CALIFORNIA BREAST CANCER RESEARCH PROGRAM

Request for Proposals (RFP)
Research Teams

A Community-Partnered Approach to Understanding the Social and Systemic Factors Influencing Breast Cancer Risk in Immigrants: Phase 1

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to apply
March 24, 2021

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About the California Breast Cancer Research Program and the California Breast Cancer Prevention Initiatives

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 fund 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.

CBCPI Priority Areas

In 2004, CBCRP launched its Special Research Initiatives. CBCRP's Breast Cancer Research Council devoted 30 percent of CBCRP research funds to support coordinated, directed, and collaborative research strategies that increase knowledge about and create solutions to both the environmental causes of breast cancer and the unequal burden of the disease.

In March 2010, CBCRP's Council decided to build on the existing SRI by devoting 50 percent of CBCRP research funds between 2011 and 2015. This new effort is titled the California Breast Cancer Prevention Initiatives (CBCPI). Approximately $24 million is being dedicated to directed, coordinated, and collaborative research to pursue the most compelling and promising approaches to:

1. Identify and eliminate environmental causes of breast cancer.
2. Identify and eliminate disparities/inequities in the burden of breast cancer in California.
3. Population level interventions (including policy research) on known or suspected breast cancer risk factors and protective measures.
4. Targeted interventions for high-risk individuals, including new methods for identifying or assessing risk.

To focus these research efforts, CBCRP issued a Request for Qualifications (RFQ) to fund a team to collaborate with CBCRP to develop and implement the California Breast Cancer Prevention Initiatives planning process. In 2010, the grant was awarded to Tracey Woodruff, PhD, MPH, Professor and Director of the University of California, San Francisco, Program on Reproductive Health and the Environment (PRHE).

In March 2015, CBCRP's Council approved 15 concept proposals to stimulate compelling and innovative research in all four topical areas of the CBCPI (environmental causes, health disparities, population-level interventions and targeted interventions for high risk individuals). To date, CBCRP has funded 22 awards under CBCPI, totaling over $19 million. "A Community-Partnered Approach to Understanding Social and Systemic Factors Influencing Breast Cancer Risk in Immigrants" is the final CBCPI initiative remaining to be competed.

A Community-Partnered Approach to Understanding the Social and Systemic Factors Influencing Breast Cancer Risk in Immigrants: Phase 1

We know that immigrating from a country of low breast cancer incidence to the United States (and California) increases a women's risk of breast cancer as well as the risk for her children and future generations. However, we do not understand why. If we understood and could intervene on the factors that make living in the United States (and California) increase breast cancer risk, we could lower the rate of breast cancer both for immigrants and for anyone else living here.

This initiative aims to advance our understanding of this increase in breast cancer risk through a two-phase approach. The aim of Phase 1 is to bring together the diverse experts, community members, and ideas to lay the groundwork for a more comprehensive Phase 2 study. Our intent is to examine factors that have not been explored in the past. For example, rather than focusing on diet and individual behavioral factors, we are interested in the impact of the social and built environment, the stressors that come with immigration, including related policy and enforcement factors, and the lived experiences of immigrants that might influence breast cancer risk.

Available Funding

CBCRP is sponsoring two open funding opportunities for "A Community-Partnered Approach to Understanding the Social and Systemic Factors Influencing Breast Cancer Risk in Immigrants: Phase 1":

1. A Request for Proposals (RFP) for community-partnered participatory research teams to apply to conduct a one-year exploratory study and participate in a series of workshops to lay the groundwork for a more comprehensive Phase 2 study.
2. A Request for Qualifications (RFQ) for a convener to facilitate the communication and forming of collaborations between Phase 1 research teams by organizing periodic meetings for the research teams and creating a framework for forming collaborations between teams and developing the scope of the RFP for Phase 2.

These funding opportunities support the generative phase of a larger initiative. The ultimate goal of the initiative is to understand the factors that cause a woman's risk of breast cancer to increase after immigrating from an area of lower breast cancer incidence to California (which has higher incidence) through a community-partnered interdisciplinary approach focused on the systemic, social, and other interrelated factors influencing breast cancer risk for immigrants in California. The purpose of this generative phase is to lay the groundwork for the larger study by forming academic/community teams and new collaborations between teams, gathering community input, exploring the feasibility and desirability of different approaches, and defining the specific scope of the full study.

