

Request for Proposals (RFP)

Testing Intervention Strategies for the Primary Prevention of Breast Cancer: Phase I

California Breast Cancer Research Program Preventing Breast Cancer: Community, Population, and Environmental Approaches

Deadline to apply: April 6, 2022 – EXTENDED DEADLINE

Table of Contents

Гable of Contents	1
About the California Breast Cancer Research Program and the Preventing Breast Cancer Initiativ	7e 3
PBC Priority Areas	3
Testing Intervention Strategies for the Primary Prevention of Breast Cancer	5
Available Funding	5
Background/Justification	6
Research Questions	8
Approaches and Methods	10
Budget	11
References	12
How We Evaluate RFPs	14
Peer Review	14
Programmatic Review	15
Application Instructions	17

Application Components	17
Detailed Description of Proposal Templates	20
Appendix A: QuickStart Training and Community-Partnered Participatory Research	27
Appendix B: Cost and Expense Guidelines	30
Appendix C: Other CBCRP Application Policies and Guidelines	32
Eligibility and Award Limits	32
Policy on Applications from PIs with Delinquent Grant Reports	33
Confidentiality	33
Award Decisions	33
Appeals of Funding Decisions	33
Pre-funding Requirements	34
Publications Acknowledgement	34
Open Access Policy	34
Grant Management Procedures and Policies	34
Contact Information	35

About the California Breast Cancer Research Program and the Preventing Breast Cancer Initiative

The California Breast Cancer Research Program (CBCRP) was established pursuant to passage by the California Legislature of the 1993 Breast Cancer Act (i.e., AB 2055 (B. Friedman) [Chapter 661, Statutes of 1993] and AB 478 (B. Friedman) [AB 478, Statutes of 1993]). The program is responsible for administering funding for breast cancer research in the State of California.

The mission of CBCRP is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities.

- CBCRP is the largest state-funded breast cancer research effort in the nation and is administered by the University of California, Office of the President.
- CBCRP is funded through the tobacco tax, voluntary tax check-off on personal income tax forms, and individual contributions.
- The tax check-off, included on the personal income tax form since 1993, has drawn over \$11 million for breast cancer research.
- Ninety-five percent of our revenue goes directly to funding research and education efforts.
- CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, CBCRP has awarded over \$280 million in 1,042 grants to 143 institutions across the state. With continued investment, CBCRP will work to find better ways to prevent, treat and cure breast cancer.

PBC Priority Areas

CBCRP's Program Initiatives integrate expertise and experience from a range of stakeholders to identify compelling research questions and fund research projects that help find solutions to reduce suffering from breast cancer and move science closer to eliminating the disease. The Program Initiatives engage scientists, advocates, people impacted by breast cancer, and the broad community in a dialogue to frame research priorities and fund meaningful research.

In 2004, CBCRP launched its Special Research Initiatives (SRI), devoting 30% of research funds to research to environmental causes of breast cancer and the unequal burden of the disease. Under this initiative, CBCRP funded 26 awards totaling over \$20.5 million. In 2010, CBCRP launched its second round of Program Initiatives, the California Breast Cancer Prevention Initiatives (CBCPI), adding population-level prevention interventions as a target area and devoting 50% of its funds to these priority areas. To date, CBCRP has funded 22 awards under CBCPI, totaling over \$19 million.

In 2015, CBCRP's Council decided to build on the existing Program Initiatives by devoting 50% of CBCRP research funds between 2017 and 2021 to a third round of Program Initiatives. This new effort is titled Preventing Breast Cancer (PBC): Community, Population, and Environmental Approaches. Approximately \$20 million is being dedicated to directed, coordinated, and collaborative research to pursue the most compelling and promising approaches to:

• Identify and eliminate environmental contributors to breast cancer.

- Identify and eliminate fundamental causes of health disparities with a focus on breast cancer in California.
- Develop and test population-level prevention interventions that incorporate approaches to address the needs of the underserved and/or populations experiencing disparities in the burden of breast cancer.

In June 2020, CBCRP's Council approved the first four concept proposals to stimulate compelling and innovative research in all three focus areas of PBC, and a second set of six concept proposals was approved in June 2021. A series of funding opportunities is being released reflecting these concepts.

Testing Intervention Strategies for the Primary Prevention of Breast Cancer: Phase I

Available Funding

This initiative aims to fill gaps in evidence about the effectiveness of community-level intervention strategies for a priority set of breast cancer risk factors detailed in <u>Paths to Prevention, the California Breast Cancer Primary Prevention Plan</u>. This initiative has two components. Component 1 is an assessment of an innovative but untested intervention strategy that had been or is being implemented in California communities, as defined by geography, culture, racial/ethnic composition or shared experience or goals, to address breast cancer risk factors from <u>Paths to Prevention</u>. Component 2 tests a new and integrated intervention strategy that specifically addresses chemical exposures and other factors, to reduce occupational and/or environmental exposures as well as align with broader community concerns.

CBCRP is currently sponsoring a Request for Proposals (RFP) for two award types: a Component 1 Full Award and a Component 2 Pilot Award. CBCRP intends to fund up to two Component 1 Full Awards, each with a maximum direct cost budget of \$825,000 and a duration of up to three years. CBCRP intends to fund up to two Component 2 Pilot Awards, with a maximum direct cost budget of \$210,000 and a duration of one year. Additional funding will be available for a five-year Component 2 Full Award for up to \$1,825,000 direct costs in the future. Information on the Component 2 Full Award is included in this RFP to give Component 2 Pilot Award applicants context for this work.

Completed responses to this RFP are due by Wednesday, April 6, 2022, 12 Noon PT. The project start date is August 1, 2022.

For more information and technical assistance, please contact:

Katherine McKenzie, PhD Senior Program Officer, CBCRP Katherine.McKenzie@ucop.edu

Technical Support During the Award

During the grant award period, awardees will execute the project as described in their application and research plan. They will also leverage participation in a CBCRP-sponsored technical support program to craft their application for follow-on funding competitions.

Specifically, awardees who have not completed <u>QuickStart</u>, CBCRP's community partnered participatory research (CPPR) technical support program, will be required to complete the program during the 2022-23 fiscal year. By applying for Component 1 or Component 2 funding, teams are also applying to QuickStart, and there are no additional application materials required for admission. Applicants whose grant application is not funded are highly encouraged to attend QuickStart, which could make teams more competitive for future funding opportunities.

Information about the program is found in Appendix A within this RFP and also here online.

The full QuickStart program is scheduled for June 2022–January 2023. The following are key program dates with required attendance. Please hold these dates in your calendars.

- Face-to-face meeting 1: June 29 & 30, 2022; 8:00 AM 8:30 PM both days. Tentatively planned for Southern CA.
- Face-to-face meeting 2: August 11 & 12, 8:00 AM 8:30 PM both days. Tentatively planned for Berkeley, CA.
- Online sessions: Ongoing, June through November.
- Technical assistance (TA) phone calls: Four rounds of calls will take place between face to face sessions, after the second face to face session, after concept proposals are submitted and after an optional mock review of the draft proposals. Dates and times of TA calls are collaboratively determined with teams during the QuickStart program.
- Concept papers due: October 3, 2022.
- Draft applications for mock review due: December 1, 2022
- Mock review of applications: January 13, 2023 (tentative)

Technical Support in Finding a Partner

Individual community members and academics who do not yet have a partner for this initiative application are eligible for technical support from CBCRP. A CBCRP program officer will assist you in looking for a potential research partner; individuals should have an initial sense of their general research interests in order to help focus in on potential partners. Support is available beginning December 1, 2021.

