SmartSimple 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.

2025 Call for Applications: Award Mechanisms (See Appendix B for details)

Award Mechanism	Purpose of Award	Max Award/Year (Direct Cost)	Max 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 to demonstrate proof-of-principle with potential for high impact, or conduct research based on preliminary data 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 addresses 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
Partnered Maternal Cessation Award	Support development and evaluation of culturally-tailored interventions for smoking cessation among individuals from Black, Indigenous, and People of Color (BIPOC), Native American, and Alaska Native communities.	$500,000 ($250,000/Co-PI)	2
Single Investigator Maternal Cessation Award	Support the creation of a data repository available to researchers with an interest in the clinical population (Black, Indigenous, and People of Color (BIPOC), Native American, and Alaska Native communities).	$250,000	2
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 template 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[4]	Environ-mental Exposure & Toxicology	Neuroscience of Nicotine Addiction & Treatment	Predoctoral/ Postdoctoral Applicants & Grantees	Health Equity	California Commercial Tobacco Endgame Initiative
Marjannie Akintunde, PhD Marjannie.Akintunde@ucop.edu			✓	✓		✓	✓	
Danyetta Anderson, PhD Danyetta.Anderson@ucop.edu	✓		✓				✓	
Debbie Colosi, PhD Debbie.Colosi@ucop.edu			✓	✓	✓		✓	
Ginny Delaney, PhD Ginny.Delaney@ucop.edu			✓				✓	
Maggie Kulik, PhD Maggie.Kulik@ucop.edu	✓	✓					✓	✓
Becky Theilmann, PhD Rebecca.Theilmann@ucop.edu			✓		✓	✓		
Tashelle Wright, PhD Tashelle.Wright@ucop.edu	✓	✓	✓			✓	✓	✓

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

[4] 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 positive 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 other negative effects of structural and social determinants of health. A primary goal of TRDRP is to reduce the negative impact of tobacco use within these "tobacco priority populations[3]". 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-informed research is needed on the behavioral effects of commercial tobacco product use and effective cessation strategies, particularly for tobacco priority populations. Research outcomes should be useful for informing policymakers and the general public about the physical harm of tobacco product use and tobacco and nicotine industry marketing practices. Communicating evidence-based research helps inform the design of 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 the TRDRP Five Year Strategic Plan, the plan of the Tobacco Education and Research Oversite Committee (TEROC), Achieving Health Equity: Breaking the Commercial Tobacco Industry's Cycle of Addiction, Death, and Environmental Degradation and the CA Endgame Initiative, which seeks to end the sale and use of all commercial tobacco products in the state.

The tobacco and nicotine industry continues to launch new products, for example, oral nicotine pouches, introduced as recently as 2022. While individual products may experience fluctuations in use over time, new commercial tobacco products remain remarkably popular, especially among adolescents and some populations that are disproportionately affected by commercial tobacco product use. Yet, the effects of nicotine itself, flavorings, synthetic cooling agents, 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 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 commercial tobacco products, TRDRP also remains committed to supporting research on prevention and cessation of the use of flavored nicotine products, including menthol and synthetic cooling agents such as WS-23 and WS-3, and on the impact or effectiveness of state and local policies banning 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 basic 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.

Differences in health outcomes among different demographic groups may be explained in part 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 commercial tobacco use the associated tobacco-related diseases. 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 systems 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 TRDRP research priorities, as detailed below.

NOTE 1: 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. Please note that studies focused on tobacco-related diseases that do not incorporate nicotine and/or other constituents of commercial tobacco products are not responsive to this Call for Applications. For full Scientific Eligibility Criteria, please see the Introduction.

NOTE 2: Applicants have the opportunity to access **Shared Research Resources**. Please see the following TRDRP Website for the list of Resources for Researchers (https://www.trdrp.org/funding-opportunities/).

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

In addition to the objectives outlined in the TEROC 2023-24 Plan[5], TRDRP encourages research that informs or evaluates the following Endgame Initiative goals and other California tobacco control goals:

1. Countering the tobacco and nicotine industry's influence and tactics that are aimed to ensure easy availability of their existing products and the creation of new ones. 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 cannabis use from undercutting past and future tobacco control progress.
2. Using intersectional approaches to counter 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 and nicotine industry's influences;

[5] Tobacco Education and Research Oversight Committee. Achieving Health Equity: Breaking the Commercial Tobacco Industry's Cycle of Addiction, Death, and Environmental Degradation, 2023-2024. Sacramento, CA: Tobacco Education and Research Oversight Committee. 2023.

b. promoting social norm change around the use of commercial tobacco 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, while mindful of the heterogeneity of communities and how different forms of disadvantage interact. 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.

