Community Practice-Based Research Planning Award

Purpose: To support the development of partnerships between academic researchers and healthcare practitioners to conduct health service research that elucidates system-level change factors to promote regularly addressing patient tobacco use in health clinics serving the Medi-Cal population across California. This grant type supports the development of research teams or consortia that include health clinics, researchers, healthcare providers, administrators, and other groups with the expertise and capacity to create sustainable system change in the delivery of tobacco cessation services in healthcare settings accessed by low-income, underserved Californians who use tobacco at high rates. The research findings are expected to be generalizable across clinical service sites and to concretely inform practical recommendations for healthcare system improvements that result in increased access to evidence-based tobacco cessation treatments, improved quality and coordination of cessation activities, increased patient satisfaction, and higher rates of tobacco abstinence and quit attempts among low-income, underserved tobacco users.

Two-Phase Funding Process

Planning Phase (offered this funding cycle) - The first phase of funding consists of a two-year planning award for the practitioner-academic research team to develop and/or strengthen a consortium of publicly-funded clinical sites interested in and willing to engage in generalizable tobacco cessation health services research. Teams are required to implement at least one signature research project in recruited clinical practice sites during the planning period, and must demonstrate the potential to conduct multiple research projects to be competitive for a full implementation award.

In the planning phase application, at least three clinical practice sites must have agreed to be part of the consortium with plans to expand the consortium to include at least six additional sites by the end of the first year of the planning award.

In addition to planning activities and research project-specific expenses, the planning award will also support an Administrative Core to support the consortium research infrastructure. The Administrative Core is expected to provide adequate infrastructure to support all research activities and communication between consortium members. The Administrative Core will support a shared data management system; and provide statistical, evaluation, and logistical support for communication between practice research partners and with external stakeholders (e.g., External Advisory Board). The functional capacity and management of the Administrative Core should be described in the application.

Implementation Phase (anticipated to be offered in an upcoming cycle, pending final approvals and availability of funds) - The second phase of funding consists of larger three-year implementation awards (offered on a competitive basis) that will provide ongoing support for consortium research infrastructure as well as research project-specific costs. Consortia supported by these full implementation awards will conduct at least three individual research projects in at least six clinical practice sites and one signature research project in all recruited clinic sites to address substantive health service-related research questions with potential to foster sustainable, generalizable, and impactful system change in the delivery of evidence-based tobacco treatment services. In order to compete successfully for a full implementation award, it is expected that the applicant consortium will demonstrate sufficient

infrastructure to support measurable and sustainable clinic practice change in the delivery of tobacco treatments at researched clinic sites with concrete plans and potential to extend promising practice recommendations for adoption by clinic sites not involved in the consortium.

At this time, it is anticipated that the future call for application for full implementation awards will require at least eight clinical practice sites to have agreed to be part of the consortium with plans to expand the consortium to include at least four additional sites by the end of the first year of the full implementation award.

As with applications for two-year planning phase awards, applications for three-year implementation phase awards will be open to all California-based investigators regardless of whether the investigator has been a recipient of a prior TRDRP planning award.

Key Consortium Planning and Development Elements:

The recipients of the Community Practice-Based Research Planning Awards will identify consortium development and research aims consistent with the following broad goals of the mechanism:

- Promote system changes that will increase the frequency of quit attempts and cessation in low-income smokers seeking healthcare in publicly-funded primary and behavioral health clinics (e.g., FQHCs)
- 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, as well as disseminate promising findings broadly through California healthcare systems
- Elucidate mechanisms and process variables that enhance the effectiveness of tobacco treatments for low-income smokers and promote practice changes in publicly funded primary care, behavioral health, and oral health clinics

It is expected that an academic or research institution-based coordinating center will provide the infrastructure for clinics (i.e., Administrative Core) and individual projects including a data sharing system and logistical coordination to support the research activities of the consortium. During the planning award period activities aimed at developing collaborative arrangements for the research include:

- identifying and training key research personnel
- execution of memoranda of understanding including data-sharing and publication agreements
- formation of an External Advisory Board (letters of support required from members)
- development of the technical systems necessary to support research data collection and analyses
- initiation of processes to identify research concepts and proposals for internal review and prioritization
- initiation of collaborative processes for data analyses and interpretation as well as the initiation of quality improvement efforts based on regular review of interim reports
- expansion to at least six additional clinical practice sites by the end of the first year of the planning award

In addition to these planning and development efforts, at least one health service research study aimed at improving delivery of cessation services in clinic settings and that elucidates factors that promote sustainable systems change must be proposed and implemented. The applicant research team should demonstrate the potential to recruit sufficient sample sizes of underserved, low-income smokers to ensure adequate power to detect key statistical relationships in the study.

