



Request for Proposals (RFP)

Intergenerational Transmission of Breast Cancer Health Inequities

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

Deadline to apply:
March 02, 2023

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

The **California Breast Cancer Research Program (CBCRP)** was established pursuant to the 1993 Breast Cancer Act (*AB 2055 (B. Friedman) [Chapter 661, Statutes of 1993]* and *AB 478 (B. Friedman) [Chapter 660, Statutes of 1993]*). The program is responsible for administering funds for breast cancer research in 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, a 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 \$13 million for breast cancer research.
- Ninety-five percent of our revenue goes directly to funding research and education efforts.
- CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, CBCRP has awarded over \$290 million in 1,249 grants to institutions across the state. With continued investment, CBCRP will work to find better ways to prevent, treat and cure breast cancer.

PBC Priority Areas

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

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

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

- Identify and eliminate environmental contributors to breast cancer.

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

In 2020, CBCRP began releasing a series of initiative based on 10 concept proposals to stimulate compelling and innovative research in all three PBC focus areas.

Intergenerational Transmission of Breast Cancer Health Inequities

Available Funding

This initiative aims to examine whether intergenerational transmission of breast cancer susceptibility can be influenced by environmental exposures (e.g. chemical exposures; multi-level exposures to social determinants of health). Studies will be viewed as responsive if they employ community-partnered participatory methods and are any of the following types of studies: epidemiology studies with stored biospecimens from earlier in life (e.g., prenatal period) and outcomes or strong intermediate markers in a least one subsequent generation (Approach 1); epidemiology studies that can utilize a mixed methods approach to analyze qualitative and quantitative data around intergenerational social determinants of health at the individual and community level (Approach 2); studies with access to one generation and breast cancer incidence outcomes in at least one subsequent generation (Approach 3).

CBCRP intends to fund up to three projects with a duration of three to five years maximum at a maximum total direct cost of \$300,000 for Approach 1 and \$425,000 for Approaches 2 or 3.

Completed responses to this RFP are due by Thursday, March 02, 2023, 12 Noon PT. The project start date is August 1, 2023.

For more information and technical assistance, please contact:

Sharima Rasanayagam, PhD

Environmental Health & Health Policy Program Officer, CBCRP

sharima.rasanayagam@ucop.edu

(510) 987-9216

Background/Justification

Breast cancer inequities: Despite the promising declines in breast cancer mortality rates across all groups in the U.S., there continue to be major health inequities in breast cancer mortality rates across racial and ethnic subgroups, particularly when comparing mortality rates in non-Hispanic Black (NHB) women with non-Hispanic White (NHW) women. Coupled with these mortality inequities are steady annual increases in breast cancer incidence in women under 55 years [1-4]. In California between 2008 and 2017, breast cancer incidence rates increased only among women 20 to 44 years of age and among all racial/ethnic groups, except for white women, for whom rates did not change significantly [5]. Both breast cancer mortality and incidence trends differ by molecular subtype of breast cancer with the highest mortality seen in women with estrogen-receptor (ER), progesterone receptor (PR), HER2^{neu} negative (also referred to as Triple Negative Breast Cancer (TNBC)). Although there is some evidence that TNBC incidence has not increased in recent years, the incidence rates of TNBC remain **two-times** higher across all age groups when comparing NHB women to NHW women [6]. Family history remains the most important predictor of cancers including breast cancer, however intergenerational risk associated with family history goes far beyond genetic predisposition. Thus, these persistent patterns need research focused on other factors that may be responsible. These trends demand new approaches to understanding the etiology and drivers of these major health inequities with a particular focus on what has been learned over

the past several decades regarding environmental exposures, intergenerational transmission of disease susceptibility, and breast cancer risk.

Environmental chemical exposures may contribute to intergenerational risk: There is growing evidence that exposure to certain environmental chemicals in early-life, particularly during the prenatal window, increases breast cancer risk in offspring [7, 8]. Endocrine active compounds are a broad group of exogenous chemicals that can disrupt normal hormonal processes [9]. Animal studies provide direct evidence that exposure to specific environmental chemicals during windows of breast tissue changes, including the pregnancy and the prenatal window, can directly or indirectly alter mammary gland development, potentially increasing susceptibility to chemical carcinogens or spontaneous tumorigenesis [10]. Strong associations between maternal exposure to diethylstilbestrol (DES), a synthetic estrogen prescribed globally to pregnant women during 1938-1971 to prevent miscarriages, and daughter's subsequent risk of clear cell vaginal cancer offered the first epidemiologic evidence that a prenatal exposure to a hormonally active chemical could causally lead to cancers later in life [11-13].

The Child Health and Development Studies (CHDS) is one example of a study which has maternal biospecimen measures of environmental chemicals and breast cancer incidence data for offspring [16, 17]. The CHDS is a pregnancy cohort of over 15,000 families residing in the area of Oakland, California enrolled between 1959 and 1966. The CHDS collected biologic specimens at baseline during the mother's pregnancy (F0) and followed both mothers (F0) and their offspring (F1) for cancer incidence over more than 50 years. This cohort produced important human evidence on the association between higher levels of specific endocrine disruptors during critical windows of susceptibility with subsequent increased breast cancer risk across generations. Based on follow-up data, there was a statistically significant 5-fold increased risk of maternal breast cancer (F0) before age 50 years associated with high levels of serum *p, p'*-DDT, an organochlorine insecticide, measured during pregnancy [18]. The CHDS also found that for women with premenopausal breast cancer, *p, p'*-DDT was associated with a 3-fold higher risk of breast cancer risk among women first exposed during infancy through puberty, but not after [19]. In a subsequent CHDS study of daughters (F1), there was a nearly four-fold increased breast cancer risk before age 50 years (odds ratio fourth quartile vs first = 3.7, 95% confidence interval 1.5-9.0) with higher in utero exposure levels to *o, p'*-DDT [20]. The CHDS landmark study provides a model for a generalized approach to systematically address the challenges in studying early life exposures and biologic responses during the prenatal window that may impact subsequent breast cancer risk in female offspring.