We anticipate that up to $600,000 in direct costs will be available for Phase 1 of this initiative. Up to $100,000 in direct costs will be available for each of up to five research teams to participate in this initiative and up to $100,000 in direct costs is available for the Convener. Additional funding will be available for Phase 2 if the initiative proves to be feasible in Phase 1.

This RFP is to select up to five Research Teams for Phase 1. A separate RFQ is being published to select the Convener for Phase 1. **Completed responses to this RFP are due by Wednesday, March 24, 2021, 12 pm PST.** The project start date is December 1, 2021.

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Background/Justification

We have known for decades that a woman's risk of developing breast cancer varies several-fold depending on where she is born (Bray et al., 2018). Most women live in the same country their entire lives, but considerable numbers of women immigrate at some point in their lives to another country, and many immigrate multiple times. We have also known for decades that when a woman immigrates to the United States, her risk of developing breast cancer increases for her and subsequent generations, eventually approaching the risk of a U.S.-born woman. For example, one study showed that risk of breast cancer among foreign-born Latinas was 50% lower than among U.S.-born Latinas, and increased with length of residence, younger age at migration, and increasing acculturation (John et al., 2005), with similar results found among Japanese American women (Shimizu et al., 1991). Although we have known this and attempted to understand why for decades, it remains a puzzle.

Overall, the balance of studies supports the idea that immigration leads to a change in breast cancer risk and thus an increase in risk for immigrants to the United States. However, although the research indicates that modifiable environmental and behavioral factors may play a role both before and/or after immigration, the precise reasons for this shift in risk is not known (Andreeva et al., 2007). Prior research has measured acculturation primarily using proxies such as years in the United States or comfort with English language. However, acculturation is a complex phenomenon that cannot be captured by such unidirectional measures. Mixed-methods may better capture biocutural drivers of breast cancer risk than the concept of acculturation.

With more time in the United States, women's behaviors, social factors (e.g. immigration status, socioeconomic status, social networks, stressors), and environments (e.g. chemical exposures, built environment, neighborhoods) are associated with their increased risk for, and incidence of, breast cancer. The experience and changes that occur with immigration are, therefore, an important area for research, in order to identify factors that influence breast cancer risk. Increased breast cancer rates as a woman is in the United States longer suggest that

a confluence of behavioral, social, psychological, and environmental factors are important and could be the key to the observed increase in breast cancer rates but so far remain largely unknown. Various efforts have been made to date to identify these factors, including by CBCRP-funded research (Morey et al., 2018; Morey et al., 2019; Wong et al., 2016). Existing research has been limited by a lack of data to examine biological, behavioral, social, psychological, and environmental factors at the same time in a cohort of women with varying amounts of time living in the United States.

In terms of women's behaviors, individual diet has been a frequent focus of efforts to understand the underlying relationship between immigration and breast cancer, but it has not been demonstrated to be the primary cause. Studies suggest that diets can change for immigrant populations once they are in the United States. For example, Asians may increase their fat and sugar intake in the United States and one study showed that soy intake is different for Asians in different locations, finding a two-fold greater intake of tofu among Asian immigrant women over U.S.-born Asian American women, with an observed protective effect against breast cancer (Wu et al., 1996a). It has been postulated that soy may be protective for breast cancer, though a strong protective effect has not been observed experimentally (Adlercreutz, 2002; Bouker and Hilakivi-Clarke, 2000). Furthermore, soy (Setchell and Cole, 2006) and other dietary factors may affect the microbiome. A recent study in immigrants from Thailand to the United States found that immigration to the United States decreased the diversity of the gut microbiome, and that diversity continues to decrease with more time spent in the United States and in ensuing generations (Vangay et al., 2018).To date, this focus on individual components of diet ignores structural issues such food access that may positively or negatively affect breast cancer risk and risk factors.

Changes in reproductive factors across the life course, such as age at menarche and menopause and age at first birth and breastfeeding, also have been posited to explain increasing incidence in immigrant populations, but they and the corresponding differences in underlying hormones do not fully explain the marked difference in incidence rates among migrant generations (Falk et al., 2002; Wu et al., 1996b). Thus other environmental factors must be at play. Exposure to endocrine disrupting chemicals and air pollution are two potential environmental risk factors where there is growing, yet inconclusive, evidence in relation to breast cancer (Rodgers et al., 2018). There is also growing evidence that features of the built environment, including spatial proximity, transportation, land use, and housing are associated with breast cancer incidence (Huang et al., 2019; Wray and Minaker, 2019). Such built environment features may impact breast cancer through influencing air quality, substance use, diet, and physical activity whether these features also explain rising incidence in immigrant populations is understudied.

