Maternal Smoking Cessation Initiative (MSCI) Award
Request for Applications

MSCI Key Dates

A letter of intent is required for the MSCI grant type. You are encouraged to contact the Tobacco-Related Disease Research Program with questions about applying for the MSCI Award.

Call Open	Monday, July 1, 2024
Applicant Webinar for MSCI Applicants	Tuesday, August 6, 2024 10:00 -11:00 a.m. PT
LOI Submission Deadline	Thursday, August 22, 2024 12:00 p.m. (noon) PT
Invitation to Full Application Announced	Monday, September 9, 2024
Due Date for New Applications and Resubmissions	Wednesday, October 30, 2024 12:00 p.m. (noon) PT
Applicants Notified	April 2025
Awards Start	July 1, 2025

Use the following link to register for and join the applicant webinar:
(https://UCOP.zoom.us/meeting/register/tJYoceugrzspGNY3pGYBr29O_6ylp7lQmfzr)
Maternal Smoking Cessation Initiative (MSCI) Applicant Webinar,
Tuesday, August 6, 2024, 10:00 a.m.- 11:00 a.m. PT
For those unable to attend, a recording of the webinar will be made available on the TRDRP website.

Contact Information for Inquiries
Tobacco-Related Disease Research Program (https://trdrp.org/)
Research Grants Program Office (https://www.ucop.edu/research-grants-program/)
Email: trdrp@ucop.edu

Introduction to Maternal Smoking Cessation Initiative Award

Purpose

This Request for Applications (RFA) prioritizes research dedicated to developing, implementing, and evaluating culturally-tailored commercial* 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. 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.

*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.

Background

Despite the success of nationally recognized commercial tobacco cessation programs, the National Center for Health Statistics reports that among any racial or ethnic group, smoking rates during pregnancy for American Indian/Alaska Native are among the highest of any racial ethnic group.[1] Trends in maternal smoking from 2016-2021 saw a decline from 7.2% to 4.6%, yet smoking was still reported as highest among younger women (under age 30), non-Hispanic American Indian or Alaska Native and non-Hispanic White mothers.[2] Furthermore, the results of the pregnancy risk assessment monitoring system, which monitors 40 sites within the US, suggests that women between the ages of 20-24, that have high-school diplomas, Medicaid coverage, and belong to the subpopulation AIAN have the highest prevalence of smoking during the prenatal and postpartum period of their pregnancy as well as the lowest prevalence of smoking cessation during pregnancy.[3] Even with the decline in maternal smoking, prenatal cigarette exposure still remains one of the most prevalent and treatable causes of infant morbidity and mortality in US populations with the highest maternal smoking prevalence.[4]

The American Congress of Obstetricians and Gynecologists report that a woman's peak reproductive years are between the late teens and late 20s, but onset of decline in fertility is observed by age 30.[5] With the most recent trends reported in maternal smoking among younger women, there is a need to better understand the obstacles to quit smoking and develop strategies to address smoking cessation during pregnancy in the United States.

The National Center for Health Statistics (NCHS) reports maternal mortality statistics in 2020 for non-Hispanic Black women of 55.3 deaths per 100,000 live births, representing a 3-4x higher mortality risk than their white

counterparts. In 2021, the maternal mortality rates for black women, which also correlated with higher maternal age, increased to 69.9 per 100,000. [6] These emerging data on mortality rates within the US were also reflected by the Maternal Mortality Review Committees (MMRC) report, which found for non-Hispanic blacks, the leading underlying cause of death was related to cardiac and coronary conditions (e.g., deaths of coronary artery disease, pulmonary hypertension, acquired and congenital valvular heart disease, etc.). The most impactful outcome from the MMRCs report was the finding that 80% of pregnancy-related deaths were determined to be preventable. This disparity in maternal mortality is on trend with the National Vital Statistics Report on increased infant mortality that showed a decline in mortality rate for infants in each respective ethnic groups, but for non-Hispanic black women the rates were more than twice as high for infants of non-Hispanic whites. [7]

The interrelatedness of stress on mental and physical health outcomes among BIPOC and AIAN and other racial/ethnic groups are the result of cumulative health disparities aggravated by societal ills.[8] The historical impact of geographical segregation and forced relocation and its influence on unequal access to educational and employment opportunities has led to increased crime rates as well as higher rates of poverty in low-income neighborhoods.[9,10] Furthermore, individuals from communities plagued by poor living wages and housing insecurity are more likely to suffer from chronic stress and to engage in negative health behaviors, particularly commercial smoking, in an attempt to mitigate adverse mental health outcomes.[11] Even perceived stress that is associated with the feeling or idea of how much stress a person experiences has been shown in several cross-sectional studies to result in greater odds of smoking.[12,13] In fact, alleviating stress by smoking has been reported to contribute to persistent smoking among African Americans.[14,15] Whatever coping strategies smoking provides, more often, poor mental health outcomes are exaggerated or initiated, thereby leading to levels of increased stress.[16,17] Several studies have even shown a strong positive association between perceived stress and nicotine withdrawal symptomatology (dependence and urges) being more impactful in women.[18,19] Environmentally, it is also shown that Blacks are less likely than white smokers to have a total ban on smoking in their homes, which means that home smoking policies do not have the same impact on cessation outcomes for African Americans.[20] Furthermore, a staggering 84.5% of African Americans who smoke use menthol flavored cigarettes, a chemical additive which makes it easier to groom a first-time smoker to cigarettes and also makes it harder to quit. [21,22]

Historical underrepresentation in research plagues BIPOC and AIAN communities, yielding limited data on their specific health needs. This dearth of cultural representation undermines the generalizability of research findings to diverse populations. Furthermore, historical trauma inflicted through colonization, forced migration, and cultural erasure has left indelible scars within indigenous communities, fostering a deep-seated distrust of medical institutions. Systemic racism and discrimination permeate healthcare systems, further contributing to skepticism among BIPOC and African American communities regarding participation in research. Treatment protocols often fail to account for cultural nuances, language preferences, and traditional healing practices, leading to cultural insensitivity that alienates potential participants. To bridge this gap, researchers must actively engage with community leaders and elders, and ensure that interventions are crafted with cultural sensitivity and respect for the customs within each community.

Collectively, the obstacles to addressing health inequity within the BIPOC and AIAN communities, must be addressed by informed data on smoking behaviors and its impact on maternal and infant health outcomes among individuals that regularly experience multiple social stressors. Further, the need to develop culturally-tailored smoking cessation programs that incorporate strategies to address societal ills related to chronic and perceived stress are imperative to address the high smoking prevalence among BIPOC and AIAN pregnant persons.

Research Objectives

Proposals submitted in response to this RFA will outline interventions that comprehensively address all forms of commercial tobacco use among pregnant BIPOC and AIAN individuals. These interventions must be firmly grounded in relevant cultural frameworks that resonate with the chosen population and draw upon evidence-based theories of behavior change specifically tailored to the context of pregnancy. The focus should be on supporting the development of behavioral cessation interventions for commercial tobacco products that are tailored to address the unique needs and challenges faced by pregnant individuals who identify as BIPOC or AIAN. Crucially, applicants will demonstrate a deep understanding of the distinct sociocultural and psychological characteristics of these populations by engaging members of these communities during the drafting of the proposal and during intervention design and testing. Applicants are encouraged to explore research approaches that foster trust and engagement within these populations. Involving community members, including pregnant individuals, community leaders, and representatives from community-based organizations, from the early stages of research can optimize intervention development and enhance the eventual adoption and implementation of effective strategies.