Collaboration: A close collaborative relationship is expected between the academic and clinical practice investigators and research team. The extent of community engagement should coincide with the capacity and readiness for a collaborative relationship at clinic sites. It is appropriate to conduct a needs assessment to determine the level of collaboration that is feasible at clinic research sites. At minimum there should be a process to collect input from clinic staff, care coordinators, patients and their families, an External Advisory Board, and other relevant stakeholders to inform health service research activities. The External Advisory Board should include at minimum members representing a local or state health department, third party payer, and patient advocate or consumer group. At least one letter of support from a local county health department and at least one letter from a third party payer must be obtained and included with the planning phase application.

Dissemination: The consortium will be responsible for disseminating promising findings to the public health care community, public, policy makers, and funders through webinars, white papers or policy briefs, clinic and community presentations, and published literature. Shared metrics will be instrumental to evaluating success towards system change factors and clinical outcomes, and evaluating the partnership building process of investigators and practitioners. The funder expects promising findings (with appropriate caveats) to be shared prior to peer reviewed publication. The funder also expects promising preliminary and peer reviewed publications to be disseminated to other clinical practitioners, California Department of Healthcare Services (DHCS), professional healthcare organizations, and efforts to receive national media attention.

Example Health Service-Related Research Questions

During the planning and future full implementation phases, it is intended that consortia will focus signature and individual research projects on mechanisms and processes related to the delivery and adoption of tobacco treatments. In addition, consortia should plan to implement at least one intervention research project focused on clinic staff behavior.

Below are potential healthcare 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. Each research question pertains to low-income, underserved tobacco users:

- How does the focus on treating tobacco affect clinic resources and clinic flow?
- What quality metrics need to be collected to inform best practices for embedding tobacco assessments, treatments, referrals, and follow-up in clinic workflow?
- How best to operationalize best practices that enhance the efficacy of existing interventions to reduce tobacco use in the Medi-Cal population?
- What strategies, tools, or processes promote staff buy-in to address tobacco use among Med-Cal beneficiaries?
- How can organizations that create and implement healthcare policy encourage practice change at the clinic-level to better address tobacco use?
- What clinical and outreach methods help to retain smokers in tobacco treatment?

- What strategies increase healthcare practitioners' delivery of evidence-based tobacco treatments (e.g., the 5A's)?
- What strategies improve assessment of tobacco use and patient engagement with tobacco interventions?
- What approaches are associated with patient satisfaction related to treating tobacco dependence?
- How can innovations in the delivery of healthcare services generally translate to improvements in implementing tobacco cessation services?
- What are motivating incentives for community health clinics to adopt evidence based tobacco treatments as a standard of care?
- How much does it cost to deliver tobacco treatments to tobacco users in healthcare clinical settings serving Medi-Cal beneficiaries?
- What are the clinical and medication costs associated with abstinence and quit attempts?
- What are effective implementation and dissemination activities and strategies to increase the uptake and sustained use of evidence-based smoking cessation interventions in community health clinics?
- What modifications are needed to create standardized, cross-site measures to assess and track intervention delivery (e.g., fidelity measures) and system change?
- What are the best evaluation methods and metrics for tracking success of the partnership, clinical service changes, and patient behavior?
- What are the downstream effects from the implementation of changes to the healthcare system (e.g., the Affordable Care Act) on tobacco-related interventions?

Expected planning phase outcomes

The consortium and infrastructure development and the research project(s) conducted under the planning phase funding should demonstrate the research team's future potential to include a larger scale signature project in additional clinic sites, as well as their potential to conduct multiple small scale research projects in clinic sites. These future phase 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 payers, elucidation of best practices and metrics that promote addressing 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., 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.

Expected planning phase metrics

A series of shared metrics are expected to be developed that can translate across clinical sites and consortia funded through this mechanism. Metrics should address clinic and patient behavior, as well as measures to detect changes in policy and clinical practice procedures. Metrics can be derived based on self-report, chart review, and/or biochemical verification. Development and refinement of metrics during the planning phase will strengthen the application for the implementation phase award. Below are examples of the types of metrics expected to be developed during the planning phase:

- Measures of clinic and organizational change that facilitate and incentivize addressing tobacco cessation
- Patient and staff tobacco point prevalence abstinence and continuous abstinence

- Tobacco and nicotine dependence changes over time
- Level of motivation and self-efficacy for tobacco abstinence and/or clinic staff ability to intervene
- Frequency practitioners employ one or more of the 5As with patients who use tobacco
- Patient satisfaction with provider delivered tobacco treatments
- Practitioner satisfaction with tobacco treatment expectations
- Measures of facilitation and disruption in clinical workflow due to cessation-related activities
- Frequency of quality improvement efforts related to tobacco treatment
- Extent of payer reimbursement for cessation services and related clinical enhancements
- Implications from policies set forth by healthcare plans.