Information about immigrants' social contexts remains incomplete. One study empirically examined the frequently-cited assumption that Hispanic immigrants have stronger social ties than their U.S.-born peers. After adjustment for both individual-level and community-level factors, the study found that immigrant Latinos were less likely to be socially integrated, and had smaller and less diverse social networks than U.S.-born Latinos (Viruell-Fuentes et al., 2013). Ethnic enclaves that maintain cultural mores, including certain behavioral factors (e.g.

diet) and social support, have been identified as a possible protective factor. However, most research has focused on characteristics of the individual and there has been little research on the social or neighborhood context of immigrants, and the associated risks and protections it might afford.

Social factors related to breast cancer risk may be impacted by immigration. Adapting to a different culture can be stressful with many newly immigrated individuals having difficulty finding work reflective of their education and training and language barriers posing challenges to obtaining necessary staples for everyday life. One study found Latino immigrants had high levels of two specific stressors, early life adversity and work stress. In contrast, U.S.-born Latinos had greater clustering of multiple stressors and higher levels of life events, financial, relationship, discrimination and neighborhood stressors than whites and Hispanic immigrants (Sternthal et al., 2011). Studies have also demonstrated that xenophobia negatively affects health (Suleman et al., 2018). The interplay between race/ethnicity and place of birth is complex, as one study found that Hispanic American women in the United States had larger breast tumors at initial diagnosis than White women, and Hispanic American women born outside of the United States had larger tumors than those born in the United States (Hedeen and White, 2001). These factors are compounded by the well-documented health disparities and inequities between racial and ethnic groups in the United States (Krieger et al., 2017; Sternthal et al., 2011; Vainshtein, 2008; Williams et al., 2016; Zhou et al., 2017). It is important that these various associated and sometimes confounding stressors be understood as they relate to breast cancer risk.

While much of the literature has focused on the negative impacts of immigration and adapting to different cultures, there has also been some limited research exploring resilience, the ability to process and cope with negative experiences and to buffer from the impacts of stress. Much of the literature on resilience focuses on the cancer experience, yet there could be potential for resilience, specifically through cultural identity and pride, to influence breast cancer risk. One study of immigrant Pacific Islander youth in Hawaii noted the importance of resilience through bicultural identity, which can increase self-esteem and lead to encouraging healthy behaviors (Lee et al., 2018). The mediating effect of resilience can influence breast cancer risk through the pathway of increasing the likelihood of healthy behaviors (e.g., exercise, healthy eating) as well as lowering stress (e.g., coping abilities). Resilience as connected to bicultural identity can be explored to understand the generational differences in breast cancer risk (Reyes and Constantino, 2016).

Much research on immigration and health has focused on individual behavioral factors and cultural factors. When structural factors are examined, the focus has often been on access to health care. However, a social determinants of health framework has the potential to provide a more fundamental and global understanding of factors affecting health and disease and, more importantly, provide actionable public health knowledge to promote a healthier society (Castañeda et al., 2015). *The most impactful public health interventions are foundational efforts at system-level change across the population that address social determinants of health and provide the context for individuals to lead healthier lives (Frieden, 2010). Therefore, this*

initiative aims to be most impactful by focusing on the social context of immigration and breast cancer.

The complexity of the interplay between immigration and health and the diversity between immigrant groups have made studies in this area difficult and prone to oversimplification. The use of mixed methods and qualitative research can help capture the intricacies of complex health phenomena (Palinkas et al., 2011; Zhang and Creswell, 2013). Employing a community-partnered approach also helps ensure that the research is guided by community priorities and the reality on the ground and better captures the diversity of different communities' experiences. Such partnerships have proven effective for community-centered research on immigrant health (Chavez et al., 1995; Martinez et al., 2008; Martinez Tyson, 2008; Meade et al., 2011; Menard et al., 2010; Seay et al., 2017; Sudhinaraset et al., 2017).

