Community Practice-Based Research Implementation (CPBRI) Award

Purpose: The TRDRP Community Practice-Based Research implementation (CPBRI) award mechanism supports collaborative health service research that elucidates sustainable systems change factors associated with quality care improvements in tobacco cessation efforts delivered through health clinics serving Medi-Cal beneficiaries. The mechanism funds collaborative research consortia comprised of a lead academic researcher and a lead healthcare practitioner with input from health providers, clinic staff, healthcare administrators, patients, and patient advocates. Reports on best practices to improve delivery of and access to evidence-based tobacco treatments are expected throughout and by the culmination of the award period. Findings are expected to generalize and be sustainable across clinical services and diverse patient populations.

Background: The Medicaid patient population has a higher smoking prevalence than individuals with private insurance. Medicaid recipients who smoke are less likely to make or be successful with their quit attempts, are more likely to experience chronic diseases, and mental illness compared to those with private insurance. In California, the cigarette smoking rate is at least three times higher among Medi-Cal beneficiaries compared to California residents not enrolled in Medi-Cal. Among 14 million Medi-Cal enrollees, an estimated 4.2 million are tobacco smokers. While California's overall tobacco smoking prevalence is the second lowest in the U.S., Medi-Cal enrollees represent a large proportion of active smokers in need of targeted intervention.

Two-phase funding process: The CPBR Planning Award supports the development of research consortia with the expertise and capacity to create sustainable systems change in the delivery, access, and quality of tobacco cessation services in healthcare settings accessed by Medi-Cal enrollees who use tobacco. Although the ultimate goal is to inform sustainable systems change associated with tobacco treatment services, planning phase activities focus on partnership development and a required signature health research project conducted in a smaller number of clinics to assess proof of concept and potential for scaling up to enhance impact. Details of the CPBR planning award are located here: http://trdrp.org/files/mechanisms/trdrp-community-practice-based-cessation-research-planning-award-mechanism.pdf.

The CPBR Implementation Award is a three-year implementation science grant that supports existing partnerships between academic researchers and healthcare practitioners to develop, extend, further test, and evaluate quality improvements and promising practices that directly address tobacco treatment services delivered in clinical settings treating California's Medi-Cal patient population. The award supports research project-specific costs and infrastructure costs that support consortium administration, evaluation, and research capacity building efforts. **One signature health service research project is required to be conducted in all recruited clinical sites.** The signature research project must be conducted in a sufficient number of clinics serving Medi-Cal patients to support the generalizability of findings across non-participating clinical service sites and geography. We strongly encourage each research consortium to conduct an additional 3 pilot research projects; however, alternative arrangements to support research efforts will be allowed with sufficient justification (e.g., pilot research projects for practitioners and health service researchers). If the signature research project focuses solely on patient-related factors, a pilot research project is required that includes practitioner (e.g., Physician, Nurse Practitioner) and other clinic staff-related factors (e.g., Medical Assistants, Vocational Nurses, and Patient Care Coordinators). Since health clinics vary in patient census and

provider-to-patient ratio, there is no minimum required number of clinical service sites for inclusion in the signature research project; however, the number and type of health clinics that will be engaged during the implementation phase of funding should be clearly described. Consortium research teams may add clinical sites over the course of the Award period. Best practices resulting from health service research projects must be sustainable, cost effective, inform healthcare policy, and generalize across health-related clinical services (e.g., community primary care, behavioral health, dental clinics, etc.) accessed by Medi-Cal enrollees.

As with applications for two-year planning phase awards, applications for three-year implementation phase awards will be open to all California-based investigators and California-based non-profit organizations regardless of whether the investigator or research consortium have been a recipient of a prior TRDRP planning award.