Given the long latency of many cancers including breast cancer, epidemiologic studies often rely on intermediate markers of cancer risk. One of the strongest risk factors for developing breast cancer, next to family history, is high mammographic breast density (MBD), defined as the proportion of fibroglandular breast tissue relative to fat as seen on a mammogram [14-17]. There is some evidence that exposure to environmental chemicals like heavy metals [18], air pollutants [19] or phthalates [20] may affect breast tissue composition and density over the life course. However, there is very limited data about the effects of breast tissue composition across generations as result of intergenerational exposure to these chemicals. Based on findings from CHDS, there appears to be some evidence that intergenerational exposures can also affect breast density with data showing a correlation between prenatal exposure to DDT and increased dense area and percent density in daughters [21].

These intriguing data support that environmental chemicals exposure in one generation may be associated with breast cancer risk in another. However, there is a major gap in understanding the magnitude and extent that these pathways can help explain the persistent effect of the greater breast cancer burden in risk and/or mortality in Black and Indigenous People of Color (BIPOC). As there has been extensive documentation of the much larger burden of pollutants and other chemical exposures in communities composed predominantly of BIPOC [22-29], the legacy of these exposure inequities needs to be studied with their intergenerational impact on cancer risk.

Upstream social factors may contribute to intergenerational risk: Chronic diseases, including breast cancer, are also driven by macro level factors like structural racism in public policies that drive differences in the physical environment, trauma, education, income and wealth. These macro upstream factors likely contribute to the legacy of the cancer burden across generations. Furthermore, the interaction of individual level exposure to environmental chemicals and macro and meso-level environmental social factors may also significantly contribute to risk and inequities. Exposure to environmental chemicals is inequitable and thus the intergenerational impact of these exposures through epigenetic changes in cancer susceptibility genes may have synergistic effects with these macro drivers.

Studies of migrants provided the first solid evidence that in addition to genetics, early-life exposures play an important role in increasing rates of breast cancer incidence across generations [30, 31]. These studies investigated women who migrated from low-risk regions (e.g., Asian countries, Caribbean) to westernized high-risk countries in Europe, North America, and Australia to explain the changing geographical patterns and temporal variations of breast cancer incidence worldwide. Findings from migrant studies showed not only an increase in breast cancer incidence among the migrants themselves resembling rates found in westernized countries, but an increase in incidence in their subsequent generations as well, suggesting that exposures related to migration may have inter- and transgenerational effects [30]. This intergenerational “transmission” of risk is particularly noted in California, a state that experiences a constant influx of immigrants. Landmark studies have documented a change in cancer incidence trends for immigrant groups compared to patterns of incidence in U.S. non-Hispanic whites in California [32-34]. For example, in a large (>2,500) population-based case-control study of Hispanic women residing in the San Francisco Bay Area breast cancer risk was 50% lower in foreign-born Hispanics than U.S.-born Hispanics, and even lower among foreign-born long-term residents who moved to the U.S. at or after 20 years of age [35]. The difference in risk between third- or higher-generation Hispanic immigrants compared to recent migrants from rural areas was about 6-fold in postmenopausal women. In addition, a reduced risk was found for those who resided in the U.S. for <10 years or migrated at age 30 years or older [35]. Other studies show similar trends of increasing breast cancer incidence among successive generations of Asian [36, 37] and Mexican-Americans [7]. It is hypothesized that changes in reproductive risk factors (e.g., higher age at first live birth, lower breast-feeding rates, earlier onset of menarche), particularly if migration takes place in early-life is the result of greater acculturation, and contributes to the possible increase in breast cancer risk [32, 38, 39]. However, the increase in incidence reported in these migrant studies are seen even after adjusting for differences in the distribution of breast cancer reproductive risk factors, lending support that the effects on risk are beyond individual-level factors.

Research Gaps: The evidence for intergenerational environmental effects on breast cancer is intriguing but there are still some notable gaps in this literature for both individual level chemical exposures, macro-level factors, and the potential synergistic relationship between multiple pathways between environmental exposures and more upstream macro factors. Studies from other fields lend support for investigating specific upstream causal factors that may contribute to health inequities. Additionally, there are significant gaps related to chemical exposures which include: 1) examining the intergenerational transmission of macro environment; 2) comprehensive analyses of environmental exposures; 3) analyses of environmental mixtures, and 4) understanding the role of paternal exposures. Addressing these gaps is important because disentangling the different contributions of genetics and environmental exposures (inclusive of social trauma) and their impact on intergenerational risk is needed for targeted breast cancer risk reduction. Figure 1 illustrates a conceptual model of intergenerational risk that reflects the levels that contribute to outcomes including community level and individual level exposures.