This initiative seeks to address these complexities and drive the field toward findings that will advance breast cancer prevention by focusing on systems-level risk factors and social determinants of health, taking a community-partnered approach, incorporating mixed methods, and employing a two-phase approach to better define the scope of the problem with both scientific and community input and to form collaborations to conduct the research to address the problem in the second phase.

Research Aims, Approaches, and Methods

The overall aim of this initiative is to understand how multiple and complex factors, with a focus on systems-level factors and social determinants of health, influence breast cancer risk across multiple generations of immigrant women, and how these factors are interrelated, are mediated or influenced by each other and change over time the longer the duration in the United States and California. This initiative will be carried out in two phases. Phase 1 is a generative phase to form teams, develop collaborations, understand the underlying issues, incorporate community input, perform exploratory research, and define approaches for a more comprehensive study.

In order to tap the knowledge and lived experiences of immigrants themselves and generate new hypotheses, in Phase 1 we will fund up to five community-academic teams to explore how the host environment for immigrants may impact breast cancer risk, including exposures to physical agents, social and emotional stress, access to food, housing, recreation and jobs, social support, and other factors. Qualitative research is welcome in this phase and may include, but should not be limited to, focus groups; examples include ethnography, participant observation, in-depth interviews, etc. Integrating qualitative data with quantitative data through systematic mixed-methods approaches is also encouraged (Palinkas et al., 2011; Zhang and Creswell, 2013). Phase 1 will include exploration of innovative methods and the collection of preliminary data to study the impact of immigration to the United States (and California) on breast cancer risk.

The Research Teams will meet periodically throughout Phase 1, through a process led by the Phase 1 Convener, to exchange ideas and learn about each other's work. One of these meetings will be a community town hall, where the impacted communities are invited to provide input to the research teams. At the end of Phase 1, the teams will gather in a sandpit meeting to present their results and engage in scoping research questions and methodology for Phase 2. Determining the details of the scope and approaches for Phase 2 will be a primary outcome of Phase 1.

Our intent is to examine breast cancer risk factors that have not been explored in the past; for example, rather than focusing on diet, we are interested in the impact of the social and built environment, the stressors of different types of immigration, and the lived experiences of immigrants that might influence breast cancer risk. Some of the factors that could be examined include those from the five broad categories below, though the primary focus of the study should be on systems-level factors, rather than individual behavioral or cultural factors:

Category	**Examples of Individual Factors**	**Examples Systems-Level Factors**
Biological	Onset of puberty, cortisol levels, microbiome, hormone levels	Reproductive norms and policies, stressors related to uncertain immigration status, food access
Behavioral	Diet, physical activity, smoking, breastfeeding	Access to fresh foods, access to recreation facilities, work stability and workplace policies, smoking policies, breastfeeding norms, mobility restrictions linked to uncertain immigration status, healthcare access related to immigration status
Social	Social support, stressors	Discrimination, socioeconomic status, issues related to living in mixed-status families, anti-immigrant policies that deny access to health care, housing, food, and other social needs (e.g., undocumented immigrants and immigrants without lawful permanent residence/ green cards)
Psychological	Group identity, religiosity	Stigmatization, stress related to one's own uncertain immigration status, stress related to the immigration status of others (family members or neighbors)
Environment	Chemical exposures from personal consumer products, pollution, neighborhood safety	Patterns in chemical exposures, segregation, city planning and the built environment, immigration enforcement and policing activities in neighborhoods and workplaces

Sample research questions that could be explored in both phases include:

1. What social determinants of health are experienced differently before, during, and after immigration and between immigrant generations that may influence breast cancer risk?
2. Are there aspects of the built, social, and/or policy environment experienced by immigrant communities that affect breast cancer risk?
3. Does breast cancer risk for immigrant women vary between women who live in ethnic enclaves compared with those who live in heterogeneous neighborhoods or with majority U.S.-born neighbors?
4. How is the average population age of puberty affected by length of time spent in the US? How does the age of puberty differ between mothers and daughters across multiple immigrant generations?
5. Which protective factors against the development of breast cancer decline over time and which risk factors increase over time?

Phase 1 will consist of up to five community-academic Research Teams, a Convener, and a Scientific Advisory Panel.