Key Components

The recipients of the CPBR Implementation Awards will identify research aims and consortium development processes consistent with the following broad goals of the mechanism:

- Promote systems change and clinic workflow modification that increases buy-in to the importance of addressing Medi-Cal patient tobacco use among clinic staff and providers, healthcare administrators, health insurance plans, and other relevant stakeholders
- Identify and collect quality improvement metrics that elucidate patient, provider and organizational factors associated with delivery and access to tobacco interventions for Medi-Cal enrollees
- Improve the patient-centeredness of evidence-based tobacco treatments and assess quit attempts and tobacco abstinence
- Address staff and provider perspectives, training needs, tobacco treatment needs, barriers, and buy-in that are essential for an increased and sustained focus on tobacco treatment interventions in clinical settings
- Promote integrating tobacco treatments within existing health programs and health systems for a more holistic approach to improving patient health and reducing health disparities
- Promote collaborative learning environments that enhance quality improvement efforts with continual monitoring of tobacco-related performance measures
- Develop generalizable evidence of clinic-based best practices that increase the frequency of delivery of tobacco cessation treatments in community primary care, behavioral health, and oral health settings
- Encourage research training opportunities to build capacity for tobacco-related research among pre and postdoctoral trainees, and engage investigators and practitioners at all levels of training from other health-related fields in tobacco-related research
- Rapidly report to stakeholders processes, incentives, and net cost savings data that encourages organizational change in how tobacco use is addressed in clinics serving Medi-Cal enrollees

An academic or healthcare institution-based administrative component must be described in the application that will provide logistical coordination, data collection, and evaluation support associated with the consortium's health service research projects and dissemination efforts. Implementation award activities aimed at developing collaborative arrangements to enhance the research impact include:

- execution of memoranda of understanding including data-sharing and publication agreements
- formation of a Consumer Advisory Board (CAB) (letters of support required from recruited members)
- invited participation of patient advocates, county health officials, health insurance plans, funders, and community-based organizations involved in healthcare access for the medically underserved
- developing a rapid reporting process for quick dissemination of promising findings and best practices to stakeholders
- a flexible structure that can expand the research effort to additional clinical service sites as resources and interest expands
- development of a learning collaborative that provides research opportunities for early career researchers and experienced investigators who are new to tobacco control research
- flexibility to include pilot research projects with complementary aims
- development of the technical systems necessary to support data collection, data harmonization across sites, and statistical analyses for rapid reporting

The applicant research consortium should demonstrate the potential to recruit sufficient sample sizes of underserved, low-income smokers to ensure adequate power to detect key statistical relationships for the signature health research project.

Collaboration & Community Engagement: Close collaborative partnerships between key research consortium members are essential for the implementation phase health service research to impact systems change in local community practice, county health services, and state healthcare services. The CA Department of Health Care Services (DHCS) and CA Tobacco Control Program (CTCP) seek best practices and metrics for the successful implementation and enforcement of tobacco-related policy for the Medi-Cal healthcare setting. The healthcare practitioner lead investigator and academic research lead investigator are expected to maintain close communication and engagement and share decision making authority as it relates to the development, implementation, and dissemination of health service research conducted under this award. Multi-sectoral collaborations and/or interventions that engage other stakeholders involved in administering public healthcare services will inform the potential of research evidence to inform population level health policy and be integrated into existing programs and systems.

The extent of community engagement should coincide with the capacity and readiness for a collaborative relationship at clinic sites and within community healthcare organizations. At minimum, there should be a process to collect input from clinic staff and providers, care coordinators, patients and their families, an External Advisory Board, managed care health plans, and other relevant stakeholders to inform health service research activities and their potential impact. The Consumer Advisory Board could include members representing the patient population, patient advocates, consumer groups, managed care health programs or third party payers.

Dissemination and Reporting: A rapid reporting process to disseminate promising findings from consortium research activities to TRDRP and DHCS prior to scientific publication is a critical component of the CPBR implementation award. The Affordable Car Act legally mandates access to evidence-based tobacco treatments in the medical setting for tobacco users; however, providers and patients are unaware certain restrictions have been removed and continue to utilize cessation resources at lower

than expected rates. The DHCS has issued systemwide policy statements (http://www.dhcs.ca.gov/formsandpubs/Pages/AllPlanLetters.aspx) to inform managed care health plans and providers treating Medi-Cal enrollees of tobacco treatments available under the ACA; however, there has been no significant change in provider or patient behavior measured following these policy statement releases. The DHCS seeks best practices for communicating the importance of addressing Medi-Cal patient tobacco use and strategies to fully implement evidence-based tobacco treatments across the Medi-Cal system with recommendations for adherence to new policies.