Examples of relevant research topics:

- How does the elimination of flavored tobacco product sales in a community impact retailing in the community overall?
- How can or did retailers transition from selling tobacco products after a ban was instituted? How can or 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 can be learned from the evaluation of activity around the compliance and enforcement of the elimination of sales of flavored tobacco products?
- What are the healthcare and environmental cost impacts attributable to state and local tobacco product restriction policies?
- 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., general public, 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 projects and collaborations from California institutions of higher learning and non-profit, community-based organizations with capacity to conduct research in diverse communities that aims to prevent or reduce tobacco use and the impact of tobacco-related diseases among California's tobacco priority groups. Applicants 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 across all age groups. Research from the social, behavioral, and public health sciences that provides evidence to battle nicotine addiction and the predatory marketing practices of the

tobacco and nicotine industry is needed. Partners in community settings including schools, clinics, tribes, tribal organizations, 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 developing, implementing, or testing strategies to prevent, reduce, or eliminate racial or ethnic disparities in tobacco use or tobacco-related morbidity and mortality. We encourage applications that conceptualize race as a social construct and use measures of race and ethnicity that allow for comparisons across studies, with an emphasis on the commercial, structural, and social inequities affecting the health of priority populations in California. Similarly, we encourage the use of innovative strategies for conceptualizing and measuring sexual and gender identity, geographic context, economic status, and other characteristics of individuals who experience tobacco-related health disparities. Research that allows for intersectional approaches in data analysis and interpretation is critical for producing research findings that reflect the lived experience of individuals affected by tobacco-related health disparities. Research that is embedded in California communities, reflects the lived experiences of community members, 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 solicit projects across the full spectrum of community engagement through Core Award mechanisms and Community-Partnered Participatory Research Award (CPPRA) mechanisms to support collaborative community-partnered investigative teams in the conduct of research that address issues prioritized by the community.

Examples of relevant research topics:

- Health behavior change interventions that promote cessation of tobacco and nicotine products among all age groups including, but not limited to: multiple tobacco product use, flavored tobacco product use, synthetic nicotine products (e.g., nicotine pouches), heated tobacco, tobacco-cannabis co-use, and/or poly-substance use that includes tobacco;
- 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 develops strategies to reduce related tobacco-related health disparities;
- 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 related to tobacco and nicotine industry marketing strategies and the tobacco retail environment, including tobacco product characteristics such as addition of non-menthol cooling agents;
- 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;
- Research that addresses practices, interventions, and policies in healthcare and public health settings to improve behavioral outcomes related to tobacco, such as quit attempts, abstinence rates, and initiation;
- Machine learning methods and other artificial intelligence technologies that focus on economies of scale in health care systems are encouraged in the implementation of science-focused research applications;

- Innovations in the measurement of social constructs and types of study designs available to examine and track changes in tobacco-related health disparity indicators over time. For example, innovations in the measurement of structural determinants and commercial determinants of health and study designs that include analysis with sufficient power to stratify by important sociodemographic characteristics for addressing tobacco-related health disparities (such as race/ethnicity, gender identity, LGBTQ+ identity, age, income, etc.) 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 Appendix A, Section 1 above.

Examples of relevant research topics:

- Evaluation of state and local tobacco regulations and their impacts on the community, public health, and the local economy such as:
    - the elimination of flavored tobacco product sales;
    - intended and unintended consequences of state and local tobacco laws, including issues related to compliance and enforcement;
    - changes to the tobacco and vapor retail environment in response to recent laws, including non-menthol cooling agent additives;
- Evaluations of how cannabis control policy interacts with and potentially undermines tobacco control policy;
- Development and evaluation of 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 diseases resulting from the use of commercial tobacco products, 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. Applications proposing research in basic and preclinical science studies of tobacco-related diseases must incorporate nicotine and/or other constituents of commercial tobacco products in order to be deemed "tobacco-related" and eligible for TRDRP funding.** *See the introductory section on Scientific Eligibility Criteria for guidance on TRDRP's refined definition on "tobacco-relatedness". *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:

- Clinical and/or pre-clinical studies on the carcinogenic potential of new tobacco products.
- Implementation strategies aimed at improving evidence-based tobacco treatment in diverse cancer care settings that evaluate cotinine and other tobacco biomarkers in priority populations.
- Mechanistic insights informing prevention strategies in patients who engage in co-use of cannabis and tobacco during cancer treatment.
- The impact of menthol synthetic cooling agents (such as WS-3 and WS-23) on cellular processes such as proliferation, cell cycle checkpoint mechanisms, and senescence.
- The development of therapeutic strategies for small cell lung cancer (SCLC) with assessments of therapeutic efficacy in smokers and non-smokers. Note*: Lung cancer studies should focus on disease types that are strongly correlated with tobacco product use (e.g., SCLC).*

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 topics:

- Innovative, cost effective, and accessible approaches to early detection of oral disease in smokers.
- Research into interventions to reduce oral cancer incidence and mortality among commercial tobacco product users from tobacco priority populations. Note*: Research on Oral Cavity and Pharyngeal Cancers should focus on disease types that are strongly correlated with tobacco product use (e.g., 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 e-cigarette aerosol indicating the role of nicotine, flavorants or non-menthol synthetic cooling agents.
- 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 in current and former commercial tobacco users.
- The role of combusted tobacco smoke or new and emerging tobacco products in the development and exacerbation of asthma, emphysema, COPD, or idiopathic pulmonary fibrosis.
- Impact of tobacco product use on the general lung health of youth or individuals in 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, diabetic retinopathy, and glaucoma;
- 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 commercial tobacco products, secondhand (SHS) and thirdhand (THS) smoke, chemical residue interactions, and tobacco product waste (TPW) bioaccumulation. 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 and nicotine products, SHS and THS in multi-unit housing, all indoor public spaces, or other settings.
- Devise strategies for vulnerable communities to mitigate environmental exposure to commercial tobacco product(s) and TPW.
- Discern environmental determinants of smoking behavior.
- Measure SHS, THS and TPW chemical exposure levels, chemical composition of dust and aerosol particle composition and chemical interactions using technologies and model systems.
- Identify biomarkers to distinguish commercial tobacco product use and cannabis product co-use.
- Determine potential toxicological, health and behavioral effects of exposure to non-menthol synthetic cooling agents (e.g., WS-3 and WS-23), nicotine alkaloids (nicotyrine) and synthetic nicotine (metatine and meta-nicotine) across the lifespan.
- Enable prediction of human health effects of tobacco and nicotine products by identifying causal links of dose-response toxicity assessments on human biological pathways and conduct validation studies using primary human cell models.
- Identify potential health impacts and devise strategies to mitigate exposure to tobacco and nicotine product 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 and nicotine products, new product waste and bioaccumulation.
- Evaluate the impact of environmental endpoints of TPW including microplastics on the environment and ecosystems such as soil, aquatic systems, waste management systems and storm drains.
- Determine the environmental burden of E-cigarette product waste components such as batteries, and metallic components.