Research Teams:
Research teams will be selected through an RFP process. Research teams should be community-partnered participatory research teams, including at least one academic co-PI and at least one community co-PI. Research teams will perform an exploratory study and participate in periodic meetings to learn from one another, form new collaborations, and develop the parameters for the Phase 2 study. Team members are responsible for conducting their proposed exploratory study, attending all meetings and teleconferences, collaborating with the other research teams, and assisting with the development of the scope for the Phase 2 study. Up to five research teams will be selected to participate in Phase 1. Research teams participating in Phase 1 will be invited to form collaborations to submit a proposal for the Phase 2 study, which will only be open to collaborations involving at least two teams participating in Phase 1.

Convener:
The Convener for Phase 1 will be responsible for all meeting and teleconference logistics, facilitating collaboration between the Phase 1 research teams, incorporating additional community input into the Phase 1 process, developing the scope of the Phase 2 RFP in conjunction with the Phase 1 research teams, and writing a final report for Phase 1. The Convener may also be a member of a research team, but is not required to be. The Convener may also participate in Phase 2.

Scientific Advisory Panel:
CBCRP and the Convener will together appoint the Scientific Advisory Panel (SAP) members. The panel will consist of advocates, scientists, clinicians, and/or members of affected communities. They will participate in all meetings and teleconferences and work collaboratively with the Co-PIs and Convener to carry out the project and develop final research questions.

Phase 1 Research Teams

Phase 1 Research Team applicants should adhere to the following approaches/methods in developing their response to this RFP:

- Form a collaboration between at least one academic Co-PI and at least one Co-PI from a community-based organization that directly works with, represents, and/or impacts one or more immigrant communities. The collaboration may be new or preexisting.
- Represent a range of disciplines, which could be accomplished by convening a cross-disciplinary advisory group to guide the research team's work.
- Develop the methods needed and/or collect preliminary data to lay the groundwork to subsequently (in Phase 2) collect data on multiple factors that could influence breast cancer risk within and across the five categories identified (biology, behavior, social, psychological and environmental), with a focus on systems-level and social factors.
- Use qualitative or mixed-methods. (A mixed-method approach aims to gain a richer understanding of research problems than if only one of the methods were used (Creswell and Plano Clark, 2018), and are usually employed with the purpose of compensating for the limitations of quantitative and qualitative methods alone (Curry et al., 2009). While it is common to use the term "mixed methods research" when referring to studies that utilize at least one quantitative and one qualitative method, it is encouraged to use a more integrated approach, following either convergent, explanatory sequential, or exploratory sequential designs.)
- Focus the research on characterizing the changes in systems-level factors that occur with immigration over time, and how these complex factors, alone and in combination, contribute to changes in breast cancer risk as time living in the United States increases.

Applicants should be prepared to work with the other investigators funded under this initiative. At a minimum, this will include presenting ideas, approaches and findings at periodic meetings, and offering feedback to other researchers on their work. Representatives of impacted communities and outside experts will also participate in these meetings. All Phase 1 Research Teams must attend all (at least two, and up to four) meetings organized by the Phase 1 Convener, with the following goals:

- Ensuring that community voices and input are incorporated into the Phase 1 process
- Fostering new research collaborations and promoting synergy between research teams
- Developing the scope of the Phase 2 research study that at least two (and up to all five) of the Phase 1 Research Teams would be willing and able to join together to undertake

The ultimate goal of Phase 1 is to generate the scope of the research for Phase 2 and form collaborations between Phase 1 Research Teams to conduct the Phase 2 study. Phase 2 will fund one project that addresses cross-cutting findings from Phase 1. It is expected to be developed at the sandpit meeting concluding Phase 1 and involve at least two teams from Phase 1. The purpose of Phase 2 is to answer the research questions and/or test hypotheses generated in Phase 1. Approaches employed in Phase 2 may include, but are not limited to, some of the following elements: a multigenerational cohort study, young people interviewing their elders, and/or comparisons of (1) mother/daughter or sister dyads, (2) first-generation to

second-generation immigrants, (3) cross-cutting factors affecting different ethnic groups, and/or (4) enclaved versus non-enclaved families. The Phase 2 project should be interdisciplinary and incorporate mixed methods (qualitative and quantitative research). The Phase 2 project should incorporate a dissemination plan that puts research into action by making clear policy recommendations.