To receive technical support in finding a partner, please contact Senaida Fernandez Poole, PhD by email at senaida.poole@ucop.edu, or by setting an appointment at https://cbcrp-senaida-poole.youcanbook.me.

Background/Justification

The impressive advances in breast cancer detection and treatment over the last few decades have reduced deaths from breast cancer but not the risk of developing breast cancer. Each year, over a quarter million women in the United States (27,000 women in California alone) are told they have breast cancer [12]. Breast cancer is more than one disease and its effects are not spread equally. Although overall breast cancer incidence rates are highest for White women [3], the incidence of triple-negative breast cancer, a more aggressive form of breast cancer with poorer prognosis, is higher among African American women [2] and Latina women [10]. Incidence rates have increased among women across all race and ethnic categories; the highest increase in incidence rates in recent years occurred among Asian American or Pacific Islander women [3].

The population of California is racially and ethnically diverse. Census estimates from 2019 showed the distribution of the female population (all ages combined) by broad racial group as: White (73.3%); Asian American or Pacific Islander (17.6%); Black or African American (7.2%); and American Indian or Alaska Native (1.9%) [13]. For all races combined, nearly 4 out of 10 girls or women in California (39.0%) are Hispanic/Latina [13].

Although five-year survival from breast cancer is nearly 90%, breast cancer remains the second leading cause of cancer death [12]. In 2017, 42,000 women, including nearly 4,600 women in California, died from breast cancer [12]. Overall deaths from breast cancer have declined in recent

years, but disparities in death rates by race and ethnicity have increased. Breast cancer death rates are highest among Black women [3]. Breast cancer is the second leading cause of cancer death, after lung cancer, for all women except Hispanic/Latina women [12]. Among Hispanic/Latina women, cancer exceeds heart disease as the leading cause of death overall [4], and breast cancer exceeds lung cancer as the leading cause of cancer death [9]. Breast cancer mortality among Asian or Pacific Islanders vary across ethnicities and immigration history [8].

The number of women who live with a breast cancer diagnosis (breast cancer survivors) continues to climb. In 2026, the number of breast cancer survivors in the United States is expected to exceed 4.5 million [7], a number greater than the populations of Los Angeles and San Diego combined. Even years after treatment, many breast cancer survivors struggle with the long-term impact of their treatment and fear of recurrence. The total annual cost of breast cancer care in 2020 was estimated to be \$20.5 billion [6].

The basic statistics on breast cancer incidence underscore the urgency to act on what we already know to decrease incidence rates, as well as the need for different approaches to primary prevention. For these reasons, CBCRP funded Breast Cancer Prevention Partners (BCPP) to develop a comprehensive, primary prevention plan for breast cancer in California. Launched in 2017, BCPP completed the project with the release of *Paths to Prevention, the California Breast Cancer Primary Prevention Plan*, in September 2020 [1]. *Paths to Prevention* described the scientific evidence for a comprehensive list of factors that affect breast cancer risk and are amenable to change, and it presented an agenda for action on these factors. It outlined intervention goals, objectives, and strategies for each of 23 factors that have been linked with either increased or decreased incidence of breast cancer, collectively called breast cancer risk factors. Because most breast cancers are thought to arise from a combination of factors over many years, such a multifaceted approach to prevention is warranted. But for a number of risk factors, the available evidence on effective, community partnered intervention strategies is limited or nonexistent.

The purpose of this funding initiative is to fill gaps in evidence about the effectiveness of community-level intervention strategies for a priority set of breast cancer risk factors in Paths to Prevention, drawing on its suggested intervention goals and strategies, and on its guiding principles. The guiding principles emphasize: 1) systemic change; 2) racism and inequities in power and access; 3) community wisdom as a source of information; 4) multi-factorial interventions; and 5) absence of the need for 100% certainty to act. Of special interest are occupational and environmental exposures and social determinants of health that disproportionately affect communities at social or economic disadvantage in California. The goal is to expand the evidence base for community-level intervention strategies to address the breast cancer risk factors of concern to underserved or historically marginalized communities in California. Such strategies, once shown to be effective, could be implemented across California and possibly in other states. Promising but untested strategies may already be in use in some California communities to address some of these risk factors; such a strategy would be rigorously assessed in Component 1 of this initiative for its effect on breast cancer risk factors. A new, integrated intervention strategy would be developed and tested in Component 2 of this initiative. Once efficacy/effectiveness is established through Component 1 and Component 2 intervention studies, these intervention strategies could be the subject of further dissemination and implementation efforts, including by funding through the

CBCRP <u>Californians Linking Action with Science for Prevention of Breast Cancer</u> (CLASP-BC) Phase 2 initiative, which is scheduled to be launched in 2023.

Research Questions

This funding initiative has two components.

Component 1

Component 1 is an assessment of an existing but untested intervention strategy that has been or is being implemented in California communities to address priority breast cancer risk factors from *Paths to Prevention*. The priority risk factors relate to harmful environmental and occupational exposures and/or the special risks faced by racial or ethnic minority groups or historically marginalized communities in California. The research could be conducted in the community where the intervention strategy was first implemented or in other communities where the intervention strategy could be replicated. The outcome of interest is community-wide change in indicator(s) of exposure to risk factors identified in *Paths to Prevention*, within a three-year project period.

Of the 23 breast cancer risk factors described in *Paths to Prevention*, a subset of 13 risk factors had goals to reduce harmful environmental or occupational exposures and/or to address the special risks faced by racial or ethnic minority groups in California. This subset corresponds to the purpose of this funding initiative. They will serve as the priority risk factors for primary prevention intervention strategies to be assessed under Component 1. The research should focus on an existing and innovative community intervention strategy conducted by the community partner that has not yet been rigorously assessed for the magnitude of effect on breast cancer risk factors and the elements responsible for the effect. The priority risk factors and the focus of associated intervention goals of special interest are:

- Breastfeeding
 - o Goal 6, reduce cultural barriers
- Chemicals in consumer products
 - o Goal 1, disclose, restrict, or remove chemicals
 - o Goal 4, counter discriminatory concepts of beauty
- Occupational exposures
 - o Goal 1, implement workplace policies and practices to control exposures
 - o Goal 4, eliminate hazardous chemicals, workers take actions to protect themselves
- Place-based chemicals
 - o Goal 1, build capacity for people to win greater protection
 - o Goal 3, ensure water free from chemicals linked to breast cancer
 - o Goal 4, reduce exposures to air pollutants
 - o Goal 5, reduce exposures to harmful exposures and pesticides in public places

Component 2

Component 2 will have two phases: Phase I offered now as a Pilot Award, and Phase II to be offered at a later date as a Full Award. Component 2 will test a new, integrated intervention strategy that addresses chemical exposures in relation to broader social contextual factors, to reduce occupational and/or environmental exposures as well as improve and promote overall health and wellness. The intervention to be tested, which could be a modification to an existing intervention

strategy not yet implemented in California, should be conducted within a cohort of women with shared workplace and/or place-based exposure to harmful chemicals or ionizing radiation. The cohort should be inclusive in terms of social (e.g., race/ethnicity) and economic demographics. The integrated intervention strategy should address intervention goals related to occupational and/or place-based exposures, within the context of the first two risk factors in *Paths to Prevention*: race, power, and inequities; and the social and built environment. The outcomes of interest are reduction in cohort-wide harmful exposures for breast cancer and improvement in cohort-wide measures of health (improvements in health behaviors or a reduction in the prevalence or severity of a chronic health condition), within a five-year project period.

