Request for Qualifications (RFQ)
California's Comprehensive Breast Cancer Primary Prevention Plan

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to Apply:
March 1, 2016

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California Breast Cancer Research Program and 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 the CBCRP is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities.

- The 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.
- The 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 $8.5 million for breast cancer research.
- Ninety-five percent of our revenue goes directly to funding research and education efforts.
- The CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, the CBCRP has awarded nearly $262 million in 1,006 grants to over 100 academic institutions and community organizations across the state. With continued investment, the CBCRP will work to find better ways to prevent, treat and cure breast cancer.

Priority Areas

In 2004, the CBCRP launched its Special Research Initiatives (SRI). With SRI, the 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 will be 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, the CBCRP issued a Request for Qualifications to fund a team to collaborate with the 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 fifteen (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). A series of funding opportunities will be released over the next two years reflecting these concepts.

California's Comprehensive Breast Cancer Primary Prevention Plan

Available Funding

California Breast Cancer Research Program is sponsoring an open Request for Qualifications to select a qualified transdisciplinary cross-sector team to develop a comprehensive plan in the form of a report that outlines opportunities to promote primary prevention of breast cancer in California. The purpose of this Breast Cancer Primary Prevention Plan is to offer strategies for addressing a broad range of potential science-based interventions to make California a less breast cancer promoting environment. This transdisciplinary project should expand the existing approach to primary prevention by adhering to the core principles and structural requirements for primary prevention as it is defined within this initiative. As such, it is also expected that aspects related to breast cancer risk such as health inequity and environmental conditions beyond the control of individuals will be emphasized over the usual expression of primary prevention including lifestyle choices and personal habits.

Up to **$300,000** direct costs is available for up to two years for this project. 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 25% indirect costs.

Completed responses to this RFQ are due by the deadline: Tuesday, March 1, 2016. Initiative start date is June 1, 2016.

For more information and technical assistance, please contact:
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Background/Justification

Breast cancer is a complex disease. Despite decades of intensive research, its causes and basic biology remain unclear. From the 1940s until very recently, the U.S. breast cancer rate has been rising, and this increase is not explained by better detection methods. Breast cancer is the leading cause of cancer deaths in women 20- 59 years with more than half of all cases diagnosed in women younger than 65 and nearly half of breast cancer deaths occurring within this same age range (Amer. Breast Cancer Soc, 2013; Siegel et. al., 2015). Breast cancer incidence and mortality varies by region. In California, breast cancer has the highest incidence rate of all cancers (15.8%), and accounts for nearly one third (31.6%) of all cancers in California's women. It also accounts for the second highest rate of cancer mortality in Californian women and for women under the age of 60, breast cancer is the site with the highest mortality rate in California (CA Dialog on Cancer 2011; CCR 2014).

It is not just one factor but many that influence the risk for breast cancer. Scientific studies have uncovered a number of known and suspected risk factors for breast cancer, including physical activity, exposure to chemicals and radiation, social and economic disparities, and others. For example, racial/ethnic differences in tumor biology and cancer genomics and differential care and

treatment systems combined increase cancer mortality rate for black women (Daly & Olopade, 2015).

Some of these risk factors can be modified by individuals to lower their risk, and others require societal or systemic changes. However, all known risk factors for breast cancer taken together can only account for a limited percentage of the disease. The percentage is in dispute, with estimates ranging from 50-70 percent. This means that for 30-50 percent of all cases of breast cancer, we cannot pinpoint what may have even contributed to causing the illness (GAPS 2013; DuPont 1985). Clearly, there is a lot yet to be understood about breast cancer origins.

Since 1998, various national and state-level efforts have taken place to make comprehensive strategic plans to reduce cancer burden. In fact, all 50 states, the District of Columbia and tribal nations have developed comprehensive cancer plans through the Centers for Disease Control and Prevention's National Comprehensive Cancer Control Program (CDC NCCCP). The World Health Organization also provides guidelines to encourage countries to adopt comprehensive cancer control plans. Many of these cancer control efforts are broad in nature to encompass all cancers and for breast cancer, usually focus on early detection and treatment options. California's plan highlights four areas for prevention, only two of which are related to breast cancer (obesity and tobacco use), while New York's plan has overlapping prevention areas (obesity and tobacco use) and two additional areas related to breast cancer prevention (environmental exposures and genetic counseling).

If these cancer control plans do address primary prevention, it is often limited to the narrow scope of personal habits-tobacco smoke, diet, exercise, etc. In fact, California's Comprehensive Cancer Control Plan 2011-2014, like many other plans, restricts the scope of breast cancer primary prevention to emphasize personal behavior changes (CA Dialog on Cancer 2011). This is in contrast to the organization's original report, issued in 2004 (CA Dialog Cancer 2004), which discussed environmental links to cancer, and specifically referenced the 2002 International Summit on Breast Cancer and the Environment's work, which identified pesticides, dioxins, and other environmental carcinogens as areas of concern.

The time is ripe for application of current scientific knowledge about breast cancer to be applied to population-based primary prevention of breast cancer to turn the tide of breast cancer in California.