Recruiting and retaining vulnerable populations in research studies has historically posed challenges. Applicants are strongly encouraged to detail their innovative, culturally-tailored approaches to engage, enroll and maintain retention of these vulnerable group(s) as defined in this RFA. Finally, applicants are expected to detail the process for obtaining parental or guardian consent, if applicable, and clearly describe how they will guide participants to overcome barriers relating to ensuring access to study clinics.

Applicants are strongly encouraged to consider leveraging cutting-edge advancements in digital and mobile technologies for smoking cessation delivery tools. These technologies hold immense promise in facilitating outreach and promoting engagement among those seeking smoking cessation support. However, applicants must carefully consider the potential need for Food and Drug Administration (FDA) review and authorization throughout the project lifecycle. This includes strategically determining the most appropriate stage to engage with the FDA for feedback to ensure regulatory compliance. Furthermore, proposals will include a comprehensive plan for the long-term adoption, implementation, and sustainability of the cessation intervention within real-world healthcare settings. This requires careful consideration from the earliest planning stages to ensure the intervention's long-term efficacy and accessibility for the target population(s).

Research designs that allow for evaluating cessation implementation endpoints are highly encouraged. Examples of such designs include hybrid effectiveness-implementation designs, pragmatic trials, and mixed-methods approaches. Additionally, it is crucial to include implementation science metrics. These metrics assess feasibility, identify facilitating factors and barriers, gauge acceptability among the study population, and measure fidelity of intervention implementation in real-world settings. Addressing cessation endpoints has the potential to decrease the timeframe from establishing intervention effectiveness to reaching key stakeholders, including the scientific community, practitioners, diverse public health organizations, and most importantly pregnant women who smoke and who can benefit from effective interventions.

Available Data Sets/Surveys:

- California Department of Public Health “Center for Health Statistics and Informatics” https://www.cdph.ca.gov/Programs/CHSI/Pages/Informatics-Branch.aspx
- California Department of Public Health “Maternal, Child, and Adolescent Health Division” https://www.cdph.ca.gov/Programs/CFH/DMCAH/Pages/default.aspx

- Center for Disease Control and Prevention, "Pregnancy Mortality Surveillance System" https://www.cdc.gov/maternal-mortality/php/pregnancy-mortality-surveillance/index.html
- NSDUH- National Survey on Drug Use and Health
- PATH- Population Assessment of Tobacco and Health
- NHANES-National Health and Nutrition Examination Survey

DETAILS ON MSCI 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 Award)** will support 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 investigate smoking behaviors and their relationship to societal stressors to generate data that supports 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.

Award Mechanism Overview

Partnered-Maternal Smoking Cessation	Single-Investigator Maternal Smoking Cessation
• Academic Co-PI, Community Co-PI • Community Advisory Board • Collaborative Agreement • Dissemination Strategy	• Principal Investigator • Data Repository • Open Access Tools

Partnered Maternal Smoking Cessation Initiative Award (Partnered-MSCI)

The **Partnered-MSCI Award** provides up to **2-years** of support for a community-academic research partnership focused on the development and evaluation of culturally-tailored interventions for smoking cessation among pregnant individuals from BIPOC and AIAN communities. In this partnered award mechanism, TRDRP solicits applications that are grounded in an equitable partnership between Co-Principal Investigators (Co-PIs); one community Co-PI and one academic Co-PI. TRDRP has funded community and academic research partnerships for over 20 years. Our firm commitment to funding research that fosters equitable collaborations between community members and experienced research scientists stems from a belief that integrating rigorous scientific methodology with community knowledge and involvement at each phase of the process leads to more sustainable and effective tobacco prevention and cessation interventions that can improve the health of Californians.

For this partnered award mechanism, the applicant must provide demonstration of proof-of-principle for the feasibility of a new paradigm in culturally-tailored maternal smoking cessation or a proposal to rigorously evaluate the utility of existing tobacco prevention paradigms or treatment programs for this cohort. Proposed culturally-tailored interventions for smoking cessation should be informed by the range of adverse perinatal as well as adverse maternal health outcomes from smoking. This entails the exploration of evidence-based tools, programs, and best practices specifically designed to address the unique needs and challenges faced by these vulnerable populations described in this RFA. Results from the Partnered-MSCI should be appropriately designed for dissemination as well as enhance the team's ability to leverage future funding from TRDRP or other funders.

Specific research questions of interest include, but are not limited to:

1. How can culturally-tailored behavioral tobacco cessation interventions be effectively adapted to address the unique risk factors faced by pregnant BIPOC individuals?
2. What evidence-based theories of behavior change are most relevant and effective for promoting smoking cessation among pregnant AIAN women?
3. How can interventions be designed to consider the cultural frameworks specific to AIAN pregnant individuals while promoting long-term tobacco cessation?
4. What strategies can be employed to engage BIPOC and AIAN pregnant populations in tobacco cessation programs, considering the confluence of cultural norms?
5. How do cultural beliefs and practices impact smoking behavior during pregnancy, and how can interventions leverage these cultural factors for positive change?
6. What role does community involvement play in the success of culturally-tailored tobacco cessation interventions for pregnant individuals from diverse backgrounds?
7. How can interventions address the intersectionality of race, ethnicity, and pregnancy-related factors to enhance smoking cessation outcomes?
8. What are the most effective ways to disseminate and implement culturally-tailored tobacco cessation interventions within BIPOC and AIAN communities during pregnancy?

Co-Principal Investigators (Co-PI) (Academic and Community); Partnered-MSCI Award:

- **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.

Additional Budget Considerations for Partnered-MSCI Awards

- Subcontracts are allowed for each Co-PI organization; must be fully justified. 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.*

- SmartSimple, TRDRP's grant management system, **treats funded Partnered-MSCI grants as one project with two budgets**. **TRDRP will issue a split-budget award, if funded**. One budget will be prepared by and awarded to the Community Co-PI's organization or institution and a second budget will be prepared by and awarded to the Academic Co-PI's organization or institution.

- **One organization will be responsible for officially submitting grant materials**. It is up to the applicant research team to decide if the Community Co-PI's or Academic Co-PI's institution will officially submit the grant application.

Eligibility for Partnered-MSCI Award

The submitted Partnered-MSCI application must include leadership from a team that includes one Community Co-PI and one Academic Co-PI. Each application can have only one Co-PI representing the community side and one Co-PI representing the academic side. If there is a need for other close collaborators, they can be designated in Key Personnel as a Co-Investigator, consultant, or collaborator.

The qualifications of a Community Co-PI:

• Based in California

• Affiliated with a tribal organization/tribe, California-Native-led nonprofit community-based group, or institution (i.e., they cannot be a lone person who is not connected to relevant community-based groups) that primarily provides services or resources to people in a community in California.
• Committed to representing the views of the community of interest
• Have the support of their organization to serve as a Co-PI for the project.
• There is not a requirement for a degree.
• U.S. citizenship is not a requirement.

A community partnership can also involve entities such as school districts, school educators and administrators, educational support service agencies, school-based health centers, county health departments, health care providers, hospitals, outpatient clinics, managed care plans, faith-based organizations, and other nonprofit community-based organizations. Partnerships that involve county health departments, state agencies, and schools or school districts should consider practical issues related to the bureaucracy and inherent structure of these entities, which can hinder a true, equitable partnership. Strategies to promote partnership within busy, under-resourced and hierarchical organizations should be discussed in your grant application. A community partner must be named and their California-based community-serving organization or institution must be named in the submitted application.