6. Neuroscience of Nicotine Addiction and Treatment

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

Examples of relevant research topics:

- Use of interdisciplinary approaches (genetic, molecular, cellular, neuroimaging, neuropsychological, cognitive, behavioral and/or developmental) to identify genetic variants and neurological biomarkers associated with nicotine dependence, metabolism and treatment responses.
- Identify potential age-related differences in progression toward nicotine addiction, nicotine withdrawal, and nicotine behavioral adaptation.
- Develop therapeutic strategies for nicotine overdose, strategies to prevent/overcome nicotine relapse after cessation, strategies to improve smoking cessation rates among heavy smokers, and therapeutic strategies for youth with nicotine dependence.
- Discern potential health effects of flavorants or tobacco products containing non-menthol synthetic cooling agents (e.g., WS-3 and WS-23), nicotine alkaloids (nicotyrine) and synthetic nicotine (metatine and meta-nicotine) on neurological health and behavior
- Understand the impact of vape product design, constituents and vape aerosols that deliver nicotine on product preference, potential mechanisms in neurological health and behavioral outcomes.
- Determine the neurological mechanisms underlying nicotine and/or dual use with cannabinoids including the involvement of reward circuits in relation to social cues/lifestyle rituals, indicators of stress, and psychiatric disorders.
- Probe the potential mechanisms for nicotine to alter neuronal cells and brain circuits and/or induce behavioral changes by engaging nicotine receptors in different regions of the brain and non-nicotinic or unknown off-target sites implicated in nicotine use.
- Translate innovative research findings of tobacco and nicotine impacts on the brain and behavior to improve cessation treatment outcomes.

APPENDIX B: DETAILS ON GRANT AWARD Mechanisms

Research Award

Purpose: Conduct next phase/fully developed, hypothesis-driven research based on promising preliminary or formative data gathered through prior pilot research. The goal is to provide continued support for highly innovative research proposals with substantial promising preliminary or supporting data that reflects a clear progression beyond the earliest phases of the work and has clear potential for future impact. Research Award applications should not be exploratory in nature and should include strong supporting data.

Eligibility: Any tobacco related topic may be submitted under the Research Award mechanism. Please note the changes in the "Scientific Eligibility Criteria" section and the refined definition of tobacco-relatedness.

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 and alignment with TRDRP goals as outlined in the Introduction.

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), 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 35 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 mechanism:** Does the preliminary data address one or more TRDRP research priorities (Appendix A) 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:** If the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users? Do basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan? Do clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use?
- **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 over 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, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate plans to include subjects of all gender identities, 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: Conduct hypothesis-driven research to gather preliminary data or demonstrate proof-of-principle to inform the feasibility of a new paradigm or research hypothesis. The goal is to provide initial support for highly innovative research proposals with clear potential for future impact and potential to successfully leverage future funding from other sources.

Eligibility: Any tobacco related topic may be submitted under the Pilot Award mechanism. Please note the changes in the "Scientific Eligibility Criteria" section and the refined definition of tobacco-relatedness.

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 and alignment with TRDRP goals as outlined in the Introduction.

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 35 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 mechanism:** Does the applicant provide information on how the study will gather preliminary data that addresses one or more TRDRP research priorities (Appendix A) 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 mechanism?

- **Tobacco-relatedness:** If the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users? Do basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan? Do clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use?
- **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:** At the completion of the study, is it likely that the results will be sufficiently compelling to secure follow-on funding? How likely is it that the applicant will leverage funding from other sources to further develop this area of research within two to three years after initial funding?

Criteria-3 (20 percent scoring weight)

- **Investigators:** Are the investigators appropriately trained and well-suited to carry out this work? Is the work proposed appropriate to the experience level of the PD/PI and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?
- **Environment:** Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations or employ useful collaborative arrangements? Is there evidence of institutional support?
- **Community Engagement 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, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate plans to include subjects of all gender identities, 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: Conduct hypothesis-driven research to gather preliminary data for proof-of-principle projects, or projects based on promising preliminary data gathered through prior pilot research. The goal is to support new investigators on independent research projects within 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 supported by preliminary evidence.

Eligibility: Any tobacco related topic may be submitted under the New Investigator Award mechanism. Please note the changes in the "Scientific Eligibility Criteria" section and the refined definition of tobacco-relatedness.

