CALIFORNIA BREAST CANCER RESEARCH PROGRAM

Request for Qualifications (RFQ)
Convener

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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Published January 21, 2021; updated January 26, 2021

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

The Phase 1 convener will be responsible for organizing at least two, and up to four, meetings to facilitate collaboration between the five research teams, encourage the exchange of ideas, bring in community input, and develop the scope for the Phase 2 study:

- Meetings should be held in California (if in-person meetings are possible); otherwise they should be held online.
- Members of impacted communities, in addition to community members participating on research teams, should be included in at least one meeting (a community town hall) so that community voices and community input are part of the process.
- The Convener should organize a "sandpit" workshop for the final meeting of Phase 1, where Phase 1 research teams and stakeholders would come together to collaboratively develop the research ideas and solutions that will form the basis of Phase 2.

The Phase 1 Convener is responsible for the following outcomes:

- Fostering new research collaborations and promoting synergy by having all research teams interact
- Ensuring that community voices and input are incorporated into the Phase 1 process
- Developing the scope of a 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

A successful Phase 1 Convener applicant should have experience facilitating meetings and facilitating collaboration between multidisciplinary teams. Phase 1 Convener applicants should also have experience working with immigrant communities and/or organizations that work with, represent, and/or impact immigrant communities.

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.

Budget (Phase 1 Convener)

CBCRP intends to fund one Convener for Phase 1. The duration of the Phase 1 Convener contract is 18 months. The maximum allowable direct costs for the Convener 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).

We anticipate that a successful Phase 1 Convener applicant may have the following items in their budget proposal:

- Key personnel with expertise in community-partnered breast cancer research among immigrant communities
- Meeting Planner
- Travel and housing for the Convener team and the Scientific Advisory Panel
- Meeting space and catering
- Postage, printing, materials development
- Subcontract(s) with community organizations to facilitate outreach to immigrant communities that will provide additional community input into the phase 1 process

Milestones (Phase 1 Convener)

The deadline for completion of this initiative is 18 months from the contract start date. Expected milestones are:

- Hold a kick-off meeting (by fourth month)
- Hold additional meetings, including final meeting (by 16th month)
- Define scope of Phase 2 research project and have collaboration of at least two teams ready to submit proposal (by 16th month)
- Submit final report (by 18th month)

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How We Evaluate RFQs

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.

- **Approach:** Does the implementation plan demonstrate a clear understanding of the scope of the initiative including specific steps/activities and experts to address each of the Aims for the project? Are the design, methods and analyses well-developed, integrated and appropriate to the aims of the project? Will the approach yield the desired outcomes that reflect the goals and objectives of the RFQ?

- **Feasibility:** Has(ve) the investigator(s) identified a project team with the expertise and leadership in coordination, facilitation and evaluation of similar strategic planning and funding priority efforts? Does the team have demonstrated experience and ability to convene and facilitate diverse, high-functioning working groups in the successful completion of similar initiatives? Does the team have scientific experience, including in breast cancer, social determinants of health, health disparities, and/or immigration? Does the team have community engagement experience, especially with immigrant communities? Has the investigator demonstrated the capacity of resources and staff to undertake the project within the timeframe? Can the team accomplish the identified aims and activities within their proposed timeline and deliverable schedule?

- **Impact:** Does the investigator or team have experience engaging with and disseminating to audiences relevant to this initiative? Will the investigator or team be able to lead the development of the scope of an impactful Phase 2 research project? What is the potential for the project, if successful, to change understanding of breast cancer risk within ethnic group(s) with recent immigration history?

- **Innovation:** Are the proposed approaches to the specified steps/activities innovative? Are the methods novel and original?

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 PI to the stated intent of the selected Initiative? Compare the PI's 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?

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:** Selected duration must be a whole number. Enter a project duration of 2 years for an 18-month award.
- **Proposed Project Start Date:** Enter a project start date of August 1, 2021.
- **Proposed Project End Date:** Enter a project end date of January 31, 2023 for an 18-month 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.** Leave this table blank since this research project will not involve human subjects.
- **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 5% minimum effort (0.6 months per year) is required for the Applicant PI.

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.

The **project duration is 18 months, 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.

Additional budget guidelines:

- **Equipment** purchases are not allowed.
- **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	**7** *(+ 3 for references)*	**Required**	**Yes**	**No**
Program Responsiveness	**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**
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 seven 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. 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. **Preliminary Work.** Describe the qualifications for the PI and his/her team in the areas of expertise listed in the Evaluation criteria. Provide details about work conducted by the PI and key staff that is similar and relevant to this initiative. Elaborate on PI and staff experience facilitating processes that include a wide variety of collaborators, particularly

scientists, clinicians, advocates and affected communities. Provide a summary of previous work with immigrant communities.

2. **Initiative Plan.** Provide an overview of your understanding of the initiative and research questions, and your plan to carry out the activities detailed in the Research Aims, Approaches, and Methods section above. Discuss in details how you would organize meetings, facilitate collaboration between research teams, and run a process that would result in a scope for Phase 2 and research team(s) prepared to conduct Phase 2. Discuss potential obstacles in your approach and which methods will be used to overcome them.
3. **Community Involvement and Communication.** Provide a detailed description of how you will engage immigrant communities and other stakeholders to ensure their input into the development of Phase 2 and their support and engagement in the resulting initiative.

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 RFQ.

Provide a clear, brief summary for the CBCRP Council of how your proposed approach addresses the specific RFQ topic area by facilitating collaboration between research teams, engaging immigrant community stakeholders, and creating a process to lay the groundwork for a successful Phase 2 of this initiative.

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.

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
Environmental Health & Health Policy Program Officer, CBCRP
nicholas.anthis@ucop.edu
(510) 987-0358

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