Community Co-PI and Partnering Community-Based Organization (CBO)

The **Community Co-PI** represents the community or tribal organization and acts as the lead community researcher. **The Community Co-PI must have a managerial or executive-level decision-making role within their respective CBO**. For the partnered-MSCI award type, the Community Co-PI will be responsible for managing their budgeted expenses while their CBO will be responsible for the fiscal administration of the community research budget as a whole. A California-based CBO must be named in the application submission. Even if an organization is identified as closely engaged in the community partnership, a lead person working at the organization must be named. The CBO must name and formerly approve an individual within their organization to serve as the Community Co-PI for this award type. A letter of collaboration is required from either the Community Advisory Board chair, Executive Director of the CBO, or Board of Directors of the CBO indicating support for Co-PI participation and confirming their review and agreement with the details described in the Collaborative Agreements application form.

Academic Co-PI and Partnering Academic Institution

The Academic Co-PI should have research expertise and publications related to the research questions in the proposal and a commitment to developing or enhancing an existing program of research focused on community-partnered participatory research or theoretical frameworks for community science. For the partnered award type, the Academic Co-PI will be responsible for managing their budgeted expenses while their university or research institution will be responsible for the fiscal administration of the academic research budget as a whole. An academic partner must be named and their California-based university or research institution must be named in the submitted application.

The qualifications of an **Academic Co-PI**:

- Based at a California academic or nonprofit research institution.

- Has a university faculty appointment or a community research scientist designation with an appointment at a community-based research organization or private research institution.
- Research scientists and community-oriented academics working at a non-university research organization that is a nonprofit can serve in this role.
- Must have PI status. PI status permits the academic applicant access to their institution's infrastructure support for managing research grants.
- Committed to conducting long-term community-partnered participatory research.
- Committed to accurately depicting the state-of-the-science for the community's benefit.
- U.S. citizenship is not a requirement.

Partnered-MSCI Review Criteria

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

- **Statement of Goals, Research Questions, and Specific Aims**: Are the goals clearly aligned, achievable, and within the scope of the RFA? For **Partnered-MSCI Awards**, does the application represent innovative smoking cessation efforts that can be further adapted within the communities identified in this cohort to apply for additional TRDRP funding in the future or funding from another agency? Are the research questions designed to address the scope of this RFA; do they encompass a reasonable amount of research activity for a two-year award? Is there a logical connection between the specific aims and a relationship to the RFA's long-term research goals?

- **Background, Significance, and Relevance to a Tobacco-Related Area:** Does the community of interest include the specific vulnerable populations outlined in this RFA? Does this study address culturally-tailored maternal/fetal smoking cessation strategies? Are the rationale and underlying proposed research question(s) well-supported and appropriately contextualized with consideration of social and structural determinants of health? To what extent is there evidence that the community-based organization or community members were involved in identifying and conceptualizing the approach to this RFA?

- **Research Plan: Research Design, Conceptual Framework, and Data Analysis Plan:** Are the conceptual or theoretical framework, design (including composition of study population and strength of recruitment plan), methods, and analyses adequately developed, well-integrated, well-reasoned, and appropriate to the aims of the project and the nature of the Partnered-MSCI grant type? Does the applicant team acknowledge potential barriers that might hinder study activities and consider alternative strategies? Are the proposed sample sizes adequate to answer the proposed research question(s)? If an intervention is proposed, are the variables and relationships to be examined clearly identified and testable? Is a data analysis plan clearly described? Are project milestones well-defined with quantifiable measures that are appropriate for assessing the success of the Pilot phase award? Is the proposed work feasible? Is the research design aligned with the capacity and expectations of the community and community-based organization (e.g., whether a randomized controlled trial (RCT) design violates community or community organization norms or is a RCT identified by the community as an acceptable design)? To what extent does the team consider relevant social and structural determinants of health factors that might reasonably be expected to impact the project from a health equity perspective?

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

- **Partnership Collaboration Plan and Team Communication Process:** Are the collaborative agreements described in the Collaborative Agreement plan clear and likely to lead to project success? Is the communication plan adequate to keep the community-based organization and, Community Advisory Board (CAB) updated on the research? Are there plans to seek input and guidance from the CAB? Is there a clear decision-making process for important project activities? Will the team monitor or evaluate the health of the community-academic partnership over time? Are plans to evaluate the strengths and growth areas of the community-academic partnership over time meaningful and likely to be useful?

- **Potential for the Proposed Work to Benefit the Community and Lead to an Intervention:** To what extent is there potential for the proposed research activity, if successful, to redress tobacco-related health disparities or promote a health equity issue among the cohort identified in this RFA within California? To what extent are community residents, community-based organizations, and academic institutions likely to benefit from the expected results from the proposed research?

- **Community Engagement and Capacity Building:** Does the applicant team propose a sound approach to engaging communities within the cohort identified in this RFA either by their collaborative partnership or by proactively informing respective community groups about the nature and significance of the research question and research outcomes? Will the team obtain feedback from the community or community scientists about the project and its findings? Will the project build capacity in the community, school, health clinic, or community organization for future research; improve tobacco-related service delivery or clinical practice change; or enhance tobacco control programming? To what extent are there opportunities for students at all levels of training and community residents at all educational levels to learn research skills that might expand the pipeline of community-based scientists engaged in tobacco control? Does the dissemination of findings include channels and tools targeting clinicians, other researchers, public health practitioners, educators, advocates, policymakers, funders, or the general public?

- **Dissemination Approaches and Sustainability Plan**: Are there plans to disseminate findings from the project to the community of interest? Will the Community Co-PI or the CAB be involved in interpreting research findings or comprehending what findings mean for the community? Are there plans to disseminate findings using channels and tools readily accessible and known by the community? Are there plans to inform the community of resources made available or improved by the findings from the proposed research? Are there plans to sustain the community-academic research partnership after the pilot or full phase of funding?
- **Statement of Future Goals:** Are future research goals clear and reasonable, and do they consider perspectives from the community of interest? Are the plans to apply for follow-up grant funding convincing?

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

- **Investigative Team:** Are the co-principal investigators and other key personnel listed in the grant proposal appropriately trained and well-suited to conduct community-partnered participatory research? Are the roles and responsibilities of the partners clearly described? Will the research process allow academic researchers to learn more about the community *and* will community members learn about the

scientific research process? Is the work proposed appropriate to the experience level of the co-principal investigators and other co-investigators (if any)? Do the investigators demonstrate access to the research population and community of interest?

- **Environment, Facilities, and Resource Availability:** Will the community locations in which the research will occur contribute to the probability of success? Does the proposed project utilize unique features of the community, institutions, or organizations involved in the research and/or utilize useful collaborative arrangements and assets to sufficiently resource the project? To what extent is the applicant team prepared to manage relevant social and structural determinants of health factors that might impact the environment in which the project is conducted? How prepared is the research team for a situation where community facilities and resources are not fully available to the team for the duration of the project? Is there evidence of academic institutional support and support from the community-based organization(s) involved in the project?

- **Community Assets**: Are community-level assets, strengths, and access channels well-described, appropriate for the study design and research question(s), and likely to contribute to the success of the project? Is the project likely to contribute to strengthening existing community assets for tobacco control in maternal and fetal health? Is there evidence of credibility of the partnering community-based organization within the community of interest, a track record of success in delivering services or programs in the community, and representation by a specific priority population within the organization?

Application Procedures for Partnered-MSCI Award

Considerations for Partnered-MSCI Applications

Programmatic Expectations of Academic & Community Co-PIs

Conducting community-partnered participatory research (CPPR) requires a continual **commitment to eliminating power differences between Co-PIs so that they are equal partners**. Strong **CPPR teams commit to engaging in bi-directional learning among the community and academic members** involved in the project. This builds capacity for future engagement in CPPR for community and academic organizations involved in the project.