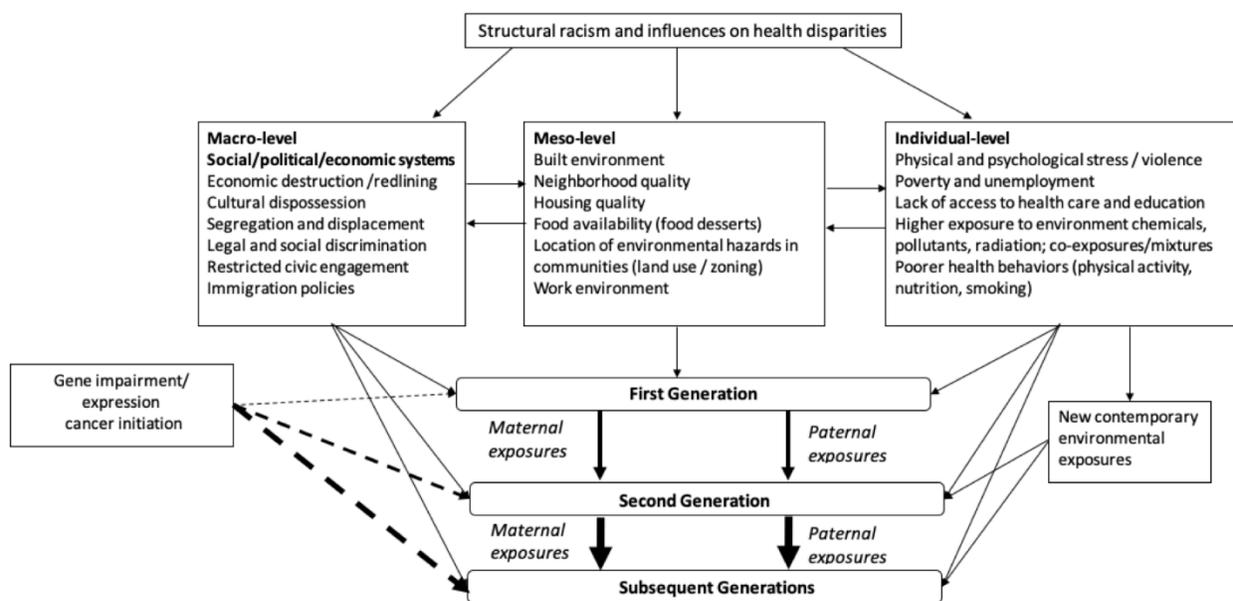


Figure 1. Conceptual model of intergenerational chronic disease risk including breast cancer

Social environment. Examination of the role of intergenerational transmission of risk requires a causal framework. For example a plausible framework for understanding social environment acting on health through several generations; specifically historical trauma, its transmission, and its implications for health have been promoted by others (e.g., [40]). In addition, there is growing and important intergenerational literature examining the impact of exposure to legal racist discrimination and breast cancer outcomes [41,42]; intergenerational transmission of paternal trauma [43]; examples of traumas across generations (e.g., impact of boarding schools on chronic illness among Crow (Apsáalooke) people, [44]; relationships among indigenous boarding schools, mental health, and

substance use, [45]); impact of significant cohort events on breast cancer and other health outcomes (e.g., estrogen receptor status differences based on race and generation, [46]; and increase in strokes among Kaiser patients following the 2016 presidential election, [47]).

Contemporary exposures. Examining the effects of widespread exposures during critical WOS and breast cancer risk in subsequent generations is needed. The CHDS findings are highly informative and provide human evidence to support a link between early life exposures and breast cancer risk across generations. However, exposure to DDT diminished after the U.S.s banned its use in 1972, thus findings about subsequent risk may only be relevant to specific F0 and F1 birth cohorts. There is a need for studying associations between current widespread and sustained environmental exposures like air pollution (inclusive of polycyclic aromatic hydrocarbons) during the prenatal and pregnancy periods and intergenerational breast cancer risk. Investigating early life environmental exposures to air pollution and intergenerational risk is important because the interaction between low SES position and air pollution may address the impact of the “triple jeopardy” effect [48-50]. The “triple jeopardy” effect is produced when groups with lower SES that are more vulnerable to adverse health outcomes due to material deprivation and psychological stress are also at the highest levels of exposure to air pollutants and environmental hazards. Thereby, higher levels of exposures lead to an increase in disease susceptibility that is usually higher than population average risk.

Environmental mixtures. Potential joint effects between co-exposure to various classes of environmental exposures in relation to intergenerational breast cancer risk remains unexplored. The impact of exposure to multiple concurrent and/or sequential environmental chemicals during early life on breast cancer risk is unknown. Addressing this gap in the literature is important because laboratory evidence shows that individual biologic effects of some endocrine disrupting chemicals are weak, but collectively may influence the onset of breast cancer via a common mechanism (e.g., estrogen receptor agonist, interference with androgen synthesis, thyroid action, etc.). Analyzing environmental mixtures is more reflective of real-world experience, particularly for vulnerable populations that are more likely to be exposed to multiple chemical compounds.