Paths to Prevention also described common breast cancer risk factors unrelated to environmental or occupational exposures, such as alcohol consumption, diet and nutrition, physical inactivity, tobacco, and body weight. These risk factors often occur together, such as alcohol consumption and tobacco use, or poor nutrition and weight gain. The evidence linking alcohol consumption and physical inactivity with breast cancer is strong. Chronic health conditions that have been linked with some of these factors and environmental exposures could promote breast cancer development through biologic mechanisms that are at least additive, if not synergistic. The prevalence of many of the behavioral risk factors that put women at higher risk of breast cancer and other co-morbidities can be higher in communities that have been economically or socially marginalized. These communities also often experience greater exposure to harmful substances.

For many women from racial and ethnic minority groups who are economically and socially marginalized, limited opportunities and resources in their communities make it difficult to make healthy behavioral choices. In the 10 listening sessions that BCPP conducted with community groups, participants frequently discussed issues such as racism, access to healthy foods, and spaces for physical activity. The listening sessions reveal that participants wanted not only to avoid harmful exposures and breast cancer; they also wanted to live in communities that promote good health. Such contextual factors have been termed social determinants of health, and these factors are reflected in the first two risk factors described in *Paths to Prevention*: race, power, and inequities; and social and built environment.

For Component 2, an integrated intervention, the strategies to be tested should attempt to reduce harmful exposures and promote health in a community by mitigating a combination of chemical and other risk factors from *Paths to Prevention*. The priority risk factors, and the focus of associated intervention goals of special interest, are:

- Race, power, and inequities
 - o Goal 2, build power and capacity for women to drive societal change
 - o Goal 3, expand culturally appropriate messaging in education and awareness
 - Goal 4, endorse and support justice movements that address discrimination, marginalization, and oppression
- Social and built environment
 - o Goal 2, develop safe walk, bicycle and public friendly cities to enhance physical activity and reduce transit-related pollution
 - o Goal 3, ensure low-income housing is free from pollutants
 - o Goal 4, accessible and safe indoor and outdoor recreation spaces

- Occupation
 - o Goal 4, objective 2, make workplaces safer
 - Strategy 1, eliminate hazardous chemicals and practices from workplaces, with an emphasis on breast cancer risks
 - Strategy 2, focus on actions specific workforces (such as salon workers and janitorial workers) can take to protect themselves immediately
- Place-based chemicals
 - o Goal 5, reduce exposures to harmful exposures and pesticides in public places

Approaches and Methods

For both Components 1 and 2, the research will be conducted as community-partnered participatory research (CPPR) [5]. A Full Award is being offered for Component 1 (three-year awards). For Component 2, two types of awards will be offered. This RFP offers the opportunity to apply for a Pilot Award (1 year, feasibility, developing methods and tools, partnership and collecting pilot data), and the opportunity to apply for a Full Award (five-year award) in the future. The Component 2 Pilot Award is most appropriate for newly formed teams. The purpose of the Component 2 Pilot Award is to enable the team to address the organizational and research issues essential to a strong, well-designed Full Award. Pilot Award research can include gathering data, analyzing existing data, developing and testing tools to be used in a full research project, solidifying the partnership, and preparing for a future Full Award application or for an application to another funding agency. For teams who have already developed these elements, and can demonstrate this in an application, the Pilot Award may not be necessary; such teams may want to wait to apply when the Phase II Full Award call is released in the future.

For both Component 1 and Component 2, where experimental study designs may not be feasible, the intervention research could involve quasi-experimental studies. For example, matched concurrent comparisons, studies with unmatched comparisons, or studies with pre-post measures may be selected. However, the rigor of the proposed intervention research design will be evaluated in the application review process.

The research teams for both the Component 1 Full Award and the Component 2 Pilot Award must include individuals representing:

- At least one California-based community organization (formal or informal)
- Community members, including patients, clients or interested people
- At least one experienced academic researcher working in California in an appropriate discipline and setting

Each team must have one person designated as the "Community co-principal investigator (co-PI)" and one as the "Academic co-PI." The co-PIs take joint leadership on the research project and ensure adequate representation of both community and scientific perspectives.

The team must work collaboratively in all phases of the research project, including:

- Identifying the problem and formulating the research questions
- Writing and submitting the application

- Designing and carrying out the research
- Analyzing the research findings
- Preparing reports to the CBCRP
- Disseminating the results to both community and scientific audiences

Teams must present evidence of broad community involvement throughout the entire proposal and proposed project. This can be accomplished by having community members on the research team (the preferred option) or by having an informed and empowered community advisory board that is confident that they can express opinions and be heard by the research team.

A key practice in building and maintaining partnerships between community leaders and academically-trained partners is the practice of taking practical steps to promote equity and inclusion in the team. To that end, the CBCRP encourages teams to use the <u>engagement principals for equity and inclusion</u> that were developed by the Patient-Centered Outcomes Research Institute (PCORI) to inform their activities.

Dissemination Plans

Each application must include a dissemination plan, which includes methods to ensure the application of findings. Each applicant will be expected to present their plans to disseminate the results with all project partners. Applicants should include an action plan for informing community participants of the results of the study. Applicants are encouraged to actively involve project partners in the wider dissemination of results to project funders, local and state stakeholders, and policy decision makers. New and evolving models (e.g., social media) that enhance dissemination [11] should be described in a competitive Component 1. The dissemination plan should include modes and channels appropriate for the populations and communities corresponding to the target population for the tested prevention strategy and include bilingual/multilingual translation of materials, as needed.

The dissemination plan should also describe the translational potential of the work. To the extent appropriate, all applicants should describe how the lessons learned from the projects, in specific California jurisdictions, could be translated (put into action) across the state by making clear recommendations. Applicants also should describe how research findings could be replicated in other jurisdictions outside the state of California and how the findings and lessons learned will be disseminated more broadly. Dissemination and implementation research grant support for interested and eligible coalitions demonstrating in their funding applications collaborative, evidence-informed breast cancer prevention approaches from the Paths to Prevention across two or more California jurisdictions (e.g., cities, counties) will be available in 2023 through the CBCRP CLASP-BC Phase 2 initiative. The applicant should consider how their Component 1 or Component 2 intervention strategies, if shown to be effective, would be potential candidates for CLASP-BC Phase II dissemination and implementation research applications.

Budget

CBCRP intends to fund up to two Component 1 Full Awards, each with a maximum direct cost budget of \$825,000 and a duration of up to three years.

• \$750,000 total direct costs to support the research plan

• \$75,000 total direct costs to support the research dissemination plan

CBCRP intends to fund up to two Component 2 Pilot Awards, with a maximum direct cost budget of \$210,000 and a duration of one year.

- \$200,000 total direct costs to support the research plan
- \$10,000 total direct costs to support the research dissemination plan

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses, which receive a maximum of 30% F&A (26% for off-campus projects). Organizations that do not have a federally approved F&A rate may request a De Minimis rate of 10%.

Supplemental funding is available for funded projects to support promising high school students, undergraduate students and/or community members from groups underrepresented in breast cancer research and/or those who wish to pursue careers focused on questions affecting underrepresented communities to breast cancer research. Applications for these supplements will be accepted during the prefunding stage of the award and will start August 1, 2022. Visit https://cabreastcancer.org/files/cbcrp-diversity-supplement.pdf to learn more.