The **spirit of the CPPR model** means that the Community Co-PI and Academic Co-PI closely collaborate on all aspects of the research process including:

- Identifying and developing the research question(s)
- Transforming community concerns into research questions
- Active, transparent, and frequent communication
- Working closely with Community Advisory Board (CAB) members
- Writing and submitting the research proposal
- Developing a plan for sustainability beyond the proposed project
- Designing and implementing the research project

- Analyzing and interpreting findings
- Preparing and submitting progress reports to the funder
- Co-authoring summaries for communities, scientific papers, policy briefs, and presentations
- Disseminating results to community and scientific audiences to foster collective impact in the community

To reach the level of collaboration described above, a community-academic research team must:

- Pay attention to the development and health of the collaborative relationship.
- Have a flexible, open communication style and plan that can accommodate differences in how community members and academic faculty work independently and collaboratively.
- Develop and engage in an equitable shared decision-making process and collaborative plan.
- Engage with a CAB that includes representation from the community of interest.
- Develop a mutually agreeable plan for sharing power, decision-making authority, daily work on the project budget, and resources including study data.
- Ensure that the budgets for community and academic partners are equitable and adequate for the activities assigned to each partner.
- Promote opportunities for the community and academic members of the team to contribute to manuscripts prepared for publication and reports for community and policy change makers.
- Develop and implement dissemination/communication strategies that are sensitive to the culture, experiences, structural social determinants of health, and needs of the community.

Community Advisory Board

Each project is required to constitute a Community Advisory Board (CAB) consisting of a minimum of three representatives of the community(ies) of interest in the project. Information about recruited CAB members and plans to recruit additional members must be entered on the **Community Advisory Board** template (2-page limit).

The purpose of the CAB is to provide feedback on all phases of the project, from early conceptualization to finalizing intervention development and implementation at the community level. The CAB should be comprised of individuals with expertise in tobacco control and other areas relevant to the project who can provide helpful feedback to the team on both community and scientific aspects of the project. Recruited CAB members must be named with a description of their organizational affiliation and proposed contribution for the project in relation to their role on the CAB. If designating CAB roles as yet to be determined (TBD), please describe areas of expertise your team will seek to recruit at a future time during the project.

One or more CAB members should represent the community of interest in the project. A CAB can provide feedback on 1) research questions; 2) recruitment plans; 3) survey questions or methods; 4) ethical considerations that will arise during the research project; 5) perspectives during data analysis and interpretation; 6) strategies to manage COVID-19 related impacts; and/or 7) non-traditional dissemination methods. There should be plans to evaluate engagement with your CAB to monitor and improve interactions with CAB members across the grant life cycle. For example, some teams periodically survey CAB members to determine if the meeting frequency and communication channels are helpful in keeping the CAB informed and receive feedback or to identify changes needed to keep members engaged over the course of the project. An approach that provides ongoing feedback on the strength of the partnership with the CAB and among CO-PIs is encouraged.

CPPR Rigor

The spirit of CPPR calls for the appropriate involvement of a community Co-PI and broader community at all stages of the research process. There must be genuine community involvement, and consideration should be given to the extent that members of the community of interest are represented on the research team and/or CAB. Community involvement should align with the capacity and expertise of members and organizations involved in the project. The ethical treatment of community members and their data is paramount. A detailed data sharing agreement plan should be prepared and described on the **Collaborative Agreements** form. The applicant team may contact the Program Officer who manages this grant type to discuss questions about the appropriate involvement of community members in a Partnered-MSCI application.

To support the scientific rigor of the Partnered-MSCI project, the applicant should not allow Co-Is, CAB members, or anyone who is shaping and implementing the project to have conflicting roles. For example, a CAB member should not be enrolled as a research participant. Research staff who are carrying out the project, whether they represent the community or academic perspective, should not also serve as research participants.

Partnership, Collaboration, and Community Engagement

The Partnered-MSCI team has an opportunity to describe (via the **Collaborative Agreements** form) how they will work together and share power, budget, resources, and outcomes with each other. In addition to the Community Co-PI and Academic Co-PI, the project team can include additional co-investigators, consultants, collaborators, mentors, students at all levels of training, and community residents at all educational levels to ensure there is culturally appropriate community and academic expertise on the team. Co-PIs should describe in their decision-making process plan how consensus or agreements will be reached for decisions that impact the research project. The team must ensure that the community and academic budgets are equitable and accurately reflect the effort contributed to the project by team members.

TRDRP values engagement with community residents and CBOs that translates to useful dissemination practices of community-partnered research findings and learning collaborative efforts for collective impact. It is imperative that applicant teams embed authentic community engagement at all levels of the research development process (from idea inception through dissemination and implementation activities). Consider innovative approaches to: support trainees from backgrounds that are underrepresented in research, support community-led efforts to redress tobacco-related health disparities affecting priority groups and promote evidence-informed public health policy. Applicant teams do not need to limit their community engagement activities to disseminating the results of completed TRDRP-funded research. Funds can be used to support community engagement activities relevant to tobacco control and tobacco-related health equity; costs can be described in the project budget.

Dissemination and Sustainability

Applicant teams must develop a *dissemination plan* and a *sustainability plan* that is described in the **Research Plan** as part of the Partnered-MSCI application package. There is a programmatic expectation for Partnered-MSCIs to effectively disseminate research findings and lessons learned from the project; plans for periodic community debriefs where Co-PIs present findings to community members and/or CBOs through in-person meetings or webinars, or regularly writing project briefs that can be used in discussions with policy change makers and community members who can benefit from the findings. In addition, teams should describe the

applicability of their research findings to other communities in California and include a plan for broader dissemination beyond their immediate community of interest in the project.

In the *sustainability plan*, efforts to continue the partnership activity after the life of the current phase of funding should be developed. Plans to evaluate the partnership over time can provide useful information on how to sustain the collaborative work. Early identification and utilization of community assets can also inform partnership sustainability and dissemination channels for findings. Plans for capacity building and maintenance on both sides of the partnership can be described in the proposal.

Cornelius Hopper Diversity Supplement (CHDS)

One of TRDRP's strategic objectives is to fund research that expands the pipeline of research trainees, community residents, and scholars engaged in tobacco prevention and treatment intervention in California. Newly funded Partnered-MSCI grantee teams have the option to apply for a Cornelius Hopper Diversity Supplement (CHDS) at the prefunding phase of the grant life cycle. This funding opportunity is available for Partnered-MSCI applications found meritorious after peer review and can be applied for during the prefunding phase. The CHDS support is 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 CHDS candidate or designee must be named and available to work on application materials in collaboration with at least one Co-PI on the Partnered-MSCI application, at the prefunding phase. All other CHDS eligibility requirements also apply when submitting CHDS paperwork during prefunding. The Supplement should support the designee's initial entry into the field of tobacco-related research, including people without a degree, or within the stated TRDRP research priorities. We hope that community residents will find this funding opportunity a useful training vehicle to explore their own research interests at a deeper level and expand the workforce of community scientists. The CHDS application instructions, candidate template forms, and budget-related forms will be made available to Partnered-MSCI grantee teams during the pre-funding process. Please do not add CHDS support to the Co-PI prime budgets, which have designated direct cost caps. The CHDS support is on top of the direct cost cap for the prime budget research activities, and budget matters will be addressed after a team is notified of the funding status. More information about the CHDS is located here: https://trdrp.org/funding-opportunities/award-mechanisms/cornelius-hopper-diversity-supplement.html.

Formatting Requirements and Important Reminders

Applicants who wish to apply for a Partnered-MSCI grant must use the University of California Office of the President (UCOP) Research Grants Program Office (RGPO) SmartSimple grants management system (https://rgpogrants.ucop.edu).

Please review the "SmartSimple TRDRP Application Submission Instructions" for the technical instructions to submit a LOI and Full Application. All required fields in SmartSimple must be completed prior to submission of the LOI and Full Application. The sections noted below provide supplemental programmatic instruction to guide the content of your submission.