Early life paternal exposures. It is well-established that the maternal environment and exposure to environmental factors during the preconception and pregnancy periods can impact breast cancer risk in daughters. It is possible intergenerational risk is influenced by paternal exposures alone or in combination with maternal exposures. However, less is known about how paternal exposures may contribute to intergenerational breast cancer risk via epigenetic processes. Experimental studies support paternally mediated developmental health effects across generations [51, 52]. Epidemiologic evidence is accumulating across various health outcomes supporting the role of paternal exposure to chemical and physical agents (e.g., radiation, PBDEs, *p,p'*-DDE, and dioxin contaminated chlorophenol) with disease susceptibility in the F1 offspring, potentially extending to the F2 offspring. For example, evidence from case control studies support a strong link between higher levels of paternal radiation exposure (fathers who lived near or worked at nuclear plants during the preconception period) with childhood leukemia and non-Hodgkin's lymphoma in the offspring [53-55]. These findings support that environmentally-induced non-genetic or epigenetic predisposition to cancer can occur from paternal exposures. Animal models now implicate preconception paternal DDT exposure with inducing intergenerational breast cancer risk in daughters [56]. The paternal DDT-induced programming of breast cancer development in daughters was mechanistically linked

to sperm non-coding RNA load, particularly miRNAs. Epidemiologic studies are needed to understand whether preconception paternal exposures can alter normal mammary development trajectories in daughters.

Research Opportunities: Examining environmental exposures and intergenerational transmission of breast cancer is critical for understanding disease etiology and informing regulatory policy (e.g., update criteria for earlier breast cancer screening). First, in terms of etiology it is essential to understand whether intergenerational mechanisms from environmental exposures seen in animal studies are seen in human studies. Evidence of this type cannot reduce current cancer risk, but it can help mitigate risk for future generations. Second, even if risk cannot be reduced in the current generation from exposures from past generations, understanding the higher risk from intergenerational transmission can be used to identify women who can benefit from early breast cancer screening. Currently, most breast cancer screening guidelines use family history, known gene mutations in breast cancer susceptibility, or radiation in early life to identify women for breast cancer screening prior to population-based breast cancer screening. If epidemiological evidence identifies increased risk of breast cancer from environmental exposures among prior generations, family exposure history could be used as a criterion to identify women for earlier breast cancer screening.

Research Questions

This Initiative specifically focuses on studies that will provide evidence on whether intergenerational transmission of breast cancer susceptibility can be influenced by environmental exposures. The definition of environment for this proposal includes environmental chemical exposures (ECEs) as well as macro and meso-social forces. **For this funding opportunity, we are interested in at least two generations, with exposure taking place in one generation and outcomes in at least one subsequent generation. In addition, community-partnered participatory methods are required to gain contextual understanding of exposures to chemicals and to social factors.** Proposals addressing specific environmental chemicals and/or broader social environment factors will be considered responsive for this RFP. The following research topics should be considered:

- a) Is the unequal burden of breast cancer seen in BIPOC influenced by intergenerational transmission of risk through early life exposure to specific environmental chemicals?

AND/OR

- b) Is the unequal burden of breast cancer incidence and/or mortality explained by persistent intergenerational macro and meso level social forces? Analysis of upstream causal factors include structural policies that contribute to systematic unequal access to resources (e.g. wealth, employment, education, housing, healthcare, etc.) and the built environment.

Studies will be viewed as responsive if they are conducted by a partnership on two co-PIs, one an experienced academically-trained researcher and the other a community leader from the impacted community and employ any of the following approaches: 1) epidemiology studies with stored biospecimens from earlier in life (e.g., prenatal period) and outcomes in a least one subsequent generation; outcomes may include breast cancer or strong intermediate markers like mammographic breast density; 2) epidemiology studies that can utilize a mixed methods approach to analyze qualitative and quantitative data around intergenerational social determinants of health at the meso

and macro level; or 3) studies with access to one generation and breast cancer incidence outcomes in at least one subsequent generation.

Projects responding to these aims will directly test whether we have undercounted breast cancer risk in communities comprised predominantly of BIPOC by a failure to measure intergenerational transmission of risk.

Approaches and Methods

Given the gaps in the literature for understanding early life exposures and intergenerational breast cancer risk, we are seeking proposals that partner academically-trained researchers and members of the affected community and fall into the following study approaches to help move this research agenda forward.

Approach 1 – Epidemiology

Suggested approaches include an epidemiology study with any or a combination of the following designs:

- Examine associations between early-life exposures to environmental chemicals and breast cancer risk (or intermediate markers for breast cancer risk) in F1 generation, if stored biospecimens from F0 generation during pregnancy are available.
- Examine associations between exposures to environmental chemicals during a WOS (pregnancy) and breast cancer risk in F0 generation, if stored biospecimens from F0 generation during pregnancy are available.
- Examine associations between exposure to environmental chemicals in early-life and intermediate markers of breast cancer risk in F2 generation, if stored biospecimens from at least F0 or F1 generations are available
- Examine whether the associations are stronger after considering social macro-level forces related to health inequities like socioeconomic status (interaction model)
- Conduct intergenerational studies of community health with documented chemical exposures (e.g., dumping)

Approach 2 - Mixed Method Analytical Approach Social Epidemiology and Economic Evaluation

Use existing cohort studies with quantitative and qualitative data that can access at least two generations within families to examine intergenerational effect of systemic inequities to:

- Apply conceptual frameworks for studying intergenerational health disparities that focus on macro- level determinants including policies affecting income, housing, education, and wealth transmission
- Identify specific intergenerational socio-ecological determinants of breast cancer risk; elucidate using social science conceptual approaches like pathways models and evaluations including multilevel economic models
- Examine historical events or man-made (including environmental racism) or natural disasters that can leverage data on exposure to events and breast cancer outcomes across F0 and F1 generations

- Examine associations between trauma experienced by F0 generation and breast cancer risk in F1 generation; assess breast cancer risk in F0 generation as well
- Examine whether associations are stronger if F0 trauma occurred earlier in life.