References

- 1. Buermeyer N, Engel C, Nudelman J, Rasanayagam S, Sarantis H. Paths to Prevention: California Breast Cancer Primary Prevention Plan. Breast Cancer Prevention Partners, San Francisco, CA, September 2020. Available at: https://www.bcpp.org/resource/california-breast-cancer-primary-prevention-plan/
- 2. Dietze EC, Sistrunk C, Miranda-Carboni G, O'regan R, Seewaldt VL. Triple-negative breast cancer in African-American women: disparities versus biology. Nature Reviews Cancer. 2015 Apr;15(4):248-54. Available at: https://www.nature.com/articles/nrc3896
- 3. Henley SJ, Ward EM, Scott S, Ma J, Anderson RN, Firth AU, Thomas CC, Islami F, Weir HK, Lewis DR, Sherman RL. Annual Report to the Nation on the Status of Cancer, part I: National cancer statistics. Cancer. 2020 May 15;126(10):2225-49. Available at: https://www.cdc.gov/cancer/annual-report/
- 4. Heron MP. Deaths: leading causes for 2017. National Vital Statistics Reports, Volume 68, Number 6 June 24, 2019. Available at: https://www.cdc.gov/women/lcod/2017/hispanic/index.htm
- 5. Israel BA, Eng E, Schulz AJ, Parker EA (eds.) *Methods for Community-Based Participatory Research for Health, 2nd Edition.* Jossey-Bass; 2012. https://www.wiley.com/en-us/Methods+for+Community+Based+Participatory+Research+for+Health%2C+2nd+Edition-p-9781118021866
- 6. Mariotto AB, Robin Yabroff K, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010–2020. Journal of the National Cancer Institute. 2011 Jan 19;103(2):117-28. Available at:

https://academic.oup.com/jnci/article/103/2/117/2568866?login=true

7. Miller KD, Siegel RL, Lin CC, Mariotto AB, Kramer JL, Rowland JH, Stein KD, Alteri R, Jemal A. Cancer treatment and survivorship statistics, 2016. CA: a cancer journal for clinicians. 2016 Jul;66(4):271-89. Available at:

https://acsjournals.onlinelibrary.wiley.com/doi/full/10.3322/caac.21349

- 8. Parise C, Caggiano, V. Breast Cancer Mortality among Asian American Women in California: Variation according to Ethnicity and Tumor Subtype. Journal of Breast Cancer. 2016 Jun 24;19(2) 112-121. Available at: https://ejbc.kr/DOIx.php?id=10.4048/jbc.2016.19.2.112.
- 9. Pinheiro PS, Callahan KE, Siegel RL, Jin H, Morris CR, Trapido EJ, Gomez SL. Cancer mortality in Hispanic ethnic groups. Cancer Epidemiology and Prevention Biomarkers. 2017 Mar 1;26(3):376-82. Available at: https://cebp.aacrjournals.org/content/26/3/376.abstract
- 10. Rey-Vargas L, Sanabria-Salas MC, Fejerman L, Serrano-Gómez SJ. Risk Factors for Triple-Negative Breast Cancer among Latina Women. Cancer Epidemiology and Prevention Biomarkers. 2019 Nov 1;28(11):1771-83. Available at:

https://cebp.aacrjournals.org/content/cebp/28/11/1771.full.pdf

- 11. Steensma JT, Kreuter MW, Casey CM, Bernhardt J. 12. Enhancing dissemination through marketing and distribution systems. In: Brownson RC, Colditz G, Proctor EK, eds. *Dissemination and Implementation Research in Health: Translating Science to Practice*. Oxford University Press; 2017:191-200. DOI:10.1093/oso/9780190683214.001.0001
- 12. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2019 submission data (1999-2017): U.S. Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute, released in June 2020. Available at: www.cdc.gov/cancer/dataviz
- 13. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, Bridged-Race Population Estimates, United States July 1st resident population by state, county, age, sex, bridged-race, and Hispanic origin. Available on CDC WONDER Online Database at http://wonder.cdc.gov/bridged-race-v2019.html

How We Evaluate RFPs

CBCRP uses a two-tier evaluation process: peer review and programmatic review. It is a combination of (i) the peer review rating, (ii) the programmatic rating, and (iii) available funding that determines a decision to recommend funding.

Peer Review

All applications are evaluated by a peer-review committee of individuals from outside of California. The committee is composed of scientists from relevant disciplines and breast cancer advocates and other community representatives.

Component 1 Full and Component 2 Pilot applications are rated using four equally weighted criteria. The first two are categorized as "collaboration elements" and the second two are termed "scientific merit".

• Partnership (Collaboration Element)

- The extent to which the strengths/nature of the proposed community partnership is reflected in leadership and involvement in all phases of the project (e.g. inception to dissemination).
- The level to which both partners' knowledge and lived experience is integrated into planning and conducting the research.
- o The level to which both co-PIs have engaged with the larger community to get their input in the application development process.
- The extent to which agreements have been reached regarding procedures for resolving disagreements among collaborators, ownership of data, and dissemination of results.
- o The potential for capacity-building for any or all of the partners.
- For Component 1 awards: Demonstrated successful collaboration in previous research projects.

• Community Benefit (Collaboration Element)

- The extent to which the community has been involved in the development of the research idea and questions, and the writing of the research proposal.
- Plans for how the broader community will be involved in the research project during the course of the research, from helping to conceptualize the research question(s) through dissemination of the results.
- The potential importance and benefit to the broader lay community of the research question(s) and expected outcomes.
- The potential for the research project to facilitate learning, further collaboration, and systems change.
- o For Component 1 awards: The plan for translating the research results into tangible benefits for the community and for engaging the community, local and state stakeholders and policy decision makers in discussions of the results of the research and the implications for them.

• Quality of the Research (Scientific Merit)

- O The scientific importance of the research questions, including consideration of the most relevant literature and whether the intervention being researched will result in a breast cancer prevention strategy.
- o The appropriateness and integration of the conceptual framework, research methods, and data analysis plan to the research question and aims.
- For Component 1 awards: The strength of the research plan to analyze the effectiveness of the prevention strategy.

• Feasibility (Scientific Merit)

- The extent to which the project can be successful given the partners' knowledge, skills, resources, and experience.
- o The likelihood of completing the project as proposed given the available funding and time frame.
- o The usefulness (validity and/or importance) of data from previous research and community experience for the proposed research plan.

Programmatic Review

This review is conducted by the California Breast Cancer Research Council and involves reviewing and scoring applications with sufficient scores from the peer review process based on the criteria listed below. The individuals on the Council performing this review include advocates, clinicians, and scientists from a variety of disciplines. In performing the Programmatic Review, the advisory Council evaluates **only a portion of the application materials** (exact forms are underlined). Pay careful attention to the instructions for each form. The Programmatic criteria include:

- **Responsiveness.** How responsive are the project and co-PIs to the stated intent of the selected Initiative? Avoid general references to the requirements of the RFP. Describe how elements of the proposed research plan are linked to one or more of the specific RFP topic areas. Compare the PIs' statements on the <u>Program Responsiveness</u> form and the content of the <u>Lav and Scientific Abstracts</u> to the PBC topic area.
- Quality of the Lay Abstract. Does the <u>Lay Abstract</u> clearly explain in non-technical terms the research background, questions, hypotheses, and goals of the project? Is the relevance to the research initiative understandable?
- Diversity, Equity and Inclusion. Do the statements in the <u>Collaborative Agreements</u> demonstrate a plan for the research team include community members representing groups that are underrepresented in breast cancer research? Do the project and the PIs' statements on the <u>Program Responsiveness</u> form demonstrate how this research will address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographical location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors)? Do the statements in the PIs' <u>Program Responsiveness</u> form describe how the research will affect systems change for historically disenfranchised groups?
- Community Involvement. Are the named community PIs and community organizations clearly driving the proposed research project? How well has the team described the strengths/nature of the proposed community partnership and how is it reflected in leadership and involvement in all phases of the project (e.g. inception and application

through to dissemination). How well has the team described how both co-PIs have engaged with the larger community to get their input in the application development process. Are meetings and other communications sufficient for substantive engagement and collaboration? Are the roles and responsibilities of the PIs clearly outlined and is the agreement for sharing of budget clear? [The Advisory Council will examine the co-PIs' statements on the <u>Lay and Scientific Abstracts</u>, <u>Program Responsiveness form</u>, and <u>Collaborative Agreements</u>.]