Key questions about Phase 2 will be addressed during Phase 1:

1. What are the specific research questions and research design for Phase 2?
2. Is a multi-generational cohort study of multiple ethnic groups feasible?
3. Which ethnic groups should be the focus of Phase 2?
4. What are cross-cutting issues across immigrant groups related to breast cancer risk?
5. Which potential systemic breast cancer risk factors should be studied in Phase 2?
6. What interdisciplinary methods and approaches should be incorporated in the Phase 2 research?
7. How should the Phase 2 research results be disseminated to ensure that research is put into action?

Research teams participating in Phase 1 will be invited to form collaborations to submit a proposal for the Phase 2 study. Only research teams who participated in Phase 1 will be eligible to apply for Phase 2 funding. Each eligible Phase 2 application will need to involve at least two teams from Phase 1, and all teams participating in Phase 1 may decide to collaborate on one Phase 2 application, or groups of teams may submit competing applications. The Phase 1 Convener may also participate in the application(s) for Phase 2.

Due to the collaborative nature of this initiative, it is the intent of CBCRP to fund multiple research teams in Phase 1 (at least three and ideally four to five teams) in order to bring in diverse approaches and perspectives and to foster a robust exchange of ideas.

Budget (Phase 1 Research Teams)

CBCRP intends to fund up to five research teams to conduct community-partnered exploratory studies. The maximum duration for each Phase 1 project is one year. The maximum allowable direct costs per project are $100,000.

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).

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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.

- **Innovation:** Extent to which the project explores new and potentially useful information about the multiple systemic factors that influence breast cancer risk in ethnic group(s) with recent immigration history in California. Are the concepts and hypotheses speculative and exploratory? Are methods novel and original? Have the investigators thought creatively about how to measure these factors and how they may impact and interact with each other? Is the focus primarily on systems-level and social factors?

- **Impact:** Potential for the project, if successful, to change understanding of breast cancer risk within ethnic group(s) with recent immigration history. Does the research have the potential to translate to population-level change? Could the data yielded by the research contribute to informing policy or to developing an intervention? Will the investigators be able to contribute to the collaborative process of generating the scope for Phase 2?

- **Approach:** The quality, organization, and presentation of the research plan, including methods and analysis plan. Will the research lay the groundwork for Phase 2? Are the design, methods and analyses innovative and likely to lead to new discoveries? Does the application demonstrate an understanding of the immigration experience? Is the research informed by the community? Does the approach incorporate mixed methods and perspectives from multiple disciplines?

- **Feasibility:** The extent to which the aims are realistic for the scope and duration of the project; adequacy of investigators' expertise and experience, and institutional resources. Is the team assembled cross-disciplinary and with appropriate expertise to address the multiple factors in the categories (biological, behavioral, social, psychological, and/or environmental) that are included in the research? Do the co-investigators have demonstrated expertise and experience working in the topic area and working collaboratively with community organizations? Can the project be completed as proposed given the available funding, time frame and the staff knowledge, skills, experience, and institutional resources?

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? Compare the Co-PIs' statements on the Program Responsiveness form and the content of the Lay and Scientific Abstracts to the CBCPI topic area.

- **Quality of the lay abstract.** Does the Lay Abstract clearly explain in non-technical terms the research background, questions, hypotheses, and goals of the project? Is the relevance to the research initiative understandable?

- **Community Involvement.** Do the Co-PIs express sensitivity to and awareness of the existing and potential human issues involved in the research and the concerns of breast cancer advocates? More specifically, have advocates from the appropriate community been engaged and involved in the development of the research questions, design of the project, and/or plans for conducting the research? Have the Co-PIs committed themselves to be proactive in disseminating the research to the lay audience? [The Advisory Council will examine the Co-PIs' statements on the Lay and Scientific Abstracts, Program Responsiveness form, and Collaborative Agreements forms.]

- **Addressing the Needs of the Underserved.** Do the project and the Co-PIs' statements on the Other Criteria template 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, geographic location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors)?

Application Instructions

Application materials will be available through RGPO's SmartSimple application and grant management system beginning on February 1, 2021. Please review the SmartSimple Application Instructions for the technical instructions for accessing and completing your application. The supplemental programmatic instructions below provide 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:** Enter a project duration of 1 year.
- **Proposed Project Start Date:** Enter a project start date of December 1, 2021.
- **Proposed Project End Date:** Enter a project end date of November 30, 2022 for a 1-year award.

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 obtain 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-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. 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.