Funded research consortia will be responsible for disseminating promising findings in a timely manner to the public health care community, patients, policymakers, and the funder through innovative communication methods. Communication methods include, but are not limited to health policy briefs and white papers, webinars and online didactic seminars, consortium team members presenting their results in public forums, online health policy blogs, and the scientific peer reviewed literature. Promising findings and best practices should be disseminated with appropriate caveats, as preliminary results are expected to be released prior to final or fully powered results. Promising preliminary and final results should be disseminated to the California Department of Healthcare Services (DHCS), other professional healthcare organizations, and through local and national media channels.

Sample health service-related research questions

During the full implementation phase, research consortia have the option to focus signature and individual health service research projects on one or more of the following: predictors/correlates, mechanisms and outcomes related to access, delivery, adaptations, and uptake/acceptance of tobacco treatments for Medi-Cal enrollees who are tobacco users. In addition, consortia have the option to implement a research project focused on knowledge, attitude, and behavior change among clinic staff and other health professionals involved in coordinated care efforts.

Below is a sample of health service-related research questions that could be considered for signature and individual research projects. This list is not exhaustive and the applicant may submit proposals that address other pertinent health service research questions. Health service research projects should be informed by a theoretical framework, may contribute to developing new health policy theory, and may or may not be hypothesis driven. The following broad research topics/questions pertain to low-income, underserved tobacco users:

- What motivates community health clinic staff and practitioners to deliver evidence based tobacco treatments or provide resources to Medi-Cal patients who smoke?
- What support is needed for staff and practitioners to have capacity to address patient tobacco use at each clinical encounter?
- What motivates managed care health plans to encourage and reimburse clinics for tobacco treatment efforts?
- What is the net financial impact of an increased clinical focus on patient tobacco use (e.g., cost benefit analyses)?
- What quality metrics inform best practices for integrating tobacco assessments, treatments, referrals, and follow-up in clinic workflow and related health programs?
- How best to operationalize health policy recommendations and clinical practice evidence to address tobacco use in the Medi-Cal population?
- What innovations are needed to enhance the efficacy and effectiveness of evidence-based tobacco treatments for Medi-Cal patients who smoke?
- How do evidence-based tobacco interventions need to be modified to enhance their

feasibility, acceptability, and usefulness for Medi-Cal patients who are smokers?

- What strategies, tools, or processes promote staff buy-in to address tobacco use among Med-Cal beneficiaries?
- What are the benefits and tradeoffs to addressing tobacco use simultaneously among clinic staff and patients?
- What strategies improve the communication pathway between managed care health plans, providers and clinic staff, and patients and their support system on covered tobacco treatment benefits?
- How can organizations that develop, fund, or implement healthcare policy encourage practice change and compliance at the clinical level to better address tobacco use and reduce disparities?
- What clinical and outreach strategies predict retention of smokers in tobacco treatment and moving patients along the quit smoking continuum?
- What strategies increase healthcare practitioners' delivery of evidence-based tobacco treatments?
- How does increased attention on tobacco treatment affect clinic resources and clinic workflow?
- What strategies improve assessment of tobacco use and patient engagement with tobacco interventions?
- What factors are associated with patient satisfaction and provider satisfaction related to treating tobacco dependence?
- How can innovation in the delivery of healthcare services generally translate to improvements in implementing tobacco cessation services?
- What are the clinical and medication costs associated with assisting a Medi-Cal patient in making successful quit attempts and achieving continuous abstinence?
- What are effective implementation and dissemination strategies to increase the uptake and sustained use of evidence-based smoking cessation interventions in community health clinics?
- What modifications and data systems are needed to develop standardized, cross-site measures that assess and monitor tobacco treatment delivery and systems change?
- What are the best evaluation methods, metrics, and systems for tracking success of the partnership, clinical service performance, and patient behavior change?
- What are downstream consequences from the implementation of the Affordable Care Act and other changes to the California healthcare system in relation to tobacco-related interventions?