• **Dissemination and translation potential.** The degree to which the applicant's statements on the <u>Program Responsiveness</u> form provides a convincing argument that the proposed research has the potential to inform real-world breast cancer prevention efforts.

Application Instructions

Application materials are available through RGPO's <u>SmartSimple application and grant management system</u>. Please review the <u>SmartSimple Application Instructions</u> for the technical instructions for accessing and completing your application. This supplemental programmatic instruction document provides guidance for the content of your application.

Application Components

Section 1: Title Page

- **Project Title:** Enter a title that describes the project in lay-friendly language. (Max 100 characters).
- **Project Duration:** Selected duration should be up to 3 years for the Component 1 Full Award and should be 1 year for the Component 2 Pilot Award.
- Proposed Project Start Date: Enter a project start date of August 1, 2022.
- **Proposed Project End Date:** Enter a project end date of July 31, 2023, 2024, or 2025 for a 1-, 2-, or 3-year award, respectively.

Section 2: Applicant/PI

A required field entitled "ORCID ID" is editable on the Profile page. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and your professional activities ensuring that your work is recognized. If you have not already obtained an ORCID ID number, you may do so at http://orcid.org/ Once you have done so, please enter your 16-digit identifier in the space provided on your profile page in the following format: xxxx-xxxx-xxxx.

Section 3: Project Information

Please use the following guidelines to differentiate between Lay and Scientific Abstracts:

Lay Abstract (Max 2400 characters): This item is evaluated mainly in the programmatic review. 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. Ask your advocate partner to read this abstract and provide feedback.

Scientific Abstract (Max 2400 characters): 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 breast cancer

Provide the critical information that will integrate the research topic, its relevance to breast cancer, 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.

Additional information: Applicants must respond to the following categories and discussion points using the online fields provided:

- **Specific aims** (Max 2400 characters/approx. 350 words). List the proposed aims of the project.
- **CBCRP Research Priorities.** Select "Etiology and Prevention" as the CBCRP priority issue that the research addresses.
- **CSO Research Type(s) and Sub-Type(s).** Select "3.0 Prevention" as the CSO Type, and please select the corresponding CSO Sub-Type(s) that best represent your project.
- Subject Area(s). See SmartSimple submission instructions for more details.
- Focus Areas(s). See SmartSimple submission instructions for more details.
- **Research Demographics.** Complete this table if the research project will involve human subjects. Enter the target demographics of the research participants that you propose to recruit. See the SmartSimple submission instructions for more details.
- Milestones. See SmartSimple submission instructions for more details.

Section 4: Project Contacts

Project Personnel. Provide contact information and effort for Key Personnel and Other Significant Contributors on your project including the Applicant Principal Investigators (Co-PIs), Co-Investigators, Advocates, Trainees, Collaborators, Consultants, and support personnel, as necessary. Upload biosketches to each of your Key Personnel members in this section, as shown in the SmartSimple instructions. A 10% minimum effort (1.2 months per year) is required for the Applicant PIs (Co-PIs).

Section 5: Budget

This section contains several sub-tabs: Institution Contacts, Budget Summary, Budget Details, and Subcontract Budget Details. Complete the information in the Institutional Contacts, Budget Summary, Budget Detail and, if applicable, Subcontract Budget Details tab as described in the SmartSimple Application Instructions.

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. The Submitting Co-PI has the ability to edit all budgets, although the invited Co-PI does not.

For Component 1 Full Awards, the maximum duration is 3 years, and the direct costs budget cap is \$825,000 (\$750,000 for research, \$75,000 for research dissemination).

For Component 2 Pilot Awards, the duration is 1 year, and the direct costs budget cap is \$210,000 (\$200,000 for research, \$10,000 for research dissemination).

The budget allocated to the research dissemination activities must be specifically labeled in the budget justification.

Additional budget guidelines:

- **Equipment** purchases up to \$10,000 are allowed. Only include individual items >\$5,000. Any items less than \$5,000 must be purchased under the "supplies" budget category.
- Other Project Expenses: Include other project costs such as supplies here.
- Travel: A minimum of \$400 must be budgeted in year 1 for travel to the CBCRP symposium. Scientific meeting travel is capped at \$2,000/yr.
- Indirect (F&A) costs. Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC*, or 26% MTDC for off-campus investigators (not retroactive to prior grants).

*Allowable expenditures in the MTDC base calculation include salaries, 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). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000 shall be excluded from the modified total direct cost base calculation. 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 10% MTDC.

Additional budget guidelines can be found in Appendix B.

Section 6: Assurances

Enter assurance information. If available, enter your institutional Federal Wide Assurance (FWA) code or equivalent for Human Subjects, an IACUC Animal Welfare Assurance code for Vertebrate Animals, and equivalent for Biohazard ad DEA Controlled Substance approvals.

Section 7: Documentation

Complete and upload all required items. All uploads must be in PDF format. Listed below are the forms and templates you download from SmartSimple, enter text, convert to PDF, and, unless instructed otherwise, re-upload to your application in this section.

Upload Item (Template/Form)	Page limit	Required or optional	Peer Review?	Programmatic Review?
Research Plan	10 (+ 3 for references)	Required	Yes	No
Program Responsiveness	3	Required	Yes	Yes
Collaborative Agreements	2	Required	Yes	Yes
Biosketches (All Personnel listed on Key Personnel form)	5 (each biosketch)	Required (upload to Project Personnel section)	Yes	Yes (PI only)
Facilities	1 per institution	Required	Yes	No
Human Subjects	No limit	Required	Yes	No
Appendix list and uploads	30	Optional	Yes	No

Detailed Description of Proposal Templates

Research Plan (required)

This section is the **most important** for the peer review. Note carefully the page limits, format requirements, and suggested format. <u>Limit the text to ten pages</u>, <u>with an additional 3 pages for references</u>.

Format issues: Begin this section of the application using the download template. Subsequent pages of the Research Plan and References should include the principal investigator's name (last, first, middle initial) placed in the upper right corner of each continuation page.

The Research Plan and all continuation pages must conform to the following four <u>format</u> <u>requirements</u>:

- 1. The height of the letters must <u>not be smaller than 11 point</u>; Times New Roman or Arial are the suggested fonts.
- 2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi).
- 3. No more than 6 lines of type within a vertical inch;
- 4. Page margins, in all directions, must be 0.75 inches.

Use the appendix to supplement information in the Research Plan, not as a way to circumvent the page limit.

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and 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 questionnaires, consent forms, interview 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.

Suggested outline:

Statement of Goals, Research Questions, and Specific Aims. In a short paragraph, describe goals for the research project. Follow with the Specific Aims—the specific tasks that will be undertaken to address the research question(s).

For Component 1 Awards, briefly state the research question(s) and hypothesis for the Full Research award. Follow with the Specific Aims—the specific tasks that will be undertaken to address the question(s). These tasks should be very clearly defined and should not include exploratory or development undertakings. The research questions, hypothesis, and aims should have a logical connection.