Scientific Abstract (Max 2400 characters)**:** This item is evaluated mainly in the peer review. 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 "Community Impact of Breast Cancer" as the CBCRP priority issue that the research addresses.
- **CSO Research Type(s) and Sub-Type(s)**. Select "2.0 Etiology" as the CSO Type and "2.1 Exogenous Factors in the Origin and Cause of Cancer" as the Sub-Type 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.
- **Milestones.** Add significant milestones that are described in your research plan to this table along with anticipated completion dates and arrange them in chronological order.

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 Investigator, Co-Investigator, Advocate, Collaborator, Consultant, 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 Applicant 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.

The **project duration is 1 year and the direct costs budget cap is $100,000**.

Note: The amount of a subcontracted partner's F&A costs can be added to the direct costs cap. 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. However, please note that prime-subcontractor relationships between two partners on a community-partnered award are rare.

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*

Additional budget guidelines can be found in Appendix D of the SmartSimple Instructions.

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	**2**	**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**
Facilities	**1 per institution**	**Required**	**Yes**	**No**
Human Subjects	**No limit**	**Required**	**Yes**	**No**
Vertebrate Animals	**No limit**	**Optional**	**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. **Limit the text to 10 pages, with an additional three pages for references.**

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 format requirements:

1. The height of the letters must not be smaller than 11 point; 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:

1. **Statement of Goals, Research Questions, and Specific Aims.** In a short paragraph, describe goals for the Phase 1 award in light of the long-term research goals. Describe how the Phase 1 research project will be used to prepare the collaborative team to pursue participate in Phase 2. State the goals and research questions for the Pilot award. Follow with the Specific Aims—the specific tasks that will be undertaken in Phase 1 to address the question(s). These should have a logical connection, and you need to make clear their relationship to the team's long-term research goals. The relationship of the project to the specific CBCPI Project Type and expectations outlined within the RFP should be clear.
2. **Background and Significance.** Concisely describe the rationale underlying the proposed research; 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.
3. **Preliminary Data.** Describe the recent work, if any, relevant to the proposed project. Emphasize any work by the Co-PIs and data specific to breast cancer.
4. **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.

5. **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. **Limit the text to two pages**. 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 CBCPI research area as outlined in the specific RFP.

- **CBCPI 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.
- **Addressing the Needs of the Underserved**. Describe how this research will address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors)

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 an equally weighted criterion, making up ¼ of each application's total score. **Limit the text to two pages.**

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. **Limit the text to one page per institution**. 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 characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and 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 sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.
4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent.
5. Describe any potential risks —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 Co-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.

Vertebrate Animals (optional)

This item is evaluated in the peer review. **This form is required only for applications that use Vertebrate Animals. Limit the text to two pages**.

If you have answered **"YES"** to the Vertebrate Animals item on the Organizations Assurances page of your application, then following **five points** must be addressed. When research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), provide this information before discussing the five points.

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic and tranquilizing drugs, and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any methods of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendations.

Documentation of Assurances for Vertebrate Animals

Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. In the appendix, if available at the time of submission, include official documentation of institutional review committee approval showing the title of this application, the principal investigator's name, and the inclusive approval dates. Do not include supporting protocols. Approvals obtained under a different title, investigator or institutions are not acceptable unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to the CBCRP as soon as possible. Funds will not be released until all assurances are received by the CBCRP.

Appendix (optional)

Follow the instructions and items list on the template. **The appendix may not 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.

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. **PIs who have previously been funded by CBCRP** are welcome to apply, but the research aims must be distinct from their previous CBCRP grants.
4. **Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. For Cycle 27 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.
5. **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 not 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.

Human Subjects and Vertebrate Animal Use
If a project proposes activities that pose unacceptable potential for human and animal subject risks, then a recommendation either not to fund or to delay funding until the issue is resolved may result.

IRB approval, human subject "exemption" approval, or animal assurance documentation must be provided prior to funding, but is not needed for application review. Applicants are encouraged to apply to the appropriate board or committee as soon as possible in order to expedite the start of the project, and you must do so before or **within 21 days of notification that an award has been offered**. If all reasonable efforts are not made to obtain appropriate approvals in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects.

Award Decisions
Applicants will be notified of their funding status by July 1, 2021. 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:
Nicholas J. Anthis, DPhil
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The California Breast Cancer Research Program is part of the Research Grants Program Office of the University of California, Office of the President.