For the purposes of this RFQ, the core principles of primary prevention[1] are:

1. Primary prevention focuses on healthy populations.

2. Primary prevention makes sense for the health and fiscal well-being of populations.

3. Primary prevention happens before the onset of disease and continues across the lifespan.

4. Primary prevention interventions are planned efforts to reduce (prevent) the incidence of new cases of disease in a population not yet demonstrating signs of the disease by removing factors known or suspected to contribute to disease occurrence and encouraging (promoting) factors known to contribute to protection from disease occurrence.

5. Primary prevention of breast cancer may also contribute to prevention of other diseases.

[1] Excerpted and expanded from Guillotta 1994.

The objective for primary prevention of breast cancer is to prohibit effective contact of an agent that contributes to the development of breast cancer (a carcinogen, a developmental disruptor, an endocrine disruptor) with a susceptible target in the human body, so that the sequence of events that culminates in the occurrence of clinical cancer does not begin or is aborted at the start. Additionally, primary prevention also promotes factors or contacts with agents known to be protective by prohibiting the development of breast cancer.

Increasingly, the literature points to the need to address breast cancer primary prevention through structural or systemic level interventions (Clarke et. al 2013, Daly & Olopade 2015). Many far reaching primary prevention strategies are ones that do not focus on individual behavior change but suggest instead the development of policies that address issues outside of an individual's control. These policies, for instance, can establish healthy communities through new zoning laws to re-engineer the built environment including repaving or establishing sidewalks and bike trails. Policies to develop green chemistry approaches that can include the regulation of chemical exposures in the workplace are other examples of primary prevention.

Current knowledge about the link between breast cancer and the environment is summarized in several large reports over the past decade; more research is definitely needed but evidence continues to grow identifying potential environmental links to breast cancer (Brophy 2012, Rudel 2007, Brody 2007, Rudel 2011) and should be prominent in any primary prevention effort. In 2007, the CBCRP published Identifying Gaps in Breast Cancer Research: Addressing Disparities and the Roles of the Physical and Social Environment (GAPS). GAPS was part of CBCRP's launch of its Special Research Initiatives, a five-year effort to select and fund the research that would lead to the progress in finding answers to the questions:

- What role does the environment play in breast cancer?
- Why do some groups of women bear a greater burden of this disease than others?

The 2007 GAPS was not a comprehensive review of all research on the environment-breast cancer connection or the reasons why some groups of women bear more of the burden of the disease. It was instead a review of existing research—gathered from a wide breadth of sources—used to discover research areas that show some connection with the disease, and recommendations for further investigations that are likely to make the most difference toward eliminating death and suffering caused by breast cancer.

In 2013, GAPS was updated with the release of the GAPS Supplement: Targeted Scans of the 2007 Gaps Document for Research Conducted between 2007 and 2012 ("Supplement"), which through a review of research conducted in those key GAPS research areas, provided a snapshot of the additional research that had transpired since publication of GAPS in 2007. GAPS and its Supplement should serve as additional guideposts for a comprehensive California Breast Cancer Primary Prevention Plan.

The need to prevent breast cancer is not going away, and in fact, the opportunity to prevent breast cancer may be growing as research and advocacy continues to expand collective understanding about risk and protective factors associated with breast cancer. The CBCRP "paradigm project" illustrates a framework for viewing breast cancer as a complex disease through inclusion of all genetic, biologic, behavioral, environmental, and social factors into one model (Hiatt et. al. 2014). Transdisciplinary approaches that incorporate multiple factors and broader approaches to primary prevention that also investigates chemical exposures and health disparities are needed.

The California Breast Cancer Research Program seeks a qualified team of California-based investigators representing deep expertise and demonstrated leadership in advocacy, policy development *and* research to lead a process to develop a Comprehensive Breast Cancer Primary Prevention Plan for California. The transdisciplinary cross-sector team should have at least one member with extensive experience and demonstrated leadership in each of the three areas: advocacy, research and policy development.

This initiative would convene leaders in advocacy, policy and research related to breast cancer prevention from across the state of California to yield a strategic plan for the primary prevention of breast cancer that directs collective efforts toward specific and measurable objectives that will reduce the incidence of breast cancer[2] by:

1. avoidance, interruption or abatement of an exposure to an agent that may contribute to breast cancer (a carcinogen, a developmental disruptor, an endocrine disruptor):
    a. over time such as chemical exposures in the workplace and during certain 'windows' that produce increased susceptibility such as pre-adolescence; and
    b. through certain behaviors, for example, by never drinking alcoholic beverages, stopping drinking, or reducing consumption of alcohol, respectively.
2. promotion, addition or rise of an exposure to an agent that may protect against breast cancer:
    a. over time and during certain 'windows' that produce decreased susceptibility to these agents, such as lactation.
    b. through certain behaviors, for example, by universal mandatory physical activity, or incentivized physical activity, respectively.