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 and alignment with TRDRP goals as outlined in the Introduction.

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), 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; 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 35 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 to not less than 10 percent 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 mechanism:** Does the applicant describe how the study will generate pilot data for future funding or will expand an established line of research? Does the applicant describe how the project will address one or more TRDRP research priorities (Appendix A)?
- **Tobacco-relatedness:** If the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users? Do basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan? Do clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use?
- **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 proof-of-concept or 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:** At the completion of the study, is it likely that the results will be sufficiently compelling to secure follow-on funding? How likely is it that the applicant will 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)

- **Investigator**: Do the Investigator(s) 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 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, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research** If human subjects are involved, are there adequate plans to include subjects of all gender identities, 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: For postdoctoral investigators to conduct hypothesis-driven research in a mentored training environment. The research project should contribute to the advancement of one or more stated TRDRP research priorities. A highly innovative project with clear potential for impact is a key component of this award type. The objective of this integrated program of research and training is to support the applicant's own research project and to enhance their development into a productive and independent scientific professional within the tobacco-related disease research field.

Eligibility: Any tobacco related topic may be submitted under the Postdoctoral Award mechanism. Please note the changes in the "Scientific Eligibility Criteria" section and the refined definition of tobacco-relatedness.

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 and alignment with TRDRP goals as outlined in the Introduction.

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
    - **Institutional 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 training plan that is prepared in consultation with the applicant. The training 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 (40 percent scoring weight)

- **Tobacco-relatedness:** If the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users? Do basic and preclinical science

studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan? Do clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use?

- **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? Has the appropriate statistical analysis been integrated into the research plan? Does the applicant acknowledge potential problem areas and consider alternative strategies? Will the proposed research training experience significantly contribute to the development of the applicants' stated career path?
- **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? Does the applicant propose an activity that is appropriate to their proposed tobacco-related research topic, their proposed career path, and community needs? 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-2 (40 percent scoring weight)

- **Training plan:** Does the proposed training plan include effective ancillary activities that will enhance the training of the applicant? 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? If gaps in the applicant's curriculum research experiences exist, does the proposed training plan address these gaps? Does the training plan clearly outline a timeline of activities, responsibilities, expectations, and assessment of completed goals for both the applicant and mentor over the duration of the award? Does the proposed training plan support the applicant's indicated career goals?
- **Qualifications of the applicant:** Does the applicant present a strong academic background and research experiences (e.g., peer-reviewed publications, presentations, health assessments, agency reports, and/or other gray literature) appropriate for their career stage to support success in completing the aims within this proposal? What is the potential for the applicant to have a successful career in tobacco-related research in either an academic, governmental, or non-governmental setting? Does their publication record indicate an appropriate contribution for their career level?

Criteria-3 (20 percent scoring weight)

- **Mentor's qualifications and commitment:** Do the mentor's qualifications and track record of mentoring individuals at a similar career stage align with the needs of the applicant? Does the mentoring team have appropriate experience to support the applicant in conducting the proposed tobacco-related disease research?
- **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?

Other considerations

- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate plans to include subjects of all gender identities, all racial and ethnic groups (and subgroups) and children, as appropriate for the scientific objectives 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: Conduct mentored training of predoctoral students engaged in hypothesis-driven research that is focused on contributing to the advancement of one or more stated TRDRP research priorities. A highly innovative project with clear potential for impact is a key component of this award type. The objective of this integrated program of research and training is to support the applicant's own research project to enhance the individual's potential to develop into a productive, independent researcher or to establish an alternative career related to tobacco-related disease research.

Eligibility: Any tobacco related topic may be submitted under the Predoctoral Award mechanism. Please note the changes in the "Scientific Eligibility Criteria" section and the refined definition of tobacco-relatedness.

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 and alignment with TRDRP goals as outlined in the Introduction.

Award Overview:

- **Maximum stipend amount per year:** Up to $60,000
- **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. 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 training plan that is prepared in consultation with the applicant. The training 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)

- **Training plan:** Does the proposed training plan include effective ancillary activities that will enhance the training of the applicant? 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? If gaps in the applicant's research experience, training, or skill development exist, does the proposed training plan address these gaps? Does the training plan clearly outline a timeline of goals, activities, responsibilities, expectations for both the applicant and mentor? Are there plans for performing regular assessments of completed goals over the duration of the award? Does the proposed training plan support the applicant's indicated career goals?
- **Qualifications of the applicant:** Does the applicant present a strong academic background and research products (e.g., peer-reviewed publications, presentations, health assessments, agency reports, and/or other gray literature) appropriate for their career stage and academic environment to support success in completing the aims within this proposal? Does the applicant present non-traditional educational experiences and/or unique lived experiences that may contribute to their professional development as an independent researcher or public health professional? What is the potential for the applicant to have a successful career in tobacco-related research in either academic, governmental, or non-governmental setting?

Criteria-2 (30 percent scoring weight)

- **Mentor's qualifications and commitment:** Do the mentor's qualifications and track record of mentoring individuals at a similar career stage align with the needs of the applicant? Does the mentoring team have appropriate experience to support the applicant in conducting the proposed tobacco-related disease research?

- **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?