Sample implementation phase metrics:

The collection and reporting of quality metrics to appropriate agencies motivates systems change at an institutional level. Quality metrics quantify, for example, healthcare processes, outcomes, patient and provider perceptions, organizational structures and electronic systems associated with high-quality health care delivery and/or relate to goals, in this case, for addressing tobacco use in clinical settings. Quality metrics are essential for the public health system and managed care health plans to make informed decisions to improve the quality of and patient/provider satisfaction with tobacco treatments offered in the clinic.

Research consortia should identify and collect quality metrics that speak to the potential for tobacco treatments to affect patient and population level health outcomes. Metrics should address

provider and patient behavior, as well as measures to detect changes in health policy and clinical practice procedures. Metrics can be derived based on observations, self-report, electronic records, and/or biochemical verification. Development and refinement of metrics during the CPBR implementation award will enhance the potential impact from health service research. Below are examples, but not an exhaustive list, of the types of metrics relevant to this award mechanism:

- Receipt of evidence-based tobacco treatment services (e.g., brief interventions such as Ask-Advise-Refer (AAR) or Ask-Advise-Connect (AAC))
- Frequency tobacco is assessed and documented at clinic visits
- Number of referrals to tobacco cessation resources in the community
- Measures of adherence to provider recommended use of Nicotine Replacement Therapy (NRT) and cessation medications
- Economic modeling and net cost savings associated with an increased clinical focus on tobacco treatment services
- Number of patient quit attempts and efforts to improve quit success
- Patient and staff tobacco point prevalence abstinence and continuous abstinence
- Patient satisfaction with tobacco intervention modality and NRT or other medication
- Adverse events and side effects associated with cessation medications
- Patient access to cessation medications and counseling
- Provider and staff satisfaction with tobacco treatment services and expectations
- Provider and staff training in tobacco treatment services
- Modifying clinic staff perception that treating tobacco use is important for Medi-Cal enrollees (i.e., promoting social norm change)
- Number of staff and providers engaged in tobacco treatment services (e.g., assessment by care coordinators, medical assistants)
- Organizational structures that facilitate and incentivize addressing tobacco cessation
- Documented clinical work flow modifications to accommodate tobacco assessment and treatment
- Change over time in tobacco use status, type of tobacco products consumed, and nicotine dependence
- Provider and staff level of motivation and self-efficacy to intervene and address patient tobacco use
- Measures of facilitation and disruption in clinical workflow due to cessation-related activities
- Quality and performance improvement measures related to tobacco treatment services
- Frequency and amount of third party payor reimbursement for tobacco treatment services and related clinical enhancements
- Quitting process for patients (steps taken, number and type of treatments, medication side effects)
- Changes in health and mental health status associated with tobacco cessation
- Implications from policies set forth by managed care health plans
- Motivators for managed care health plans

Implementation phase outcomes:

The research consortium structure and research project(s) conducted should yield findings that inform facilitators and barriers to systems change for tobacco treatment services delivered in healthcare settings accessed by Medi-Cal enrollees. Research methods and outcomes or recommendations should be transparent and written for a general audience for quick dissemination

to local and state health departments. Coordination with an institutional Clinical & Translational Science Institute (CTSI) and Communications experts, if available, is advised to assist translating research findings to practical clinical application and writing health policy reports. Research consortia may be asked by the funder to prepare rapid policy briefs and reports that include practical application of results from their health service research during and after completion of study aims.