Formatting Requirements

Proposal templates (such as the Research Plan) can be downloaded from the Documentation tab of your Full Application in SmartSimple, after your LOI is approved. Please follow all formatting instructions listed at the top of each template.

Deviations from the page format, font size, specifications, and page limitations, especially the page limit for the *Research Plan*, will be grounds for the TRDRP to reject and return the entire application without peer review.

Important Reminders

- Each Co-PI must be registered with SmartSimple (see SmartSimple instructions) and must select an institution with a tax ID (EIN) number.
- Other Documents Necessary to Review Prior to Submission: TRDRP Call for Applications— pertains to all award types.
- Technical Assistance is Available: For many community groups and scientific researchers, collaborations of this type are new and a bit confusing. Community groups may also be unfamiliar with the scientific research award process and the online application submission system. Please feel free to email trdrp@ucop.edu to request technical assistance. Our staff is not involved in the scoring process; any questions you ask will not affect the evaluation of your application in any way.

Letter of Intent Instructions

A letter of intent (LOI) is required for the Partnered-MSCI grant types. It will be used to assess the application eligibility requirements for this grant type as well as alignment of the project and TRDRP goals. The Community Co-PI or the Academic Co-PI can initiate the LOI process in SmartSimple (https://rgpogrants.ucop.edu). The Community Co-PI or Academic Co-PI must be identified at time of LOI submission; however, it is acceptable to identify one Co-PI after LOI submission. For example, the Community Co-PI can initiate and submit a LOI for programmatic review without an Academic Co-PI being listed, as long as there is a clear plan and timeline describing when the named Academic Co-PI will finalize their agreement to serve on the award. Both the Academic Co-PI and Community Co-PI must be named with organizational affiliation at time of submission of application materials for peer review.

Lay Abstract

Please use the following guidelines to write your Lay Abstract:

- **Lay Abstract:** This item is evaluated mainly in the programmatic review. **The text is also entered in the appropriate box in the "abstracts" page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the "abstracts" box. The **Lay Abstract** must include the following sections:
  - A **non-technical introduction** to the research topics
  - The **question(s) or central hypotheses** of the research in lay terms
  - The **general methodology** in lay terms
  - **Innovative elements and potential impact** of the project in lay terms

The abstract should be written using a style and language comprehensible to the general public. Avoid the use of acronyms and technical terms. The scientific level should be comparable to either a local newspaper or magazine article. Avoid the use of technical terms and jargon not a part of general usage. Place much less emphasis on the technical aspects of the background, approach, and methodology. If the partner of the submitting Co-PI has been identified, include the name and organization in the abstract. This abstract should be revised jointly by the academic and community partners for the Full Application.

Application Instructions

Responses entered at the LOI stage will be automatically entered in the Full Application stage. Please review all of the pre-populated information, make updates or changes as necessary, and save the form(s).

Application Section: Project Information

Please use the following guidelines to differentiate the Scientific Abstract from the Lay Abstract (described in "Letter of Intent Instructions" section above):

- **Scientific Abstract:** This item is evaluated mainly in the peer review. Do not use symbols or other special text, as these will not transfer to the "abstracts" box.

The Scientific Abstract should include:

- A short introductory paragraph indicating the **background** and overall topic(s) addressed by the research project.
- The **central hypothesis** or **questions to be addressed** in the project.
- A listing of the **objectives or specific aims** in the research plan.
- The major research **methods and approaches** used to address the specific aims.
- A brief statement of the **impact** that the project will have on tobacco.

Provide the critical information that will integrate the research topic, its relevance to tobacco, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum level of information. Make the abstract understandable without a need to reference the detailed research plan.

Application Section: Project Contacts

Project Personnel. Provide contact information and effort for ALL personnel on your project including the Applicant Co-Principal Investigators, Co-Investigator, Trainee, Collaborator, Consultant, and support personnel. **The applicant principal investigator should be listed with the role of "Applicant Principal Investigator" and the partner principal investigator should be listed with the role of the "Co-Principal Investigator."** Upload biosketches to each of your Key Personnel members in this section, as shown in the SmartSimple instructions.

Application Section: Budget

Each institution that is a partner in the project must complete a budget. This means the Community Co-PI and the Academic Co-PI will each have their own Budget. If a collaborative partner on the project has a subcontract, then that subcontracting organization can complete a budget, or the prime partner can complete the budget for the subcontracting organization.

Applicants should ensure that the direct costs on the *Budget* tab do not exceed the cap for each Co-PI on the award type.

Additional budget guidelines can be found in **Appendix** B of this document.

Application Section: Documentation

All required uploads are listed in the table below, and templates must be downloaded from the *Documentation* tab of SmartSimple. Templates must be completed, converted to PDF, and uploaded to your application, unless otherwise instructed.

Upload Item (Template/Form)	Page limit	Required or optional
Collaborative Agreements	**2**	**Required**
Community Advisory Board	**2**	**Required**
Letter of Commitment	**1**	**Required**
Community Engagement Plan	**1**	**Required**
Biosketches (All Personnel listed on Key Personnel form)	**5 (each biosketch)**	**Required**
Facilities	**1 per institution**	**Required**
Research Plan	**15 + references**	**Required**
Human Subjects	**No limit**	**Required**
Vertebrate Animals	**No limit**	**Optional**
Appendix list and uploads	**30**	**Optional**

Detailed Description of Proposal Templates

1. Instructions – COLLABORATIVE AGREEMENTS

This form is used in Peer Review in part to score the "PARTNERSHIP" criteria.

<u>Limit the text to three pages</u>: To be collaboratively prepared by the Community and Academic Partners. Remove descriptive text to ensure sufficient space for a thorough response to each section.

The **Community Co-PI Applicant** is required to verify the decision process addressed in this form by submitting a statement that the governing body representing their Community-Based Organization (e.g., Board of Directors) has reviewed and approved this agreement or provide a copy of a Community Agency Resolution or the section of minutes from a meeting of the Community Co-PI's governing body indicating their review and agreement with details outlined in the *Collaborative Agreements* form. The **Academic Co-PI Applicant** is responsible for ensuring the decision process addressed in this form is acceptable to and enforceable within their appointment at their research institution and is in accordance with policies at the research institution where they hold their appointment. A **letter of commitment** from a Department Chair or Director of Research at a non-university research institute that speaks to the academic commitment of the research center to adhere to processes detailed in this form is required. If a Letter of Commitment is not applicable, please upload a document with the text "Not Applicable" in order to bypass the system validation.

Ownership of Data. Describe the applicant team's decision about who will own the data from this project, the timeliness within which data will be shared with their partner, acceptable uses of data from this proposed project, and intellectual property rights AND how the team derived the decision (i.e., what factors were considered to be important in making this decision). If the applicant team decided that the data will be owned by only one of the collaborators, please consider that the need to continue to work together will likely extend well beyond the grant period. Will the partner who owns the data be willing to volunteer their time well after the grant period to provide access to the data for the other partner? Be sure to discuss ownership of identified and de-identified data, how IRB and the ethical treatment of participant data will be managed and include arrangements both partners have agreed to ensure access to the data by the other partner (including beyond the study period).

Conflict Resolution. Describe the process you will go through to manage disagreements that might arise during the study and afterwards. Occasionally, community-academic research teams have had to resolve issues around data ownership, conduct of the research, exclusion/inclusion criteria, addressing the needs of the community, cultural humility, dissemination of data and manuscript preparation for publication, administrative, timely payments, and other budget issues. Describe how your decision process and resolution plan will work for your team.

Plans for Broader Community Involvement in ALL phases of the Research Project. Describe how individual community members not on the research team or community-based organizations not directly overseeing the project (e.g., staff or board of a community agency) will or might be involved in the planning, conducting, evaluation, or dissemination of research activities and study findings. Describe how broader community participation will be managed by the co-principal investigators and research team.