If possible, studies should oversample vulnerable populations that are traditionally impacted by social inequities.

Approach 3 - Case Control of BC under 45

Create new de novo retrospective cohorts that can access at least two generations within families to examine intergenerational transmission of inequities. Sampling based on F2 breast cancer status with any of the following suggested designs or combinations of them:

- Apply the same study design aims as Approach 2
- Recruit F2 women with and without breast cancer with documented environmental exposures at the community level of inequitable environmental exposures (e.g., dumping).
- Collect lifecourse data on F2's mother (F1) and grandmother (F0)
- Establish potential for assessment of breast cancer risk in the F3 generation based on intermediate markers of risk
- Assess epigenetic factors in biospecimens
- Collect data on paternal exposures

For each of these proposals we recommend that interdisciplinary teams be established with expertise in breast cancer epidemiology, social science and intergenerational modeling in collaboration with community stakeholders. For new data collection, we recommend community-partnered participatory research methods. For established cohorts, we recommend community participation for assisting in data gathering and interpretation and developing dissemination and communication strategies.

For each proposal, we are seeking investigators to collaborate with community members using community-partnered participatory research methods (CPPR) for the development of study questions and protocols including recruitment and retention (particularly for newly initiated studies under Gaps 2-4) and interpretation (including language) and dissemination of results (all studies). Proposals should outline the strategies that will be used to connect with the communities and attain access to multiple generations.

Resources to be Used or Considered for Use

Any of the three approaches needs to address health inequities faced by historically marginalized communities. If the study is not specific to more marginalized communities, the relevance of the findings to health equity needs to be outlined.

Approach 1 - Epidemiology

Requirements would include a large existing cohort with biospecimens and/or other measures of chemical environment. Ability to link to breast cancer outcomes (incidence or mortality) or risk (mammographic density, benign breast disease) across generations.

It is important to note that while this approach could include hallmark studies that have biospecimens, it may also include intergenerational studies of environmental risk factors without biospecimens.

Approach 2 - Mixed Method Analytical Approach Social Epidemiology and Economic Evaluation

Requirements would include an interdisciplinary team of scientists and may include merging existing data from social science sources and/or indicators of environmental exposures. New data collection may include qualitative and/or quantitative data.

Approach 3 - Case Control of BC under 45

Requirements include new data collection specific to recruited early onset breast cancer in BIPOC and their mothers and/or daughters to address a specific research question related to intergenerational transmission of environmental exposures (including chemical, physical and social environment).

Dissemination Plans

The project plan needs to include a dissemination plan and should discuss if the dissemination plan will be ongoing throughout the project or at the end and justify the frequency of the dissemination elements. Each plan should specify who on the project will be part of the dissemination team, who will be the target audience including non-research audiences, especially community members, practitioners and policy makers. The dissemination plan requirements should take into account audiences, messages, channels, milestones, and appropriate resources to reach milestones. Given the focus of this project on understanding the potentially large undercounting of risk based on intergenerational transmission, communication to both clinical and public health practitioners as well as policy makers is essential.

Dissemination team members. The dissemination plan should include a description of who on the project team will be reaching out to stakeholders. Will it be the co-principal investigator(s) on the project? Will it be project team members? Projects are encouraged to integrate expertise in community outreach and communications in developing their project team. With the description of the team members, there should also be a description of potential dissemination partners and why they are appropriate partners to help carry out the dissemination plan.

Dissemination target audiences. Applicants should include a plan to ensure dissemination to multiple audiences throughout the project period, as appropriate. This includes lay audiences as well as scientific audiences. Successful applications will include descriptions of stakeholders/audiences that will be dissemination targets (e.g. community groups, policy advocates, policy makers), as well as the rationale for including the stakeholder group as a target of dissemination.

Goals and methods of dissemination. The dissemination plan should include a description of what type of information will be shared (e.g. summary of data, videos) and the dissemination activities and

mechanisms. Applicants should tailor activities to the appropriate strategies for the various stakeholder groups (e.g. online, face-to-face, executive summaries, newspaper articles) to ensure the most effective, productive, and positive engagement. Describe what agreements have been made about the timing of dissemination. Include a timetable of dissemination tasks that will be completed.

The dissemination plan should reflect an effort to disseminate the information to an audience that reflects the great diversity of California (geography, race, ethnicity, income level, urban/rural) as well as to the specific communities directly involved in the project. Dissemination activities can range from newsletter text and web content, presentations, press releases for news media and other project- and topic-specific collateral materials for and to key stakeholders. Describe how results will be disseminated to ensure that this research is put into action. The team should describe potential barriers to dissemination and how the team will address barriers through potential alternative strategies.

Budget

CBCRP intends to fund up to three projects with a duration of three to five years maximum at a maximum total direct cost of \$300,000 for Approach 1 and \$425,000 for Approaches 2 or 3. Costs commensurate with the Dissemination Plan should be included in the Budget.