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, public health, healthcare administration, economics, and political science.

Funding for each consortium will be through a single award to a prime recipient with one or more sub-recipients and include a single Principal Investigator (PI) and one or more Co-Investigators (Co-I[s]). 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 Core is constituted and managed.

Community practice sites eligible to participate in the consortia must provide healthcare services to a majority of low-income Californians (i.e., at least 50% Medi-Cal beneficiaries based on annual patient census data) with high rates of tobacco use and low utilization of evidence based tobacco treatments. Examples of eligible sites include but are not limited to federally qualified health centers (FQHCs); publicly funded community primary care, mental health, addiction treatment, jail behavioral health, rural, Indian health service, or border health clinics; and managed healthcare system clinics that serve a predominantly low-income or Medi-Cal population with demonstrated high rates of current tobacco use and low utilization of tobacco cessation services. These patient populations include but are not limited to tobacco users: with mild, moderate, and severe mental illness; 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.

Planning Phase Awards

Anticipated Start Date: April 1, 2018
Maximum Award Amount per Year: $200,000 (direct cost cap)
Maximum Duration: 2 years
Allowable Direct Costs: Salaries, fringe benefits, supplies, equipment*, travel.
Project-Related Travel: As needed (must be fully justified).
Consortia 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.
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 assessments and referral tracking measures for inclusion in an existing electronic health records database. The Administrative Core 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.
- The lead applicant PI is required to commit at least 10% of their research effort each year to activities supported by this award.
- U.S. citizenship is not a requirement

Implementation Phase Awards (Anticipated to be offered in a future cycle, pending approvals and availability of funds)

Anticipated Start Date: July 1, 2018
Maximum Award Amount per Year: TBD
Maximum Duration: 3 years

Planning Award Review

Criteria

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

Impact (scored separately): The potential for achieving a clear, short-term and long-term impact on the health services field related to tobacco cessation research as well as on system level policies and practices aimed at advancing tobacco treatment for low-income Californians with high rates of tobacco use and low utilization of cessation treatments.

Criteria-1 (30% scoring weight)

Responsiveness to Intent of the Award Type: Does the application propose developmental activities aimed at forming a consortium of publicly funded clinics serving predominantly low income smokers to conduct tobacco cessation service research? Does the application propose a research study with potential to impact system level change? Does the applicant describe how the planning effort will lead to the consortium's ability to conduct rigorous and generalizable health service research, should it continue beyond the planning period?

Potential for the Proposed Work to Inform Practice and Policy: To what extent can the funders expect the proposed consortium activities to produce short-term and long-term impact on clinical practice and policy in the delivery of tobacco treatments to low-income smokers with high rates of tobacco use and low utilization of cessation resources? To what extent can the planning and implementation phase funding be expected to contribute to actionable policy recommendations that could be adopted by 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 to new uses or with understudied populations? Does the proposed research represent more than an incremental advance upon published data? For example, does the project 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 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? Will the Administrative Core 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 about the nature and significance of the research and research outcomes? To what extent does the dissemination of relevant results of funded research include channels and tools targeting clinicians, public health practitioners, tobacco control advocates, policymakers, and the general public?

Other Considerations

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

KEY DATES:

Fiscal Year 2018-2019	2018A	2018B
Call open	Friday, July 7, 2017	Friday, December 15, 2017
LOI submissions invited	July 7 - August 21, 2017 12 p.m. PT	December 15, 2017 - February 2, 2018 12 p.m. PT
Direct access to application materials after LOI acceptance in proposalCENTRAL	Beginning July 17, 2017	Beginning December 15, 2017
Due date for new applications	Monday, September 25, 2017 12 p.m. PT	Wednesday, February 28, 2018 12 p.m. PT
Due date for resubmissions*	Monday, September 25, 2017 12 p.m. PT	Thursday, March 15, 2018 12 p.m. PT
Applicants notified	January 26, 2018	June 1, 2018
Awards start	April 1, 2018	July 1, 2018
Implementation award details	Fall 2017 (tentative)	TBD

***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

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