Team Communication Plan. Describe the frequency and modes of communication that will be utilized to ensure the co-principal investigators stay abreast of the research progress and challenges when they arise. Describe how the Community Co-PI and their community organization will communicate with one another to facilitate input and decision-making. Describe how the Academic Co-PI and their research institution will communicate with one another to maintain buy-in and departmental support for the project and ensure the research adheres to institutional policies and best practices for academic research.

Decision-Making Process for Community and Academic Co-PIs. Develop and describe a multiple PI decision-making process and plan. Given there might be multiple co-investigators, consultants, and collaborators, in addition to the Community Co-PI and Academic Co-PI, involved in the proposed community-partnered research project, it is imperative that a plan is in place that considers multiple perspectives from the research team and community advisory board and includes a process that can lead to a consensus, majority decision, or other decision process that is mutually agreed on. Describe how project-related decisions will be finalized. A decision-making process that clarifies whether consensus-making or another decisional framework will be used is recommended. Describe why the decision-making plan is well-suited for your research team and how it can contribute to the success of the project.

Plans for Turn-over of Personnel. Describe how the turn-over of personnel or temporary work departures at the community or academic sites will be handled. Describe how the Community Co-PI or Academic Co-PI will interact with their respective institutions if a temporary or permanent replacement is needed, and what steps will be taken to select a replacement Community Co-PI or Academic Co-PI. Please keep in mind that the replacement of the Community Co-PI, Academic Co-PI, community-based organization, or academic research institution will need to be approved by TRDRP in accordance with the process detailed in the Grants

Administration Manual available on the RGPO website: https://www.ucop.edu/research-grants-program/grant-administration/index.html. TRDRP or RGPO does not oversee employment issues (e.g., hiring) for project staff.

Plans to Evaluate the Strength of the Research Partnership. Attention to building and strengthening community-academic research partnerships is critical to the success of community-based research and the longevity of the collaborative effort. Describe the strategy your team will implement to evaluate how the partnership develops over time. Issues to consider include frequency and method of communication; meeting location - will meetings be held in the community, university, both sites, or alternative locations; and frequency and method of sharing information. Consider creative evaluation tools that include qualitative, quantitative, and technology-driven information gathering methods and monitors changes in knowledge, attitudes, and behavior over time.

Plans for Dissemination of Findings. Dissemination of research findings to both the lay community and the scientific community is important to this research award. This is sometimes a difficult issue as scientific dissemination is often a lengthy process and may impede community dissemination or what information or deliverables a community needs from the project. Please describe what agreements have been made as to how research findings will be disseminated to both the community of interest and the scientific community and the expected timing of dissemination. The level of information presented in community settings needs to align with the strength of the evidence from the project or field.

Plans to Sustain the Research Partnership Beyond the Life of the Grant. Community-partnered participatory research requires consideration of the longer-term impact a community-academic collaborative research team can have in their community of interest. While challenging to know exactly how long the research partnership will last, describe, according to best intentions, how the research partnership could continue after the life of the current phase of funding, regardless of if there are continued funds or no continued funding streams. Please consider that many multiple underserved communities in California have experienced research teams collecting their data, but not reporting back to the community nor using findings to improve health-related programs or policies in the community.

2. Instructions – COMMUNITY ADVISORY BOARD (CAB)

The Co-PIs are to use the *Community Advisory Board (CAB)* application form to describe the composition of recruited CAB members at the time of application submission and members/expertise for future recruitment. Recruited CAB members must be named with a description of their organizational affiliation and proposed contribution to the project in relation to their role on the CAB. Co-PIs must list the names, organizational affiliations, and expertise of CAB members that have been confirmed at time of application submission and use the TBD designation when describing expertise proposed for future CAB member recruitment. It helps peer reviewers to link CAB-related duties and guidance to specific project activities and milestones. The applicant team may describe eligibility criteria used to recruit CAB members, how the team proposes to solicit input from the CAB, a communication style and evaluation framework, how frequently the CAB will be convened, whether payment or other incentives will be provided. Describe how the research partners plan to communicate and interact with CAB members. The communication between the applicant team and CAB should be evaluated or monitored with plans to modify as needed. An evaluation tool that monitors strengths and weaknesses of community-academic partnership development over time is recommended. The CAB does not have to be fully comprised at time of submission. A letter of collaboration from recruited CAB members or the CAB committee chair is recommended, if possible, to obtain, and should be included in the Appendix section.

3. *Instructions* – Community Engagement Plan

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.

4. Instructions – BIOGRAPHICAL SKETCH

Complete a biographical sketch for each person listed in the Key Personnel section only, beginning with the co-principal investigators. To complete your biosketch, please use the template named "Biosketch Template" provided within SmartSimple and upload it in the Project Personnel section. Do not send reprints or manuscripts as part of this form.

5. Instructions – FACILITIES (Required for Partnered-MSCI Applicants)

Briefly describe the facilities and resources (e.g., core facilities, access to populations, statistical resources, and 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.

6. Instructions – RESEARCH PLAN

[Page limits are exclusive of bibliographical references, which should follow the Research Plan.]

Follow the formatting instructions in "General Items" above.

Both co-principal investigators' names (last name, first name, middle initial) must be printed in the upper right-hand corner of every page.

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its collaboration elements, as described below. If you don't use all the pages to describe your research plan, it might be best to review what you have written and explain in more detail anything not fully explained. **However, note that a concise, focused research plan of less than the maximum number of pages is preferable to one less concise and made longer by overly elaborate or unimportant details.**

Supporting materials (such as sample survey items, consent forms, interview or focus group questions, letters of collaboration) that are directly relevant to the proposal may be included in the **Appendix**. **The research plan must be self-contained and understandable without having to refer extensively to supporting materials.**

Special Note: The content below is included to guide your thinking process when preparing the Research Plan. There is no requirement to address each topic or question, but rather it should inform the collaborative discussion among research team members. Addressing each topic does not guarantee your application will be funded. Applicant teams should focus on topics most relevant to their research question(s) and approach(es).

Statement of Goals, Research Questions, and Specific Aims. For **Partnered-MSCI** applications: In a brief paragraph, describe the goals and research question(s) that will be addressed over the project timeline that will directly address the objectives of the Partnered-MSCI RFP. Describe how the Partnered-MSCI, if awarded, will be used for dissemination as well as enhance the team's ability to leverage future funding from TRDRP or other funders.

State the research question(s) for the project. Follow with the Specific Aims—the specific tasks and research-related activities that will be undertaken to address each research question. These should have a logical connection, and clear linkages to the MSCI RFP.

Research Plan:

Research Design, Conceptual Framework, Approach, and Data Analysis Plan. Describe in detail the exact tasks associated with the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. Provide a theoretical or conceptual framework that informs the study design and research activities. Describe the methodology to be employed; how feasibility will be determined (i.e., what measures will be used to assess feasibility); if appropriate, the methodologic approach (or possible approaches that seem at present most appropriate to be used). For example, explain how pregnant persons will be surveyed; provide rationale supporting sample size(s); how pregnant persons will be recruited; why you believe you will be able to reach and recruit the estimated number of expected pregnant persons; what questions you will ask them; whether you will use face-to-face, social media, or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed and rigorous as possible. Provide this information for each specific research activity. Discuss potential pitfalls and how you will overcome them if they occur, or alternative methods that you will use if the intended methods are not fully realized. Provide a realistic timeline. Clearly state a collaborative data analysis plan that will adequately address the Specific Aims. Include milestones, with quantifiable measures, anticipated over the course of the research project. Demonstrate that the research design is aligned and consistent with the capacity and expectations of the target community (BIPOC and AIAN) and community-based organization (e.g., whether a randomized controlled trial design violates community or community-based organization norms or is deemed acceptable). Consider how social and structural determinants of health can reasonably be expected to impact the project from a health equity perspective, and what the research team can do to address them.