For Component 2 Pilot Awards, describe how the Pilot, if awarded, will be used to prepare the collaborative team to apply for the Full Award Component 2 Award. These should have a logical connection, and you need to make clear their relationship to the team's long-term research goals. Do not include tasks that you expect to undertake in the full research project or with future funding from another agency.

The relationship of the project to the specific PBC Project Type and expectations outlined within the RFP should be clear.

Background and Significance. Concisely describe the rationale underlying the proposed research and intervention strategy; the hypotheses to be investigated; the methodology to be employed; and the experience, knowledge, and skills of the research team. Emphasize positioning the research in the context of existing relevant scientific literature and preliminary data that the team may have collected in preparing for the research. Demonstrate a grasp of the current state of the knowledge relevant to the problem. Provide up-to-date references, acknowledge controversies and contradictory reports, and be comprehensive and accurate. If there is little literature on the topic, draw on information from related fields. Demonstrate the community interest, participation in the plan development from the beginning, and the potential contribution of the proposed research. Briefly state the long-term potential of the research: the problems, issues, or questions which, through the execution of this award, can be further developed, specified, and sharpened into testable hypotheses; and the methodologic approach (or possible approaches that seem at present most appropriate to be used). Keep discussion of the general problem of breast cancer brief; emphasize the specific problem addressed by your research proposal.

Preliminary Data. For Component 1 applications, describe the prior experience with the intervention to be investigated. Emphasize any work by the Co-PIs and data specific to breast cancer. Present any data obtained in detail, with a description of how the data was obtained and analyzed. Describe any pitfalls or problems that arose, as well as how they were overcome. Provide justification and support for the potential for useful knowledge and interventions to result from the research.

Research Methodology: Research Design, Conceptual Framework, and Data Analysis.

Describe in detail the exact tasks listed in 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. For instance, if women are to be surveyed, explain how many women will be surveyed; why you chose this number; how the women will be identified and recruited; why you believe you will be able to reach and recruit this many women; what questions you will ask them; whether you will use face-to-face 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 as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline. Be sure to include a hypothesis and conceptual framework.

Component 2 Pilot award applicants should focus the discussion on how research methodologies and resource needs will be established for a full study.

Partnership Collaboration Plan and Community Benefit. Begin this section by describing the community of interest for this study. Is the community distinct because of geography, age, gender, associated by disease status or risk, race, sexual orientation, or socio-economic status? Describe the interest of the community in the research question and how they have participated in identifying it. Discuss the importance and benefit to the community of the research question and expected outcome. Specifically answer how the broader community of interest was involved in developing the research proposal. Describe the relationship between the community co-PI and their community organization and the community of interest. How will the community of interest be included on the research team? Discuss how the leadership of the community organization (the Executive Director, the Board of Directors, or the individuals of an informal organization) will ensure that the organization or group is committed to the research project? Describe how the Community Co-PI and the community organization will communicate with one another to facilitate input and decision-making.

Program Responsiveness (required)

This item is evaluated in the peer review and programmatic review. <u>Limit the text to three pages</u>. The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan. The information on this template allows the CBCRP Research Council to rate the application for adherence to the objectives of the PBC research area as outlined in the specific RFP.

PBC Focus (Responsiveness): Provide a clear, brief summary for the CBCRP Council (1 or 2 paragraphs) of how your proposed research addresses the specific RFP topic area, by increasing or building on specific scientific knowledge; by pointing to additional solutions to identify and eliminate environmental causes, and or disparities in, breast cancer; and/or, by helping identify or translate into potential prevention strategies. Avoid general references to the requirements of the RFP. Describe how elements of the proposed research plan are linked to one or more of the specific RFP topic areas. As this is a community-partnered participatory research project, do highlight the strengths/nature of the proposed community partnerships as reflected in the leadership and involvement in all areas.

<u>Diversity and Inclusion</u>: Describe how the project will address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographical location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors) and how it will affect systems change for historically disenfranchised groups.

<u>Dissemination and Translation Potential</u>: Describe how research findings will be shared with various stakeholder audiences (i.e., policymakers, community members, breast cancer advocates, other researchers/agencies, health care providers, funders etc.). Describe the potential for how the research findings will be translated into policy and/or other practice to inform real-world breast cancer prevention efforts.

Collaborative Agreements (required)

This form is reviewed in the peer review and the programmatic review. Applicants should remember that a fully collaborative and power-sharing partnership is a key aspect of this application. <u>Limit the text to two pages</u>.

Avoid general references to the requirements of the RFP. Highlight the strengths/nature of the proposed community partnerships as reflected in the leadership and involvement in all areas. Describe how the community PI has been in a leadership role in the application development process and how the team has engaged with the larger community to get their input in the application development process.

The Community Applicant is required to verify the agreements addressed in this form by submitting a statement that the governing body (Board of Directors for a nonprofit organization or the individuals responsible for organizing an informal organization) has reviewed and approved these agreements.

The collaborative agreement should include the following elements:

- Ownership of Data: Describe what decision you made about who will own the data and intellectual property rights and why you came to that decision (i.e. what factors you considered, what was important to you in making this decision). If you decide 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 his/her 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, including arrangements both partners have agreed to ensure access to that data by the other partner (including beyond the study period).
- Handling Disagreements: Describe what decision you made about the procedures you will go through to handle disagreements during the course of the study and afterwards. Past teams have had to resolve issues around data ownership, conduct of the research, dissemination of data and publications, administrative and budget issues, etc. Describe why you believe your decision on handling disagreements will work for you.

- Recipient of Grant Award: Describe what decision you made about whether the grant award will be contracted directly to one partner or to both partners and why you came to that decision. CBCRP suggests that if both applicant agencies have the administrative capacity to manage grant awards, that each agency receives a separate award.
- Plans for Broader Community Involvement: Describe how individual community members not on the research team (including staff and board of the community agency applicant as well as community members outside of the organization) will be involved in the planning, conducting, and dissemination of research. Describe how the community co-PI will be overseen by the community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).
- 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. Please describe how research findings will be disseminated to both the community of interest and the scientific community and what agreements have been made about the timing of dissemination.
- Plans for Turnover of Personnel: Describe how the turnover of personnel will be handled (who will hire, fire, etc.) Describe how the community co-PI, specifically, will be overseen by the community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).

Biographical Sketch (required)

This item is evaluated in the peer review and the programmatic review. Use the NIH form (version 2015 or later) for each key person and attach it in the Project Personnel section. Limit the length of each biosketch to no more than five (5) pages.

Facilities (required)

This item is evaluated in the peer review. <u>Limit the text to one page per institution</u>. Follow the instructions on the template.

Human Subjects (required)

This item is evaluated in the peer review. This form is required to be completed for applications that use Human Subjects, including those in the "Exempt" category. Applications that do not utilize Human Subjects should state "N/A" on the form and upload, as well. Use additional pages, if necessary.

For applications requesting "Exemption" from regular IRB review and approval. Provide sufficient information in response to item #1 below to confirm there has been a determination that the designated exemptions are appropriate. The final approval of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation must

be provided before an award is made. Research designated exempt is discussed in the NIH PHS Grant Application #398 http://grants2.nih.gov/grants/peer/tree_glossary.pdf. Most research projects funded by the CBCRP falls into Exemption category #4. Although a grant application is exempt from these regulations, it must, nevertheless, *indicate the parameters of the subject population* as requested on the form.