Research projects and activities should have the potential to result in practice and policy recommendations at the state or local health jurisdiction levels, evidence to support long-term changes in coverage by third-party payors, elucidation of best practices and metrics that encourage assessing and treating patient tobacco use at every clinical encounter with minimal burden on staff and clinic workflow, electronic health record functional enhancements, and practice change toolkit(s) (e.g., culturally sensitive assessments, electronic health record enhancements, communication strategies), thus improving tobacco cessation in underserved populations, as well as resulting in research publications, community presentations, and the securing of follow-on external funding. To increase the probability of future funding, it will be important to obtain abstinence-related outcome data stemming from project activities.

Eligibility

The submitted application must identify at least one academic investigator with expertise and/or potential to successfully conduct health service research and at least one healthcare practitioner investigator positioned within their organization to substantively influence healthcare practice and policy. The academic investigator should have research expertise and publications related to the delivery and/or assessment of healthcare services. The academic investigator must have an appointment and principal investigator status at either a California research institution or the research department of a healthcare organization. The healthcare practitioner investigator must have a leadership or Director-level appointment at a California healthcare organization or community clinic.

Health service researchers are represented in diverse disciplines including but not limited to medicine, nursing, psychology, social work, medical anthropology, public health, healthcare administration, economics, and political science.

Funding for each consortium will be through a single award granted to a prime recipient with one or more sub-recipients funded through subcontract(s) and include a single Principal Investigator (PI) and one or more Co-Investigators (Co-Is). It is up to the applicant team to decide if the academic investigator or healthcare practitioner investigator will serve as the PI for the consortium. In either case, the PI is required to have an appointment with the organization that is the prime recipient of the award and where the Administrative Component is constituted and managed.

Community clinical practice sites eligible to participate in a research consortium must provide healthcare services to low-income Californians (i.e., at least 50% Medi-Cal beneficiaries based on annual patient census data, which must be reported in the application). Examples of eligible clinical service sites include but are not limited to federally qualified health centers (FQHCs); publicly funded community primary care, oral health, mental health and behavioral health, addiction

treatment, jail behavioral health, rural, Indian health service, or border health clinics; and clinics within a managed healthcare system that serve a predominantly low-income or Medi-Cal population. These patient populations include, but are not limited to tobacco users: with mild, moderate, and severe mental illness; California residents with physical and developmental disabilities; residing in rural regions of California; who are immigrants including individuals with undocumented status and residing at the border; who are low income racial/ethnic minorities (especially American Indians); who are low income LGBTQ; who are currently or recently incarcerated.

Implementation Award Details

Anticipated start date: July 1, 2018
Maximum award amount per year: $500,000 (direct cost cap)
Maximum duration: 3 years
Allowable direct costs: Salaries, fringe benefits, supplies, equipment*, travel.
Project-related travel: As needed (must be fully justified).
Consortium meetings: Travel and related meeting expenses (at least one annual meeting is mandatory)

Scientific conference travel: up to $2,000 per year may be applied to attend scientific meetings. If both the Principal Investigator (PI) and Co-Investigator (Co-I) wish to each attend a scientific meeting in the U.S., up to $4,000 per year may be budgeted.

Indirect costs: Full indirect costs are allowed to non-UC institutions. Indirect costs to UC campuses are capped at 25%.

Budget: TRDRP will issue award funds as one grant to a lead institution or organization, which must support the Administrative Core and have the capacity for fiscal management of grant funds including subcontracts to support the consortium activities. The majority of funds for the Administrative Core are not intended to support the ground up development of a shared electronic health records database, but a small portion of funds may be used to support the addition of tobacco-specific enhancements such as improved assessment methods and referral tracking measures for inclusion in an existing electronic health records system. The Administrative Component is expected to be affiliated with the lead institution or organization.

*Any item costing $5,000 or more

Award Requirements

- The lead applicant must have a PI-status at the sponsoring institution.
- Both lead academic research and healthcare practitioner investigators are required to commit at least 20% of their research effort each year to activities supported by this award.
- U.S. citizenship is not a requirement

Administrative component: The administrative component will provide oversight and infrastructure support for consortium research and dissemination activities. The administrative component will support a data management system; coordinate communication and

dissemination efforts; incorporate pilot research project activity into the consortium; and provide statistical, evaluation, and logistical support for the consortium including organizing meetings with stakeholders, including the External Advisory Board, funder and DHCS. The functional capacity and management of the administrative component should be described in the application. The PI must include budgetary support for an administrative component in the CPBR implementation application.