Criteria-3 (20 percent scoring weight)

- **Tobacco-relatedness:** If the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users? Do basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan? Do clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use?
- **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? Has appropriate statistical analysis been integrated into the research plan? 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 stated career path?
- **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? Does the applicant propose an activity that is complementary to their proposed tobacco-related research topic and career stage? Are there adequate resources to the applicant to carry out the proposed activities?

Other considerations

- **Protection of human subjects from research risk:** If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed.
- **Inclusion of women, minorities and children in research:** If human subjects are involved, are there adequate plans to include subjects of all gender identities, 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 Award mechanism 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: Conduct the initial phase of a hypothesis-driven community-partnered research project, up to 2-years of support, 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 goal of the Pilot CPPRA is to provide initial support for community-partnered research projects with potential to inform a prevention or cessation intervention in the future.

Eligibility: There are multiple eligibility criteria required for this award mechanism which are explained in the standalone CPPRA Request for Applications.

Letter of Intent Requirement: A Letter of Intent (LOI) is required for the Pilot CPPRA Award mechanism. Please see "Letter of Intent Instruction" section in the CPPRA RFA and in the Letter of Intent section in the Core RFP.

Award Overview:

- **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*, costs to develop print and digital intervention materials, 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 35 percent, or 25 percent for projects conducted off-campus.

*All out-of-state subcontracts 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 Award mechanism 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 Award mechanism 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: Conduct the continuation of hypothesis-driven, community-partnered research projects, up to **3-years** of support to development, evaluation, testing, or examination of a community tobacco prevention intervention or treatment intervention. Applicants to the Full CPPRA Award mechanism are expected to focus the project on building from pilot or preliminary data and to be focused on tobacco-related research issues of importance to the community. The goal of the Full CPPRA is to provide continued support for community-partnered research projects with potential to inform a prevention or cessation intervention in the future. **Full CPPRA** applications should include strong supporting data.

Eligibility: There are multiple eligibility criteria required for this award mechanism which are explained in the standalone CPPRA Request For Application.

Letter of Intent Requirement: A Letter of Intent (LOI) is required for the Full CPPRA Award mechanism. Please see "Letter of Intent Instruction" section in the CPPRA RFA and in the Letter of Intent section in the Core RFP.

Award Overview:

- **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 35 percent, or 25 percent for projects conducted off-campus.

*All out-of-state subcontracts 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 Award mechanism 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/.

Maternal Smoking Cessation Initiative

**** The Maternal Smoking Cessation Initiative (MSCI) Award has a separate Request for Application (RFA), which must be read and adhered to by the applicant terms. The separate RFA can be found on TRDRP's website under Funding Opportunities****

Purpose: Prioritizes research dedicated to developing, implementing, and evaluating culturally-tailored commercial[6] tobacco cessation interventions specifically designed to improve health outcomes for pregnant individuals who identify as Black, Indigenous, and People of Color (BIPOC), American Indians, and Alaska Native (AIAN). The core objective is to cultivate sustainable interventions that effectively address the unique needs and challenges faced by these populations. Project proposals must demonstrate a firm grounding in relevant cultural frameworks, informed by established theoretical models of behavior change specific to the context of pregnancy.

[6] Any reference to tobacco uses among AIAN communities is specific to regular recreational use of commercial tobacco and not to be confused with ceremonial use of traditionally grown tobacco which is recognized as an important cultural and spiritual ritual within these communities.

Applicants will present a well-defined plan for either data collection or intervention development and implementation with the potential for long-term sustainability. TRDRP strongly encourages inclusion of community members and organizations representing the populations under study throughout all research stages, fostering collaboration from design inception to implementation.

Award Mechanisms: This RFA will support two award mechanisms to address two different TRDRP strategic objectives. **The Partnered-Maternal Smoking Cessation Initiative Award (Partnered-MSCI)**, which is for a hypothesis-driven research project that focuses on the development and implementation of culturally-tailored interventions for smoking cessation among pregnant individuals from BIPOC and AIAN communities, highlights TRDRP's objective of supporting research collaborations developed and led by community and academic partners as Co-Principal Investigators (Co-PIs). **The Single Investigator-Maternal Smoking Cessation Initiative Award (Single Investigator-MSCI)**, will support the creation of an open access data repository that will be made available to researchers with an interest in maternal smoking behaviors and cessation within the populations outlined in this RFA. The Single Investigator-MSCI highlights the importance TRDRP places on supporting innovative research on tobacco-related diseases. This comprehensive approach aims to generate not only effective smoking cessation interventions but also robust epidemiological data that can inform future research directions and public health strategies to improve pregnancy outcomes for these vulnerable populations.

Eligibility: The eligibility criteria for the MSCI award mechanisms are outlined in the standalone MSCI Award RFA.

Letter of Intent Requirement: A letter of intent (LOI) is required for both award mechanisms (Single Investigator-MSCI and Partnered-MSCI). You are encouraged to contact Tobacco-Related Disease Research Program with questions about applying for the award.

Award Overview:
Partnered Maternal Smoking Cessation Initiative Award (Partnered-MSCI)

- **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 Award 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 35 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 requirements for the Partnered-MSCI Award mechanism and expectations for Community and Academic Co-PIs are outlined in the separate MSCI Award RFA.

Review criteria: Detailed review criteria are described in the MSCI Award RFA.