For applications needing full IRB approval: If you have answered "YES" on the Organization Assurances section of the application and designated no exemptions from the regulations, the following seven points must be addressed. 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 project.
- 2. Describe the <u>characteristics of the subject population</u>, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and the CBCRP that research involving human subjects must include members of underserved groups in study populations. Applicants must describe how minorities will be included and define the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. 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.
- 3. Identify the <u>sources of research material</u> 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 <u>plans for recruiting subjects</u> 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.
- 5. Describe any <u>potential risks</u> —physical, psychological, social, legal, or other. 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 Assurances tab, if available at the time of submission, include official documentation of the approval by the IRB, showing the title of this application, the principal investigator's name, and the approval date. Do not include supporting protocols. Approvals that are 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, an USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

Applications that include Phase I-III clinical trials may be required to provide a data and safety monitoring board (DSMB) as described in the NICI policy release, http://grants.nih.gov/grants/guide/notice-files/not98-084.html. This ensures patient safety, confidentiality, and guidelines for continuing or canceling a clinical trial based on data collected in the course of the studies. The CBCRP may require documentation that a DSMB is in place or planned prior to the onset of the trial.

Appendix (optional)

Follow the instructions and items list on the template. The appendix may <u>not</u> be more than 30 pages in length.

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 or renewal report may be included; the appendix is not to be used to circumvent page limitations of the application.

Appendix A: QuickStart Training and Community-Partnered Participatory Research

Co-PIs who have not undergone community partnered participatory research (CPPR) training together will be required to attend QuickStart, CBCRP's training for CPPR teams, in the first year of their project. By applying for a grant under this initiative, you are also applying to be part of QuickStart. During the award period, awardees will execute the project as described in their application and research plan. In addition, they will use the QuickStart program resources to craft their application for follow-on funding.

Applicants whose application is not funded are still highly encouraged to attend QuickStart, which could make you more competitive for future funding opportunities.

What is QuickStart?

QuickStart is an innovative program for both newly forming and experienced collaborative community-academic research partnerships. It has previously been offered via a mix of face-to-face, web-based, and phone-based sessions. Collaborative partnerships include two Co-Principal Investigators (Co-PIs). In each partnership there must be one community Co-PI and one academic Co-PI. QuickStart provided support to teams to stimulate community-partnered participatory research (CPPR) that addresses breast cancer, including disparities, environmental causes, and/or primary prevention.

It is expected that enrolled partnerships that are based in California and complete the program will be prepared to submit competitive grant applications to CBCRP Community-Academic partnered awards including Community Research Collaborations (CRC) awards and partnered program initiatives.

What is Community-Partnered Participatory Research?

Community-partnered Participatory Research (CPPR) is research conducted by a partnership that includes at least one community Co-PI and one academic Co-PI. Together, as equals, the partnership decides which research questions are most important to them, determines how to study these questions, gathers and interprets data, and communicates findings to other community members, scientists, and the general public. By combining the knowledge and interest of communities with the expertise and resources of research scientists, partnerships are responsible for conducting research that answers important questions in a way that has immediate impact on knowledge, programs, and policies.

What will the program help teams learn to do?

- Create or deepen an equitable partnership and conduct successful CPPR;
- Create a pathway from vision to research project;
- Design innovative studies that include questions about breast cancer and tobacco related disease;
- Prepare for completing a successful study, including planning additional research, policy and services impact, and community/scientific education.

What are the program topics?

Over the course of the program, topics covered will include:

- CPPR
 - o Partnership vision
 - o Partnership agreements and assessments
 - o CPPR benefits and challenges
- Pathway from vision to research project
 - o Basic scientific methods and research ethics
 - o Research specific aims
 - o Impact of scientific methods on community
- Understanding the State of the Science
 - o Risk factors for breast cancer
 - o A new paradigm of breast cancer causation
 - o Role of services and screening in health disparities
- Preparing for Impact
 - o Using a pilot study to prepare for a full application
 - o Research impact on policy and services
 - o Personal report back of individual environmental data
 - o Community and scientific dissemination

How will the program be structured?

QuickStart includes both face-to-face sessions and online sessions. The first face-to-face includes a welcoming dinner session followed by two full days. The second face-to-face is two full days.

We plan to have one in-person session take place in the Greater Los Angeles area and the other take place in the San Francisco Bay Area. **Please note:** Once the geographic distribution of accepted teams is known, it may be necessary to revise this plan so that both sessions take place in the San Francisco Bay Area. As noted below, transportation will be covered for California-based participants, regardless of location. Before applying, please consider your availability for the additional time needed for travel.

The face-to-face sessions will be a combination of presentations, small group work and work as individual teams. The online sessions reinforce and expand on the learning that takes place in the face-to-face sessions. The online portion is "asynchronous" – you and your partner will engage with the rest of the class, online, at any time of the day or night.

Participants must attend all sessions.

To fully participate in QuickStart, partnerships will need to share their research ideas, plans, and draft grant proposals at various times throughout the program with staff, teachers, and other participants. In additional to completing assignments for your team, all participants are expected to read and comment on other teams posting when relevant. All participants will be required to sign a confidentiality statement and will agree to rigorous ethical conduct, including protection of other classmates' intellectual property.

What is the financial commitment?

• The program is offered free of charge.

- Participants who live in California and do not live within a reasonable driving distance of
 the program sites will be provided transportation costs and offered a free hotel room. In
 previous programs these have been shared rooms with another fellow (either from your
 team or another team). Fellows who have preferred their own room have covered the cost.
 Our policy for the 2022 will be consistent with public health guidelines at the time of inperson meetings. Local participants should plan to sleep at home.
- Participants from outside California will need to cover their own travel expenses, though the cost of the program and hotels will be covered.
- Breakfast and lunch will be provided for all participants during the program. There will be a limited number of group dinners included. Participants will need to pay for their own dinners on the nights when no group activities are planned.
- Participants are required to have their own computer and online access.
- Costs associated with regular partnership work that takes place outside of the program (phone calls, transportation to meetings etc.) will be paid by the individuals themselves.

What is the time commitment?

- A series of four days of presentations. Two-days are planned in in June and 2 days in August. (~46 hours total; historically offered in-person)
- Online weekly assignments before and after face-to-face sessions. Assignments include literature reviews, developing draft research questions, writing concept papers, participating in educational webinars and others. (Approximately 10 hours of educational sessions plus written assignments)
- Up to four technical assistance calls to give teams feedback on potential research questions, methodologies, partnership development, concept papers, and (optional) grant application. (up to 4 hours)

When will the program take place?

The full QuickStart program is scheduled for June 2022–January 2023. Key dates include:

- Online Sessions: Ongoing, June through November
- Face-to-face meeting 1: June 29 & 30, 2022; 8:00 AM 8:30 PM both days. Tentatively planned for Southern CA.
- Face-to-face meeting 2: August 11 & 12, 8:00 AM 8:30 PM both days. Tentatively planned for Berkeley, CA.
- Concept papers due: October 3, 2022.
- **Technical Assistance calls:** Four rounds of calls will take place between face to face sessions, after the second face to face session, after concept proposals are submitted and after an optional mock review of the draft proposals
- Draft application for mock review due: December 1, 2022
- **Mock review of applications:** January 13, 2023 (tentative)

Online sessions will occur in a private online classroom. The online site will have additional instructions, materials for download, and homework for the partnerships to complete. The online site has a messaging function that will be used for participants to maintain contact and share ideas throughout the program. Webinars will also be hosted (schedule to be announced).

Appendix B: Cost and Expense Guidelines

For all budget categories, clearly label all costs associated with research dissemination activities in the budget justification.