Evaluation: Sufficient funds should be available in the administrative component to evaluate:

- progress towards generating systems change at the clinic and community levels
- development and strength of community clinic research partnerships
- feasibility and acceptability of implementing promising findings or best practices for tobacco treatments in community clinics
- practical issues in implementing recommended changes from the perspective of healthcare administration and managed care health plans

Investigator development and pilot research project support*:* Tackling the complex issues that will make tobacco assessment and treatment as standard care in community health clinics requires a diverse, well-trained scientific and clinical workforce and a transdisciplinary framework that cuts across scientific and clinical disciplines and organizational silos. Research consortia should be open to coordinate with pilot health service research projects conducted by graduate students, post-doctoral fellows, other early stage investigators, and health researchers new to tobacco control science to generate preliminary data that are complementary to the overall Aims of the consortium's signature research project. TRDRP will oversee review of pilot projects and recommend meritorious projects for possible inclusion in consortium activities. Consortia flexible to include additional projects should assist new investigators in the implementation of their health service research and share resources including data systems to facilitate integration and to enhance data analysis. The consortium PI and Co-Is that include additional projects may request resources to support the increased effort.

Applicants may submit applications for the TRDRP Student Research Supplement Award (http://trdrp.org/funding-opportunities/award-mechanisms/student-research-supplement-award.html) and the Cornelius Hopper Diversity Award Supplement (CHDAS) (http://trdrp.org/funding-opportunities/award-mechanisms/cornelius-hopper-diversity.html) when submitting application materials for the CPBR implementation phase of funding and a later time if funded. Please refer to the funding opportunities section of TRDRP's website (http://trdrp.org/funding-opportunities/award-mechanisms/index.html) for details.

Data safety monitoring board: The applicant research consortium should justify the need to constitute or not constitute a Data Safety Monitoring Board (DSMB). Applicants proposing a RCT or Phase III clinical trial for their signature research project or pilot project(s) are advised to consider whether a DSMB is warranted. Applicants are encouraged to review NIH Policies and Guidance for Data and Safety Monitoring of Clinical Trials (https://humansubjects.nih.gov/data_safety). Describe efforts to constitute a DSMB in the application if data and safety monitoring is deemed appropriate for the proposed research project(s).

Review Criteria

This is an open competition and grant applications will be peer-reviewed according to the following criteria:

Criteria-1 (30% scoring weight)

Responsiveness to intent of the award type: Does the application propose activities aimed at forming a consortium of publicly funded clinics serving predominantly low income smokers to conduct tobacco cessation service research? Is the signature research project fully developed rather than pilot or exploratory? Does the study build upon work performed as part of prior pilot work? Does the application propose a research study or studies with potential to impact systems change? Does the applicant describe how the implementation research effort will lead to the consortium's ability to inform best practices for addressing tobacco use in clinical settings serving California's Medi-Cal patient population with potential to sustain efforts beyond the funding period?

Potential for the proposed work to inform practice and policy: To what extent could the proposed research be expected to contribute to a clear, short-term and long-term impact on the health services field related to tobacco cessation efforts, as well as on system level policies and practices aimed at advancing tobacco treatments for the Medi-Cal patient population who are tobacco users? To what extent does the implementation phase of funding contribute to actionable policy recommendations that could be adopted by managed care health plans or the California Department of Healthcare Services for statewide efforts to address Medi-Cal beneficiaries' tobacco use?

Innovation: Does the research propose new paradigms, challenge existing paradigms, or is otherwise highly creative in one or more of the following ways: the concept or question, research methods or technologies, adaptations of existing methods or technologies for new uses or with understudied populations? Does the proposed research represent more than an incremental advance upon published data? For example, does the project or projects challenge existing paradigms, interventions, clinical practice, or policy; address an innovative hypothesis or critical barrier to progress in the field?