Single Investigator Maternal Smoking Cessation Initiative Award (Single Investigator-MSCI)

- **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 35 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: The requirements for the Single Investigator-MSCI Award mechanism and expectations for Community and Academic Co-PIs are outlined in the separate MSCI Award RFA.

Review criteria: Detailed review criteria are described in the MSCI Award RFA.

For more details read the Maternal Smoking Cessation Initiative (MSCI) Award Request for Applications: https://trdrp.org/funding-opportunities/.

Cornelius Hopper Diversity 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 Supplement to a Core Call award must be submitted as part of a scientific progress report for an active, non-mentored TRDRP grant. CPPRA grantees may apply for a Cornelius Hopper Diversity Supplement as part of pre-funding activities during the post-award period.

There must be at least one year remaining on the 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 Award 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 Award Supplement.
- Principal Investigators of Postdoctoral and Predoctoral Awards are **not** eligible to apply for a Student Research Award Supplement.

Trainee eligibility:

- Undergraduate and master's students are eligible for a Student Research Award 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.

There must be at least one year remaining on the 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:
  - http://grants.nih.gov/grants/policy/person_months_faqs.htm
- NIH Calculation Scheme:
  - http://grants.nih.gov/grants/policy/person_months_conversion_chart.xls

Provide a justification for all budgeted personnel, identifying each individual by name, role on the project, and proposed effort. 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). The program does not enforce a salary cap, as long as the overall budget adheres to the costs & expenses guidelines and the amount requested stays within the allowable costs.

Student Tuition Fees, Graduate Student Stipends

For non-fellowship awards: Graduate students may be paid as personnel and may also receive tuition remission and compensation in line with the relevant collective bargaining agreement. Stipends may not exceed $60,000 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. Please provide documentation of current institution rates and/or scales for requested tuition & fees and stipends.

Other Project Expenses

Include expected costs for supplies and other research expenses not itemized elsewhere. Please pay special attention to expenses that include or exclude associated indirect costs by selecting from options in the drop-down menus in the “Included in IDC” and “Not-Included in IDC” sub-categories. Cost should be broken out by year, include overall cost by category, an itemized sub-category list, and description of costs.

Examples of justifications that meet these requirements are as follows:

- General lab supplies, chemicals, and biochemicals and chemicals (Year 1: $16,123; Year 2: 15,884; and Year 3: 12,810) – This cost includes purchasing routine lab supplies such as plasticware and glassware for various preparations and disposable items, including pipettes, filter units, conical tubes, gloves, etc. Research cigarettes will be needed for the studies. The use of biochemicals, proteins, extracellular matrix substances, and molecular biology enzymes, markers for various protein and nucleic acid studies will be needed throughout the study. Materials to run various agarose and polyacrylamide gels are required. CO2, dry ice, liquid nitrogen, oxygen, and various small instruments are necessary for the daily procedures performed in a molecular biology laboratory. Chemicals used throughout the various studies will be required to produce various solutions.

- Cell isolation and culture (Year 1-3: $3000/year) - The project will employ the culture of cardiac myocytes from the various mouse models. This cost will cover collagenase, LiberaseTM, trypsin, serum, antibiotics, media, and other various chemicals and supplies related to these studies.
- Office Supplies / Computer (Year 1-3: $5,000/year) - Costs are required to purchase office supplies and computer software for statistical analysis.

Pooled expenses (e.g. insurance surcharges such as GAEL, system wide networking surcharges, and other pooled training and facilities 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.

Participant Support Costs are direct costs for items such as stipends for subsistence allowances, travel allowances, and registration fees paid to or on behalf of study participants or trainees (but not employees) in connection with conferences, or training projects. If allowable, these costs are excluded from Modified Total Direct Costs (MTDC). Participant Incentives encourage an individual to participate as a research subject, and may include payments. gift cards, dependent care costs, parking fees and transportation reimbursement. These costs are allowable and included in MTDC. Please ensure any Participant Incentives are described clearly 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. A quote may be requested during the pre-funding period prior to the issuance of an award.

Travel

Please provide itemized details as to the number of travelers and mode of travel for each travel category relevant to your project.

- **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 Research Grants Program Office (RGPO) 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-TRDRP 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). Provide hours/rate for consultant effort on the project if applicable.

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, Cornelius Hopper Diversity Award Supplements, Dissemination Projects, or Scientific Conference Awards. For other awards, Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 35% 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, participant support costs, 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 capped by the statewide rate agreement as described in the RFP). 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 mechanisms. The LOI must be submitted electronically. LOI submission instructions should be strictly followed as stated. LOIs will be programmatically reviewed for eligibility and alignment with TRDRP goals after the Thursday, August 22, 2024, deadline and applicants .will be notified whether they are invited to submit a full application by Monday, September 9, 2024. *See sections "Scientific Eligibility Criteria" and "Letter of Intent" (LOI) process for updates to this process. *All applicants should review the Call for Applications and SmartSimple Submission 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 mechanism 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, which 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., 2024) and resubmitted under the current Call for Applications (i.e., 2025). TRDRP will accept only a single resubmission of the same or very similar project, regardless of a change in the 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 SmartSimple Submission Instructions for the specific award mechanisms). All other applications are considered new applications.