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 (25% for off-campus projects). Organizations that do not have a federally approved F&A rate may request a De Minimis rate of 25%.

Supplemental funding is available for funded projects to support promising high school students, undergraduate students and/or community members from groups underrepresented in breast cancer research and/or those who wish to pursue careers focused on questions affecting underrepresented communities to breast cancer research. Applications for these supplements will be accepted during the prefunding stage of the award and will start August 1, 2023 Visit

<https://cabreastcancer.org/files/cbcrcp-diversity-supplement.pdf> to learn more.

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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.

Applications are rated using four equally weighted criteria. The first two are categorized as “collaboration elements” and the second two are termed “scientific merit”.

- **Partnership** (*Collaboration Element*)
 - The extent to which the strengths/nature of the proposed community partnership is reflected in leadership and involvement in all phases of the project (e.g. inception to dissemination).
 - The level to which both partners’ knowledge and lived experience is integrated into planning and conducting the research.
 - The level to which both co-PIs have engaged with the larger community, including but not limited to cohort membership, to get their input in the application development process.
 - The extent to which agreements have been reached regarding procedures for resolving disagreements among collaborators, ownership of data, and dissemination of results.
 - The potential for capacity-building for any or all of the partners.
 - Demonstrated successful collaboration in previous research projects.
- **Community Benefit** (*Collaboration Element*)
 - The extent to which the community has been involved in the development of the research idea and questions, and the writing of the research proposal.
 - Plans for how cohort members and the broader community will be involved in the research project during the course of the research, from helping to conceptualize the research question(s) through dissemination of the results.
 - The potential importance and benefit to the broader lay community of the research question(s) and expected outcomes.
 - The potential for the research project to facilitate learning, further collaboration, and systems change.
 - The plan for reporting back results to cohort members and their families.
 - The plan for translating the research results into tangible benefits for the community and for engaging the community, local and state stakeholders and policy decision makers in discussions of the results of the research and the implications for them.
- **Quality of the Research** (*Scientific Merit*)

- The scientific importance of the research questions, including consideration of the most relevant literature and whether the intervention being researched will result in a breast cancer prevention strategy.
- The extent to which existing cohorts can be leveraged – especially for Approach 3.
- The appropriateness and integration of the conceptual framework, research methods, and data analysis plan to the research question and aims.
- **Feasibility** (*Scientific Merit*)
 - The extent to which the project can be successful given the partners’ knowledge, skills, resources, and experience.
 - The likelihood of completing the project as proposed given the available funding and time frame.
 - The usefulness (validity and/or importance) of data from previous research and community experience for the proposed research plan.

Programmatic Review

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

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

with cohort members and the larger community to get their input in the application development process. Are meetings and other communications sufficient for substantive engagement and collaboration? Are the roles and responsibilities of the PIs clearly outlined and is the agreement for sharing of budget clear? [The Advisory Council will examine the co-PIs' statements on the Lay and Scientific Abstracts, Program Responsiveness form, and Collaborative Agreements.]

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

Application Instructions

Application materials are available through RGPO's [SmartSimple application and grant management system](#). Please review the [SmartSimple Application Instructions](#) for the technical instructions for accessing and completing your application. This supplemental programmatic instruction document provides guidance for the content of your application.

Application Components

Section 1: Title Page

- **Project Title:** Enter a title that describes the project in lay-friendly language. (Max 100 characters).
- **Project Duration:** Select a duration of 3 to 5 years
- **Proposed Project Start Date:** Enter a project start date of August 1, 2023.
- **Proposed Project End Date:** Enter a project end date of July 31, 2026, 2027, or 2028 for a 3-, 4-, or 5-year award, respectively.

Section 2: Applicant/PI

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

Section 3: Project Information

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

Lay Abstract (Max 2400 characters): This item is evaluated mainly in the programmatic review. Do not use symbols or other special text, as these will not transfer to the “abstracts” box. The Lay Abstract must include the following sections:

- A **non-technical introduction** to the research topics
- The **question(s) or central hypotheses** of the research in lay terms
- The **general methodology** in lay terms
- **Innovative elements and potential impact** of the project in lay terms

The abstract should be written using a style and language comprehensible to the general public. Avoid the use of acronyms and technical terms. The scientific level should be comparable to either a local newspaper or magazine article. Avoid the use of technical terms and jargon not a part of general usage. Place much less emphasis on the technical aspects of the background, approach, and methodology. Ask your advocate partner to read this abstract and provide feedback.

Scientific Abstract (Max 2400 characters): This item is evaluated mainly in the peer review. Do not use symbols or other special text, as these will not transfer to the “abstracts” box. The Scientific Abstract should include:

- A short introductory paragraph indicating the **background** and overall topic(s) addressed by the research project
- The **central hypothesis** or **questions to be addressed** in the project
- A listing of the **objectives or specific aims** in the research plan
- The major research **methods and approaches** used to address the specific aims
- A brief statement of the **impact** that the project will have on breast cancer

Provide the critical information that will integrate the research topic, its relevance to breast cancer, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum level of information. Make the abstract understandable without a need to reference the detailed research plan.