Partnership Collaboration Plan. Describe the relationship between the Community Co-PI and their community organization and the community of interest. How will the community of interest be represented on the research team and Community Advisory Board? Discuss how the leadership of the community organization (e.g., the Executive Director, the Board of Directors, or the individuals of an organization) will ensure that the organization or group stays committed to the research project.

Describe in detail the plan for carrying out the collaborative research partnership. Describe your specific collaboration plans, including how and when the partners will interact; what the specific roles and responsibilities of each partner will be through each step of the research process; and how all members will be brought into the design, data analysis, and decision-making process. Briefly summarize how the collaborative agreements (e.g., ownership of data, handling disagreements, process describing how project-related decisions will be finalized) described in more detail in the **Collaborative Agreements** plan will contribute to strengthening the partnership, the successful completion of Study Aims, and other project objectives.

Dissemination Approaches and Sustainability Plan. Describe how the research partnership and findings will be broadly distributed and applicable to BIPOC and AIAN communities in California and how the community will be involved in interpreting study outcomes. Describe efforts that will ensure the partnership activity will likely continue after the current phase of funding.

Investigative Team. Describe how the experience, knowledge, and skills of the research team can contribute to the success of the overall project. Provide evidence that the co-principal investigators and other key personnel are appropriately trained and well-suited to carry out the research. Be clear about the roles and responsibilities of the research partners. Highlight experience and successes working with the community of interest. Describe what is expected to be learned by the collaborative research team during the study.

Environment, Facilities, and Resource Availability. Describe how the community locations for the project will contribute to the success of the research project. Highlight resources and access that the Community Co-PI and community-based organizations will provide that will encourage success of the project. Demonstrate awareness of relevant social and structural determinants of health factors that might impact the environment in which the project is conducted. Demonstrate readiness to adjust research activities for situations where community facilities and resources are not fully available to the team for the duration of the project s. Describe resources available through the Academic Co-PI's institution that will uniquely benefit the project. Demonstrate access to the research population of interest.

Community Assets. Describe community-level assets, strengths, and access channels the applicant team proposes to utilize over the course of the study or during the dissemination phase. Describe how the project will contribute to building capacity in the community of interest for future research, tobacco control policy change, or programming activities. Provide evidence of credibility of the partnering community-based organization within the community of interest, a track record of success in delivering services or programs in the community, and representation by the community or priority population(s) of interest within the organization.

Literature Cited (No Page Limit for this Section). 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.

7. Instructions – HUMAN SUBJECTS

This form is required for all applications but only needs to be completed if the proposed study will involve human subjects.

Special Note to Applicants: If you are planning on data from your studies with individual identifiers being accessible and possibly even maintained by both the Community Research Partner and the Academic Research Partner, please address this issue in your *Human Subjects approval* application. If you received *Human Subjects approval* through one partner's IRB, and you did not include in the IRB application that the other partner will receive a copy of the identified data during or after the study, you may be precluded from sharing the data.

Provide sufficient information in response to item (1) below to confirm there has been a determination that the designated exemptions are appropriate. Determination of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation of IRB review must be provided before an award is made. Research designated exempt is discussed in the U.S. Department of Health and Human Services, Public Health Service Grant Application #398 Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Pages 4-5. Although a grant application is *exempt* from these regulations, it must, nevertheless, **address the issues of racial/ethnic composition of the subject population**, as instructed in item (2) below.

If your proposal will involve human subjects, and you have not applied for or received an exemption, you must address the seven points below. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s) provide this information before discussing the seven points. Although no specific page limitation applies to this section, be succinct.

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 State of California, the University of California, and TRDRP that research involving human subjects must include males, females, and members of minority groups in study populations. Applicants must describe how racial/ethnic minorities will be included as research participants and identify the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. For example, adequate inclusion of minorities 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. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated. It is not necessary in this application to document inclusion of women.

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 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 and 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 on the subjects. Also, where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.

7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of knowledge that may be reasonably expected to result.

Documentation of Assurances for Human Subjects. In the Appendix to your application, include official documentation of the approval by the IRBs of all participating institutions, if available at the time of submission, showing the title of this application, the principal investigators' names, and the inclusive approval dates; do not include supporting protocols. IRB approval is not required at time of application submission.

Approvals obtained under a different title, investigator, or organization are not acceptable, unless they cross-

reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, a USPHS-approved IRB must provide the assurance. If review is pending, please note that and send the final assurance as soon as possible to TRDRP. Funds will not be released until all assurances are received by the TRDRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, approvals from the boards of each will be required.

8. Instructions – VERTEBRATE ANIMALS

This form is required ONLY for applications involving vertebrate animals. Please refer to the TRDRP 2025 Core Call for Applications Appendix E if you require additional information on Vertebrate Animals.

9. Instructions – APPENDIX COVER SHEET

The research plan must be self-contained and understandable without having to refer to the Appendix. Only those materials necessary to facilitate the evaluation of the Research Plan may be included; the Appendix is not to be used to circumvent page limitations of the application. No supplemental materials are allowed after the submission deadline unless requested by the TRDRP. While there are no page limits for the Appendix, we strongly recommend that the Appendix be no more than 30 pages in length.

ALL APPENDIX MATERIALS will need to be "uploaded" to the SmartSimple website (so therefore in PDF format). If the applicant plans to attach print materials (brochures, handbooks, etc.) they are advised to begin preparing those documents in uploadable formats well before the application deadline.

Community Agency Resolution. Provide a copy of a resolution or the section of minutes from a meeting of the Community Applicant governing body (Board of Directors for a nonprofit organization or the individuals responsible for organizing an informal organization) indicating their review and agreement with the details outlined on the **Collaborative Agreements** form. The resolution or minutes should include the date of approval and should be signed by an officer of the organization.

Letters of Support and Letters of Collaboration can be important in showing support for the research project from community partners. The letters should be as specific as possible in describing the specific involvement of the individual or organization in designing the research project or the anticipated involvement in working with the research team in carrying out their role on the project. General letters of support, without addressing the specific involvement of the individual or organization in the research project, are not as important as letters of collaboration, showing anticipated involvement in the project.
ALL LETTERS SHOULD BE COMBINED INTO ONE PDF DOCUMENT; DO NOT UPLOAD INDIVIDUAL LETTERS OF COLLABORATION.

Supporting Documents. Supporting materials (such as questionnaires, consent forms, interview questions) that are directly relevant to the proposal may be included in the Appendix. Note that the Research Plan must be self-contained and understandable without having to refer to the Appendix. Only those materials necessary to facilitate the evaluation of the research plan may be included: the Appendix is not to be used to circumvent page limitations. Please itemize materials on the Appendix Cover Sheet.

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

The Single Investigator-MSCI award will investigate smoking behaviors and their relationship to societal stressors to generate data that supports the creation of a TRDRP-managed open access data repository that once established, will be made available to researchers with an interest in maternal smoking cessation within the populations outlined in this RFA. Studies can focus on the relationship between cigarette smoking during pregnancy, and the range of adverse perinatal outcomes including low birth weight, preterm birth, stillbirth, and neonatal death within the first seven days of life up to 1 year. Studies can also focus on adverse maternal health outcomes from smoking, including premature membrane rupture, placental abruption, ectopic pregnancy, placental previa, and preterm delivery. Robust demographic information should be collected as it will be an integral part of the data in the open access repository, allowing for intersectional approaches in data analysis and interpretation. The goal is to collect accurate and robust information for a TRDRP-managed data repository that will be instrumental in facilitating multivariate analysis and the identification of potential causal relationships between smoking and these adverse outcomes within the specific maternal population under study.