Multiple Submissions Policy

Applicants may submit LOIs for no more than two projects as Principal Investigator, provided that the proposed research topics and aims are significantly different for each project. Predoctoral and Postdoctoral applicants may submit an LOI for only one project.

Principal Investigator 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.

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. NOTE: The organization must also meet our liability insurance requirements; please contact the appropriate Program Officer for more information. 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.

Pre-Funding Requirements

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

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

Publications Acknowledgement and Open Access

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

RGPO is committed to disseminating research as widely as possible to promote the public benefit. All publications based on funding received from RGPO are subject to the University's Open Access Policy which went into effect on April 22, 2014. To assist the RGPO in disseminating and archiving the articles, the grantee institution and all researchers on the grant will deposit an electronic copy of all publications in the 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 2024 Call Appendix B for the review criteria in each award mechanism). Applicants must read and follow all submission and application instructions in this document, SmartSimple Submission Instructions as well as the 2025 Call for Applications. In particular, the current application templates for grant documentation must be used. See SmartSimple to download the latest templates. Applications failing to use the correct templates will be administratively rejected.

Instructions for completing templates in the DOCUMENTATION tab of SmartSimple

Research Plan

(Required for Research (10-page), Pilot (10-page), New Investigator (10-page), Postdoctoral(10-page) and Predoctoral (6-page) Award Applicants)

Note: Submitted Research Plans will be truncated to the page limit indicated on the template by RGPO Staff prior to peer review. The page limits are indicated on the Research Plan Template in the Documentation tab of SmartSimple and in the Smart Simple Submission Instructions.

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

1. **Revision Statement (IF APPLICABLE):** A revision statement is limited to two pages immediately preceding the Research Plan. The revision statement should summarize any substantial additions, deletions, and changes that have been made. It must also include responses to criticisms in the summary statement provided in response to the previous submission. These changes should be highlighted within the text of the Research Plan by appropriate bracketing, indenting, or changing of typography. The "Preliminary Studies" section should include any relevant work done since the prior version was submitted. 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 Research Award, New Investigator Award, Postdoctoral or Predoctoral Award. Preliminary data submitted in New Investigator Award and Pilot Award applications will be subject to peer review.
4. **Responsiveness and Innovation:** Describe how the proposed research addresses one or more of the TRDRP research priorities. (Please see Appendix A of the 2025 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 Pilot or New Investigator Applications*, at the completion of the study describe how the results will be sufficiently compelling to secure follow-on funding. Explain how funding from other sources will be leveraged 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 (1 page)

(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 (1 page)

(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 Science Technology Engineering and Mathematics (STEM);
    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;
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.

Training Plan

(Required for Postdoctoral (4 page) and Predoctoral (6 page) Award Applicants)

The Applicant, in collaboration with the Mentor(s), must construct a detailed, well-rounded training plan. The training plan should demonstrate the anticipated value of the proposed mentored research and training in relationship to the trainee's unique research and career goals. The training plan should also indicate how the plan prepares the Applicant for the next stage of their career. If selected for funding, a complete individual development plan will be required as part of the Year 1 Annual Progress Report.

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

(i) Description of the Applicant
   a. Provide a brief description of the applicant's academic background and research interests that illustrates their path to their chosen research field and mentor.
   b. the Applicant's long-term plans for a scientific career,
   c. how the Applicant envisions the current project will prepare them for their next career stage;

(ii) Description of the Mentor
   a. how the Mentor's laboratory, research experience, and staff support the Applicant's proposed research and career goals
   b. specific resources (e.g. equipment, laboratory space, computer time, subject populations, etc.) that will be provided to meet the needs of the proposed study and the career goals of the Applicant
   c. how the institution provides appropriate and sufficient opportunities for the Applicant to gain professional and scientific skills

(iii) Applicant and Mentor Partnership
   a. Outline a proposed training plan to address gaps in the applicant's academic and/or research experience;
   b. Create a timeline of activities, responsibilities, expectations, and assessment of completed goals for both the Applicant and Mentor over the course of the award;
   c. Identify scientific research methods including research design, experimental methods, and analytic techniques appropriate for proposed research;
   d. Explain what additional experiences, classes or scientific techniques will be planned to supplement the trainee's knowledge and support future independence, such as professional skills and building effective collaborations;
   e. Identify and indicate in timeline of activities for training on the ethical conduct of research (Required);

f. Provide opportunities to present and publish research findings and to interact with members of the scientific community at meetings and workshops;
g. Propose methods on how to disseminate research in a manner readily understandable by non-scientists;
~~h.~~ 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 (2 pages)

(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 disease or tobacco control area of research.

Vertebrate Animal Subjects (No page limit)

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 (No page limit)

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 people, 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 Investigational New Drug (IND) Application 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 application number and title, 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 if the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users. Explain how basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan. Describe how clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use.
	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 generate pilot data or expand an established line of research that addresses one or more TRDRP research priorities. Describe how the proposed research demonstrates proof-of-principle to support the feasibility of a new paradigm or research hypothesis or 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 if the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users. Explain how basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan. Describe how clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use.
	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 they will advance scientific knowledge or clinical practice.