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

- **Specific aims** (Max 2400 characters/approx. 350 words). List the proposed aims of the project.
- **CBCRP Research Priorities.** Select “Etiology and Prevention” as the CBCRP priority issue that the research addresses.
- **CSO Research Type(s) and Sub-Type(s).** Select “2.0 Etiology” as the CSO Type, and please select the corresponding CSO Sub-Type(s) that best represent your project.
- **Subject Area(s).** See SmartSimple submission instructions for more details.
- **Focus Areas(s).** See SmartSimple submission instructions for more details.
- **Research Demographics.** Complete this table if the research project will involve human subjects. Enter the target demographics of the research participants that you propose to recruit. See the SmartSimple submission instructions for more details.
- **Milestones.** See SmartSimple submission instructions for more details.

Section 4: Project Contacts

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

Section 5: Budget

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

Each institution that is a partner in the project must complete a budget. This means the Community Co-PI and the Academic Co-PI will each have their own Budget. If a collaborative partner on the project has a subcontract, then that subcontracting organization can complete a budget or the prime

partner can complete the budget for the subcontracting organization. The Submitting Co-PI has the ability to edit all budgets, although the invited Co-PI does not.

Maximum duration is 5 years and the direct costs budget cap is \$300,000 for Approach 1 and \$425,000 for Approaches 2 or 3.

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 25% MTDC for off-campus investigators (not retroactive to prior grants).

**Allowable expenditures in the MTDC base calculation include salaries, fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of \$25,000 shall be excluded from the modified total direct cost base calculation. If a grantee or subcontractor does not have a federally negotiated F&A rate at the time of the proposal submission, they may request a “De Minimis” F&A rate of 25% MTDC.*

Additional budget guidelines can be found in Appendix A.

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 and DEA Controlled Substance approvals.

Section 7: Documentation

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

Upload Item (Template/Form)	Page limit	Required or optional	Peer Review?	Programmatic Review?
Research Plan	10 (+ 3 for references)	Required	Yes	No
Program Responsiveness	3	Required	Yes	Yes
Collaborative Agreements	2	Required	Yes	Yes

Biosketches (All Personnel listed on Key Personnel form)	5 (each biosketch)	Required <i>(upload to Project Personnel section)</i>	Yes	Yes (PIs only)
Facilities	1 per institution	Required	Yes	No
Human Subjects	No limit	Required	Yes	No
Appendix list and uploads	30	Optional	Yes	No

Detailed Description of Proposal Templates

Research Plan (required)

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

Statement of Goals, Research Questions, and Specific Aims. In a short paragraph, describe goals for the research project. Briefly state the research question(s) and hypothesis for the project.

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

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

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

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

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

Describe in detail the exact tasks listed in the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. For instance, if women are to be surveyed, explain how many women will be surveyed; why you chose this number; how the women will be identified and recruited; why you believe you will be able to reach and recruit this many women; what questions you will ask them; whether you will use face-to-face or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline. Be sure to include a hypothesis and conceptual framework.

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 three 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 PBC research area as outlined in the specific RFP.

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

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

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

Collaborative Agreements (required)

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

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

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

The collaborative agreement should include the following elements:

- **Ownership of Data:** Describe what decision you made about who will own the data and intellectual property rights and why you came to that decision (i.e. what factors you considered, what was important to you in making this decision). If you decide that the data will be owned by only one of the collaborators, please consider that the need to continue to work together will likely extend well beyond the grant period. Will the partner who owns the data be willing to volunteer his/her time well after the grant period to provide access to the data for the other partner? Be sure to discuss ownership of identified and de-identified data, including arrangements both partners have agreed to ensure access to that data by the other partner (including beyond the study period).
- **Handling Disagreements:** Describe what decision you made about the procedures you will go through to handle disagreements during the course of the study and afterwards. Past teams have had to resolve issues around data ownership, conduct of the research, dissemination of data and publications, administrative and budget issues, etc. Describe why you believe your decision on handling disagreements will work for you.
- **Recipient of Grant Award:** Describe what decision you made about whether the grant award will be contracted directly to one partner or to both partners and why you came to that decision. CBCRP suggests that if both applicant agencies have the administrative capacity to manage grant awards, that each agency receives a separate award.
- **Plans for Broader Community Involvement:** Describe how individual community members not on the research team (including staff and board of the community agency applicant as well as community members outside of the organization) will be involved in the planning, conducting, and dissemination of research. Describe how the community co-PI will be overseen by the community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).
- **Plans for Dissemination of Findings:** Dissemination of research findings to both the lay community and the scientific community is important to this research award. This is sometimes a difficult issue as scientific dissemination is often a lengthy process and may impede community dissemination. Please describe how research findings will be disseminated to both the community of interest and the scientific community and what agreements have been made about the timing of dissemination.
- **Plans for Turnover of Personnel:** Describe how the turnover of personnel will be handled (who will hire, fire, etc.) Describe how the community co-PI, specifically, will be overseen by

the community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).

Biographical Sketch (required)

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

Facilities (required)

This item is evaluated in the peer review. **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 PI is the responsible applicant) and there is no institutional performance site, an USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

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

Appendix (optional)

Follow the instructions and items list on the template. **The appendix may 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.