Specific research questions of interest include, but are not limited to:

1. What impact do social determinants of health have on commercial tobacco product use and adverse health outcomes among infant and maternal health within this cohort?
2. What adverse perinatal and maternal health outcomes are attributable to prenatal smoking among this cohort? Is the relationship causal?
3. Are there predisposed health or behavioral risks (e.g., maternal metabolic disorders, mental health illness, etc. .) that when combined with maternal smoking result in more severe and adverse infant and maternal health outcomes?
4. What is the prevalence of commercial tobacco product use among this cohort during the postpartum period (4th trimester)? Is there an increase in adverse maternal health outcomes, during this period (4th trimester)? Are these outcomes preventable?

*** NOTE:** *To promote the sharing of scientific data generated by this RFP, TRDRP will maintain a data repository for public access in a manner consistent with copyright law.*

Single Investigator-MSCI Award 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.

* **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.

**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 pilot study will generate data on the relationship between adverse perinatal and maternal health outcomes due to maternal cigarette smoking among pregnant persons, with a specific interest in the vulnerable population identified in this RFA? Does the study represent a novel research trajectory that is not currently funded from other sources?
- **Tobacco-relatedness:** To what extent does the application focus on tobacco prevention, treatment, regulation, or tobacco-related disease? See Appendix A of the main TRDRP Call for Applications for a detailed description of TRDRP Research Priorities.
- **Innovation:** Does the research adapt existing methods or technologies to new uses, propose new paradigms, challenge existing paradigms or is it otherwise highly creative in one or more of the following ways: research methods or technologies? Does the proposed research represent more than an incremental advance upon published data? For example, does the project provide methods to establish novel relationships among adverse perinatal and maternal health outcomes that fill existing gaps within maternal smoking literature, clinical practice or policy; or provide data that could inform critical barriers to progress in the field of maternal smoking cessation and adverse maternal/fetal health as a result of maternal smoking? Does the applicant describe how the pilot study could lead to an expanded research effort in the design of culturally tailored smoking interventions among pregnant people with consideration for the social determinants of health that impact smoking behavior?

Criteria-2 (50 percent scoring weight)

- **Significance:** If the aims of the application are achieved, how will they advance scientific knowledge or clinical practice in addressing adverse maternal and fetal health outcomes due to maternal smoking? 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 within this field of research and cohort?
- **Approach:** Is the study design (including methods and analyses) adequately developed and appropriate to contribute to a data repository to satisfy the aims of this award? Has the applicant adequately considered whether their study design will contribute to the development of effective smoking

cessation interventions as well as towards epidemiological outcomes that can inform future research directions and public health strategies to improve pregnancy outcomes for the cohort described in this RFA? 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-up 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 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 identified within this application 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, is protection from research risk relating to their participation in the proposed research adequately addressed?
- **Inclusion of women and minorities in research:** If human subjects are involved, are there adequate plans to include maternal subjects of all gender identities, all racial and ethnic groups (and subgroups), as appropriate for the scientific goals of the RFP? Are plans for the recruitment and retention of human subjects adequate?

Application Section: Instructions

All required uploads are listed in the table below, and templates must be downloaded from the *Documentation* tab of SmartSimple. Templates must be completed, converted to PDF, and uploaded to your application, unless otherwise instructed.

Upload Item (Template/Form)	Page limit	Required or optional
Biosketches (All Personnel listed on Key Personnel form)	**No limit**	**Required**
Research Plan	**10**	**Required**
Facilities	**1 per institution**	**Required**
Community Engagement Plan	**1**	**Required**
Letter of Commitment	**1**	**Required**
Vertebrate Animals	**No limit**	**Optional**
Human Subjects	**No limit**	**Required**
Appendix list and uploads	**30**	**Optional**

Research Plan

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 gaps that the proposed project is intended to fill and how data collection is intended to fill critical gaps within the literature related to adverse maternal and fetal health outcomes as a result of maternal smoking.

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 in smoking cessation strategies among BIPOC and AIAN pregnant persons, 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:** 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. 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

Briefly describe the facilities and resources (e.g., access to populations, statistical resources, and/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 or the community group.

Community Engagement Plan

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:

4. Educate the public about the health consequences of tobacco product use, tobacco related disease, and/or the social determinants of health
5. 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;
6. 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.

Letter of Commitment

A **letter of commitment** from a Department Chair or Director of Research at a non-university research institute that speaks to the academic commitment of the research center to adhere to processes detailed in this form is required. If a Letter of Commitment is not applicable, please upload a document with the text "Not Applicable" in order to bypass the system validation.

Vertebrate Animal Subjects

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

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic,

anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendation.

Human Subjects Accrual

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

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

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.

Appendix: Additional Applicant Guidance Instructions for (MSCI) Award Mechanisms

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) for the Partnered-MSCI and the Single-Investigator MSCI Awards. 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.

Appendix A: Resources to Understand (Partnered-MSCI) Awards

It is critical that community and academic Co-PIs fully understand what it means to do community partnered research. Colleagues entrenched in this work fully grasp the importance of humanity, cultural humility, active listening skills, moving through work processes in a slow and purposeful way, and the gentle conversations that help leaders reach consensus on the expectations and approaches used when working across diverse community groups.

The literature references in this section are included to provide examples of the types of successful community partnered research conducted in the United States. Materials listed below do not comprise the totality of issues to consider when conducting partnered research through authentic community-academic partnership. This is included to provide examples of equitable power sharing across the research process, how community benefit from research can be described in a publication, evaluation approaches of community-academic partnerships, and to convey the spirit of this type of research.

A. The National Academy of Medicine (NAM; https://nam.edu/) has supported the development of a conceptual model to inform an equity-forward approach to community engaged scholarship. The concepts in this model are responsive to TRDRP's conceptualization of CPPR and includes helpful concepts for consideration by Partnered-MSCI applicant teams. Applicants for this grant type are encouraged to review the NAM's Achieving Health Equity and Systems Transformation through Community Engagement Conceptual Model, which is located here: https://nam.edu/programs/value-science-driven-health-care/achieving-health-equity-and-systems-transformation-through-community-engagement-a-conceptual-model/.
B. The community-partnered participatory research (CPPR) model https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4841676/ was developed by Healthy African American Families, with the support of the Centers for Disease Control and Prevention, and Charles R. Drew University of Medicine and Science.
C. The academic journal *Ethnicity & Disease* has multiple examples of CPPR reported in publications in their Volume 28 (2018) supplement 2: Advances in Community-Partnered Participatory Research: Behavioral Health and Beyond. You can view all publications for free (open access) in this special supplement https://www.ethndis.org/edonline/index.php/ethndis/issue/view/34.
D. *Ethnicity & Disease* has also released Volume 31 (2021), Supplement 1 -Structural Racism and Discrimination: Impact on Minority Health and Health Disparities

https://ethndis.org/edonline/index.php/ethndis/issue/view/54 which is particularly relevant to CPPRA applications aiming to address social structural determinants of health.

The articles found at the above links are not exhaustive for CPPR-based scholarship or frameworks to advance community science. Other readings relevant to collaborative research partnerships also pertain to this award type and should be considered in a thoughtfully designed research plan.

Appendix B: Cost and Expense Guidelines

1) 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.

2) 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.

3) 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.

4) 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.

5) 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.

6) Service Contracts and Consultants

Both categories require additional description (Budget Justification). Provide hours/rate for consultant effort on the project if applicable.

7) 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).

8) 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 C: 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 of the 2025 Call for Core Applications" 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 an 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

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