Pilot Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
	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 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	Describe how, at the completion of the study, the results will be sufficiently compelling to secure follow-on funding. Explain how funding from other sources will be leveraged to further develop this area of research within two to three years after initial funding.
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 PD/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 Mechanism	Research Plan	Explain how this project will (1) generate pilot data for future funding or (2) to expand an established line of research that is supported by preliminary evidence. 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 if the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users. Explain how basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan. Describe how clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use.
	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 proof-of-concept or more than an incremental advance upon published data. For example, explain how the project challenges 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, please clearly state the

New Investigator-Review Criteria (Percent scoring weight)		Where in the app to address	Guidance
			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 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	Describe how, at the completion of the study, the results will be sufficiently compelling to secure follow-on funding. Explain how funding from other sources will be leveraged to further develop this area of research within two to three years after initial funding.
Criteria 3 (20%)	Investigator	Biosketches; Letters of Support.	State how the investigator(s) 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 Plan	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 (40 %)	Tobacco-Relatedness	Research Plan	Describe how if the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users. Explain how basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan. Describe how clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use.
	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, strength of recruitment plan, and statistical analyses), 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 stated career path. 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. 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.
	Community Engagement Plan	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 how the approach is connected to the proposed research, Applicant's career path, and community needs. Describe to what extent dissemination of relevant results of funded research goes beyond the research community and includes 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 2 (40%)	Training Plan	Mentor/Training	Describe ancillary activities that will enhance the training of the applicant. Explain additional experiences planned that will 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. If gaps in the applicant's curriculum research experience exist, describe the proposed mentoring plan to address these gaps. Describe the timeline of activities, responsibilities, expectations, and assessment of completed goals for Applicant and Mentor(s) over the course of the award. Describe how the training plan supports the Applicant's indicated career goals.
	Qualifications of the Applicant	Applicant's Biosketch; Letters of Reference	Describe the applicant's academic background and research experiences (e.g., peer-reviewed publications, presentations, health assessments, agency reports, and/or other gray literature) which are appropriate for their career stage. Describe how such background and experiences will support the success to complete the aims stated within this proposal. Describe the potential for the applicant to have a successful career in tobacco-related research in either academic, governmental, or non-governmental setting. Explain how their publication record is appropriate for their career level.
Criteria 3 (20%)	Mentor's Qualifications and Commitment	Mentor's Biosketch; Mentor/Training 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. Describe how the Mentor's qualifications and track record align with the training needs of the applicant. Describe how the mentoring team has the experience to support the applicant in conducting tobacco-related disease research. Please note that if a Postdoctoral Award Applicant is planning to have more than one mentor, the main mentor's role should be designated as "Mentor" in the Project Personnel List. An additional co-mentor can be designated as "Research Advisor".
	Environment	Facilities; Letters of Reference	Describe how the institutional 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 and commitment, as appropriate.

Predoctoral Award – Applicant Instructions			
Predoctoral Award- Review Criteria (Percent Scoring Weight)		**Where in the app to address**	**Guidance**
Criteria 1 (50%)	Training Plan	Mentor/Training Plan; Letters of Reference	Describe ancillary activities that will enhance the training of the applicant. Explain additional experiences planned that will 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. If gaps in the applicant's curriculum research experience exist, describe the proposed mentoring plan to address these gaps. Describe the timeline of activities, responsibilities, expectations, and assessment of completed goals for Applicant and Mentor(s) over the course of the award. Describe how the training plan supports the Applicant's indicated career goals.
	Qualifications of the Applicant	Applicant's Biosketch; Letters of Reference; Mentor/Training Plan	Describe the applicant's academic background and research experiences (e.g., peer-reviewed publications, presentations, health assessments, agency reports, and/or other gray literature) which are appropriate for their career stage. Describe how such background and experiences will support the success to complete the aims stated within this proposal. Describe the potential for the applicant to have a successful career in tobacco-related research in either academic, governmental, or non-governmental setting. Explain how their publication record is appropriate for their career level.
Criteria 2 (30%)	Mentor's Qualifications and Commitment	Mentor's Biosketch; Mentor/Training 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. Describe how the Mentor's qualifications and track record align with the training needs of the applicant. Describe how the mentoring team has the experience to support the applicant in conducting tobacco-related disease research. Please note that if a Predoctoral Award Applicant is planning to have more than one mentor, the main mentor's role should be designated as "Dissertation Advisor" in the Project Personnel List. An additional co-mentor can be designated as "Research Advisor".
	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

Predoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
			features of the scientific environment, or subject populations or employ useful collaborative arrangements. Provide evidence of institutional support and commitment, as appropriate.
Criteria 3 (20%)	Tobacco-Relatedness	Research Plan	Describe how if the proposed research is completed would the outcomes be informative or beneficial for current and prior commercial tobacco product users. Explain how basic and preclinical science studies of tobacco-related diseases, substantially incorporate nicotine and/or other constituents of commercial tobacco products into the research plan. Describe how clinical, translational, or implementation studies inform prevention and/or involve human subjects that have a history of commercial tobacco product use.
	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, strength of recruitment plan, and statistical analyses), 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 stated career path. 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. 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. 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 stated career path.

Predoctoral Award- Review Criteria (Percent Scoring Weight)		Where in the app to address	Guidance
	Community Engagement Plan	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 how the approach is connected to the proposed research, Applicant's career path, and community needs. Describe to what extent dissemination of relevant results of funded research goes beyond the research community and includes channels and tools targeting clinicians, public health practitioners, advocates, policymakers, and the general public.