Criteria-2 (40% scoring weight)

Research plan: Are the conceptual or clinical 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 grant type? Does the applicant report non-duplicated annual patient census data for each clinic they propose to include in the research project(s)? Do proposed clinics provide healthcare services to at least 50% Medi-Cal beneficiaries based on annual patient census data? Does the applicant clearly describe relationships to be examined? Does the applicant acknowledge potential problem areas and consider alternative strategies? Are the sample sizes identified adequate to answer proposed research question(s)? Is there a power analysis and is it appropriate to the study design? If an intervention is proposed, are the variables and relationships to be examined clearly identified and testable? Is it appropriate for the research team to collect patient-level data and are methods adequately described for collecting patient-level data? Are milestones well-defined with quantifiable measures that are appropriate for assessing the success of the

implementation phase award? Will the administrative component provide adequate infrastructure to support all research activities and communications between consortium members? Is the functional capacity of the administrative core clearly described?

Criteria-3 (30% Scoring weight)

Collaboration: Are procedures identified to establish or strengthen a collaborative partnership between clinical practitioners and academic researchers? Does the team have the potential to include additional collaborative investigators and clinics in the consortium? Does the research process apply the knowledge of clinical staff including care coordinators and patients including their families, as well as other stakeholders relevant to the success of consortium aims and goals? Are measures included to assess the health of the partnership? Will the proposed collaborative relationship and communication pathways empower healthcare sites to pilot and implement quality improvement and practice change in addressing tobacco use? Are researchers, practitioners, and other stakeholders prepared to work together for an extended period of time?

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)? Do the investigators demonstrate access to the population (i.e., low-income patients with high rates of tobacco use and low utilization of tobacco cessation treatments)?

Environment: Do the scientific and clinical environments in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific and clinical environments, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

Community engagement and communication plan: Does the applicant propose a sound approach to engaging communities affected by tobacco use in either a collaborative partnership or by proactively informing groups about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results of funded research include channels and tools targeting clinicians, patients and patient advocates, public health (e.g., county health departments), tobacco control advocates, policymakers, healthcare administrators including managed care health plans, and the general public?

Additional Review Criteria
Reviewers will evaluate the following additional items while determining scientific and technical merit, but will not give separate scores for these items.

Protection of Human Subjects from Research Risk: If human subjects are involved, protections from research risk relating to their participation in the proposed research will be assessed. If plans are proposed to include patient or client health information, efforts to be compliant with the Health Insurance Portability and Accountability Act (HIPAA) and other relevant laws in the collection and management of human subjects' data should be described.

Inclusion of Women, Minorities and Children in Research: If human subjects are involved, the adequacy of plans to include subjects of all genders, all racial and ethnic groups (and subgroups),

and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.

Care and Use of Vertebrate Animals in Research: If vertebrate animals are involved in the project, plans for their care and use will be assessed.

Relevance of the proposed research to a tobacco-related area: Assess whether the projects' relationship with tobacco-related diseases or tobacco control is high, marginally relevant, or not related.

KEY DATES:

Fiscal Year 2018-2019	**2018B**
Call open	Wednesday, November 1, 2017
LOI submissions invited	November 1, 2017 - February 2, 2018 12 p.m. PT
Direct access to application materials after LOI acceptance in proposalCENTRAL	Beginning November 1, 2017
Due date for new applications	Wednesday, February 28, 2018 12 p.m. PT
Applicants notified	June 1, 2018
Awards start	July 1, 2018

***Letter of Intent:** A letter of intent is required to be considered for the Community Practice-Based Research Mechanism Award open competition

Contact Information for Inquiries

Norval J. Hickman III, PhD, MPH
Social and Behavioral Sciences Program Officer
Tobacco-Related Disease Research Program
University of California, Office of the President
Phone: 510-987-9032
Norval.Hickman@ucop.edu
VI2101817