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:
 - o NIH Guidelines:
 - o http://grants.nih.gov/grants/policy/person months faqs.htm
 - o NIH Calculation Scheme: http://grants.nih.gov/grants/policy/person months conversion chart.xls
- When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income (e.g., clinical or consulting incomes).
 CBCRP 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. Tuition remission, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition listed in this category) may not exceed \$30,000 per project year (total for all students). A maximum of \$10,000 per year is allowed for the combined costs of tuition/enrollment fee remission, fringe benefits, and health insurance. Stipend may be budgeted as salary (and included in the MTDC cost calculation) if the institution pays these expenses through a personnel line item.

3) Other Project Expenses

- Include expected costs for supplies and other research expenses not itemized elsewhere.
- Pooled expenses may be allowed as a direct cost at the discretion of the Program with certification of the following: 1) the project will be directly supported by the pooled expenses, 2) the pooled expenses have been specifically excluded from the indirect cost rate negotiation, and 3) the pooled expenses have been allocated consistently over time within

- the organization. Please explain any requested pooled expense requests in the budget justification.
- Advocate (s) Expenses. Include any travel, meeting, and consultation costs/fees associated with advocate engagement.

4) Equipment (Unit Cost over \$5,000)

• Each requested equipment item must be >\$5,000 and explain in budget justification.

5) Travel

- Travel CBCRP Meeting: CBCRP may organize an event requiring your travel within the funded grant period. All applicants should budget a one-time minimum expense of \$400 under year 1 in the travel budget line labeled: "Travel CBCRP Meeting".
- <u>Travel Project Related</u>: 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.
- <u>Travel Scientific Meetings</u>: Scientific conference travel is limited to \$2,000 per year (excluding a mandatory allocation of \$400 in one year of the project for travel to the CBCRP Conference under Travel CBCRP Meeting). Label such expenses as "Travel-Scientific Meetings" and explain in budget justification.

6) Service Contracts and Consultants

• Both categories require additional description (Budget Justification).

7) Subcontracts

• 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 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 30% MTDC (26% for off-campus projects).
- Modified Total Direct Costs (MTDC) include salaries and wages, fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract) to an outside institution. MTDC does not include (indirect costs are not allowed on): capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, equipment purchases more than \$5,000 per item, the portion of each sub grant and subcontract in excess of the

- first \$25,000, and the total cost of any subcontract from one UC to another UC campus. On a non-fellowship award, you may apply indirect costs to graduate student salary (under salary only, not as stipend) but not to tuition & fees.
- For all eligible projects that allow grantees to recover the full amount of their federally negotiated indirect cost rate agreement, grantees must also accept the full federally recognized F&A rate for all award subcontractors (except for subcontracts to another UC institution, where F&A is not allowed). If a grantee or subcontractor does not have a federally negotiated F&A rate at the time of the proposal submission, the grantee and/or subcontractor may estimate what the federally negotiated rate will be at the time of award and include this rate in the proposed budget, or may request a "De Minimis" F&A rate of 10% 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

- o The award recipient institution will pay indirect costs to the subcontractor.
- o For non-UC subcontracted partners, CBCRP will allow full F&A of the Modified Total Direct Cost (MTDC), as defined above.
- o F&A costs are not allowed for one UC institution's management of a subcontract to another UC institution.
- O 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 CBCRP Application Policies and Guidelines

Eligibility and Award Limits

- 1. Any individual or organization in California may submit an application. The research must be conducted primarily in California. We welcome investigators from community organizations, public or privately-owned corporations and other businesses, volunteer health organizations, health maintenance organizations, hospitals, laboratories, research institutions, colleges, and universities. Applicants at California-based Nonprofit Institutions: CBCRP will accept applicants from PIs at non-profit organizations or institutions, provided that the organization can manage the grant and demonstrate financial health. The organization must also meet our liability insurance requirements. If the application is recommended for funding, the University 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.
- 2. We encourage researchers new to breast cancer to apply. Applicants who have limited experience in breast cancer research should collaborate with established breast cancer researchers.
- **3. Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. Applicants are limited to a maximum

- of two (2) grants either as PI or co-PI, and these must be in different award types. The Program Initiative grants are not included in this limit. A PI may have more than one Program Initiative grant in a year.
- 4. University of California Campus Employees: 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.

Policy on Applications from PIs with Delinquent Grant Reports

PIs with current RGPO grant support will <u>not</u> be eligible to apply for additional funding unless the required scientific and fiscal reports on their existing grants are up-to-date. This means that **Progress/Final Scientific Reports or Fiscal Reports that are more than one month overdue may subject an application to disqualification unless the issue is either, (i) addressed by the PI and Institution within one month of notification, or (ii) the PI and Institution have received written permission from CBCRP to allow an extension of any report deadlines.**

Confidentiality

CBCRP maintains confidentiality for all submitted applications with respect to the identity of applicants and applicant organizations, all contents of every application, and the outcome of reviews. For those applications that are funded CBCRP makes public, (i) the title, principal investigator(s), the name of the organization, and award amount in a "Compendium of Awards" for each funding cycle, (ii) the costs (both direct and indirect) in CBCRP's annual report, (iii) the project abstract and progress report abstracts on the CBCRP website. If the Program receives a request for additional information on a funded grant, the principal investigator and institution will be notified prior to the Program's response to the request. Any sensitive or proprietary intellectual property in a grant will be edited and approved by the PI(s) and institution prior to release of the requested information.

No information will be released without prior approval from the PI for any application that is not funded.

Award Decisions

Applicants will be notified of their funding status by July 1, 2022. The written application critique from the review committee, the merit score average, component scores, and programmatic evaluation are provided at a later time. Some applications could be placed on a 'waiting list' for possible later funding.

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 CBCRP program director.

Final decisions on application funding appeals will be made by the Vice President for Research & Innovation, University of California, Office of the President. Applicants who disagree with the scientific review evaluation are invited to submit revised applications in a subsequent grant cycle with a detailed response to the review.

The full appeals policy can be found in the online the University of California, Office of the President, "RGPO Grant Administration Manual – Section 5: Dispute Resolution":

https://www.ucop.edu/research-grants-program/ files/documents/srp forms/srp gam.pdf

Pre-funding Requirements

Following notification by CBCRP of an offer of funding, the PI and applicant organization must accept and satisfy normal funding requirements in a timely manner. Common pre-funding items include:

- 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 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

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

Open Access Policy

As a recipient of a California Breast Cancer Research Program (CBCRP) grant award, you will be required to make all resulting research findings publicly available in accordance with the terms of the *Open Access Policy* of the Research Grants Program Office (RGPO) of the University of California, Office of the President (UCOP). This policy, which went into effect on April 22, 2014, is available here: https://www.ucop.edu/research-grants-program/grant-administration/rgpo-open-access-policy.html.

Grant Management Procedures and Policies

All CBCRP 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. Details concerning the requirements for grant recipients are available in a separate publication, the University of California, Office of the President, "*RGPO Grant Administration Manual*." The latest version of the Manual and programmatic updates can be obtained from the Program's office or viewed on our website: http://www.ucop.edu/research-grants-program/files/documents/srp_forms/srp_gam.pdf

Contact Information

Technical support and questions about application instructions and forms should be addressed to the Research Grant Programs Office Contracts and Grants Unit:

RGPOGrants@ucop.edu

For scientific or research inquiries, please contact:

Katherine McKenzie, PhD Senior Program Officer, CBCRP Katherine.McKenzie@ucop.edu

Partnership technical support, please contact:

Senaida Fernandez Poole, PhD Community Initiatives and Public Health Sciences Program Officer, CBCRP senaida.poole@ucop.edu

The California Breast Cancer Research Program is part of the Research Grants Program Office of the University of California, Office of the President.