Appendix A: Cost and Expense Guidelines

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

1) Personnel

- The Budget Summary line item for Personnel should reflect the total cost of all individuals identified as supported by the grant and their level of effort. In the personnel section of the application, be sure to name all individuals to be supported by the grant and provide their percent effort (months devoted to the project). All paid individuals must also be listed on the budget.
- Follow the NIH Guidelines and Calculation scheme for determining Months Devoted to Project, available at the links below:
 - NIH Guidelines:
 - http://grants.nih.gov/grants/policy/person_months_faqs.htm
 - NIH Calculation Scheme:
http://grants.nih.gov/grants/policy/person_months_conversion_chart.xls
- When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income (e.g., clinical or consulting incomes). CBCRP does not enforce a salary cap, as long as the overall budget adheres to the costs & expenses guidelines and the amount requested stays within the allowable costs.

2) Student Tuition Fees, Graduate Student Stipends

- For non-fellowship awards: Graduate students may be paid as personnel and may also receive tuition remission. Tuition remission, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition listed in this category) may not exceed \$30,000 per project year. A maximum of \$16,000 per year is allowed for the combined costs of tuition/enrollment fee remission, fringe benefits, and health insurance. Stipend may be budgeted as salary (and included in the MTDC cost calculation) if the institution pays these expenses through a personnel line item.

3) Other Project Expenses

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

- Advocate (s) Expenses. Include any travel, meeting, and consultation costs/fees associated with advocate engagement.

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

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

5) Travel

- **Travel – CBCRP Meeting:** CBCRP may organize an event requiring your travel within the funded grant period. All applicants should budget a one-time minimum expense of \$400 under year 1 in the travel budget line labeled: "Travel - CBCRP Meeting".
- **Travel - Project Related:** Project-related travel expenses are allowable only for travel directly related to the execution of the proposed research activities. Label such expenses as "Travel – Project Related." These expenses must be fully justified in the budget justification.
- **Travel - Scientific Meetings:** Scientific conference travel is limited to \$2,000 per year (excluding a mandatory allocation of \$400 in one year of the project for travel to the CBCRP Conference under Travel - CBCRP Meeting). Label such expenses as "Travel-Scientific Meetings" and explain in budget justification.

6) Service Contracts and Consultants

- Both categories require additional description (Budget Justification).

7) Subcontracts

- In the case of University of California applicants, subcontracts need to be categorized and broken out as one of two types, University of California-to-University of California (UC to UC) sub agreements or transfers; or, Other. A subcontract is not allowed to have another subcontract. Requires additional description (Budget Justification).

8) INDIRECT (F&A) COSTS

- **Indirect cost policy:** Indirect costs are NOT allowed for Conference Awards. For other awards, non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC (25% for off-campus projects).
- **Modified Total Direct Costs (MTDC)** include salaries and wages, fringe benefits, materials and supplies, services, travel, and up to the first \$25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract) to an outside institution. MTDC does not include (indirect costs are not allowed on): capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, equipment purchases more than \$5,000 per item, the portion of each sub grant and subcontract in excess of the first \$25,000, and the total cost of any subcontract from one UC to another UC campus. On

a non-fellowship award, you may apply indirect costs to graduate student salary (under salary only, not as stipend) but not to tuition & fees.

- For all eligible projects that allow grantees to recover the full amount of their federally negotiated indirect cost rate agreement, grantees must also accept the full federally recognized F&A rate for all award subcontractors (except for subcontracts to another UC institution, where F&A is not allowed). If a grantee or subcontractor does not have a federally negotiated F&A rate at the time of the proposal submission, the grantee and/or subcontractor may request a “De Minimis” F&A rate of 25% MTDC. A higher indirect rate that has been accepted for state or local government contract or other California grantmaker contract may be approved at the discretion of the Program Director and the Research Grants Program Office Executive Director.
- **INDIRECT COSTS ON SUBCONTRACTS**
 - The award recipient institution will pay indirect costs to the subcontractor.
 - For non-UC subcontracted partners, CBCRP will allow full F&A of the Modified Total Direct Cost (MTDC), as defined above.
 - F&A costs are not allowed for one UC institution's management of a subcontract to another UC institution.
 - The amount of the subcontracted partner's F&A costs can be added to the direct costs cap of any award type. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.

Appendix B: 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 by Principal Investigators who are resident in California. We welcome investigators from community organizations, public or privately-owned corporations and other businesses, volunteer health organizations, health maintenance organizations, hospitals, laboratories, research institutions, colleges, and universities. **Applicants at California-based Nonprofit Institutions:** CBCRP will accept applicants from PIs at non-profit organizations or institutions, provided that the organization can manage the grant and demonstrate financial health. The organization must also meet our liability insurance requirements. If the application is recommended for funding, the University will collect additional information, such as tax ID numbers and financial reports, to review the organization during the pre-funding process to ensure all financial management and project management eligibility criteria can be met.
- 2. We encourage researchers new to breast cancer to apply.** Applicants who have limited experience in breast cancer research should collaborate with established breast cancer researchers.
- 3. Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. For Cycle 29, 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 and Policy Initiative grants are not included in this limit. A PI may have more than one Program and Policy Initiative grant in a year.
- 4. University of California Campus Employees:** In accord with University of California policy, investigators who are University employees and who receive any part of their salary through the University must submit grant proposals through their campus contracts and grants office (“Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University,” Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the investigator is employed.

Policy on Applications from PIs with Delinquent Grant Reports

PIs with current RGPO grant support will 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.

Award Decisions

Applicants will be notified of their funding status by July 1, 2023. 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:

Sharima Rasanayagam, PhD

Environmental Health & Health Policy Program Officer, CBCRP

sharima.rasanayagam@ucop.edu

(510) 987-9216

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