The comprehensive Breast Cancer Primary Prevention Plan for California, in the form of a report, should highlight the key factors that may be increasing breast cancer risk for women in California, including environmental exposures and areas of disproportionate impact from these exposures. The report must include objectives for reducing these risks and promoting primary prevention efforts; strategic priorities and action plans for addressing these risks, and an actionable implementation plan to put this plan into motion. The implementation plan should ensure the report's content is rooted in existing and ongoing efforts, if they exist. This implementation plan will also ensure that the report is disseminated appropriately. This report will be released publicly and shared widely, especially with key decision makers in California. This report will set the foundation for identifying science-based intervention targets in California.

Research Aims

The goal of this initiative is to develop a comprehensive overview of opportunities to promote the primary prevention of breast cancer in California. This research project has the following aims:

Aim 1: Identify key stakeholders who will be strong advocates of primary prevention, have complementary scientific expertise as well as policy development expertise, who can be engaged to develop the plan.

Aim 2: Building on the California Breast Cancer's 2007 GAPS and the 2013 Supplement as well as recent federal reports on breast cancer (IBCERCC 2013, IOM 2012, PCP 2010), identify key primary prevention areas for breast cancer, disparities and the roles of the physical and social environment. Areas not under an individual's control that are of concern for their role in

[2] Adapted from Adami et. al. 2001.

increasing breast cancer risk and/or greatest opportunity for reform in California are of special interest and should be emphasized.

Aim 3: Identify objectives for reducing these risks to the population and promoting primary prevention of breast cancer.

Aim 4: Identify strategic priorities for addressing these risks, promoting primary prevention of breast cancer and increased opportunities for optimizing the health and wellbeing for Californians.

Aim 5: Develop a report outlining the components of the California Breast Cancer Primary Prevention Plan that includes an action plan for each component that identifies ways individuals, organizations, businesses or government agencies can contribute to realizing the priorities set forth in the Plan. The report should also include an implementation plan including activities and a timeline to ensure the Breast Cancer Primary Prevention Plan is disseminated to and actualized by the key stakeholders in California.

Project Guidelines and Methods

The aim of this initiative is to develop and initiate implementation of a comprehensive plan to promote primary prevention of breast cancer in California.

Specifically the initiative requires the following milestones:

I. *Identify and convene key stakeholders who will be strong advocates of primary prevention who can be engaged to develop the plan.*

Key stakeholders must include members of the California Department of Public Health and stakeholders involved in prior California Cancer Plans. In addition to the research team, leading researchers, advocates, regulators and other decision makers who can provide leadership in developing the plan will be identified and invited to the initiative's advisory committee. Leadership should come from areas that address a range of issues including inequality/disparities, environmental exposures, occupational health, environmental justice, physical activity, built environment and others. These experts should be mainly interested or have experience with breast cancer research or work but it may also be appropriate to seek some experts who have knowledge and experience addressing primary prevention from the perspective expected in this initiative (e.g. Diabetes or Cardio Vascular Disease). At least one member of this larger advisory committee should have extensive experience in communications strategy to ensure that the project develops with effective dissemination as a core goal. Translation and dissemination of results should be designed into the project from the inception. The advisory committee will be consulted throughout the project's duration through email, conference calls and in-person meetings.

Hold an initial "Breast Cancer Primary Prevention Summit" early in the project period with the key stakeholders to introduce them to the project, refine the objectives and gain their insights into how to implement the aims to develop the report. The stakeholders will meet at least one more time in-person over the duration of the project to review the report, offer revisions, and develop and discuss implementation and dissemination plans for the report.

II. *Building on the California Breast Cancer's 2007 GAPS and the 2013 Supplement as well as recent federal reports on breast cancer and the environment (IBCERCC 2013, IOM 2012, PCP 2010), identify key primary prevention areas in breast cancer, disparities and the roles of the physical and social environment. Areas not under an individual's control that are of concern for their role in increasing breast cancer risk and/or greatest opportunity for reform in California must be identified.*

Survey the above-referenced documents to determine which topics are of greatest concern in California. Use additional literature searches as needed and query the stakeholders to determine the areas of focus for the Primary Prevention Plan. The Plan must have breadth enough to cover areas that will address the primary prevention of breast cancer but with enough depth to lead to meaningful objectives and strategic priorities. Through research and consultative process with the stakeholders and others, identify California's key areas of concern for primary prevention of breast cancer, considering but not limited to areas of high environmental burden, occupational hazards, as well as regulatory and legislative barriers to primary prevention. The advisory committee will play an active role in determining which areas of concern to highlight in the report and which topics to explore in depth for Aims 3 and 4. These topics should be the ones that show the greatest potential for impact.

III. *Identify objectives for reducing these risks and promoting primary prevention.*

Through research and consultative process with the advisory committee and others, identify key objectives for preventing breast cancer in California through both risk and protective factors and the broader spectrum of known agents associated with breast cancer.

IV. *Identify strategic priorities for addressing these risks.*

Through research and consultative process with the advisory committee and others, identify key opportunities for action and intervention to prevent breast cancer in California that adhere to the structural requirement for primary prevention strategies and offer implementation activities that either avoid/interrupt a contributing agent or promote/add a protective agent leading to breast cancer primary prevention.

The structural requirements of primary prevention strategies[3]:

1. must be group- or mass-, than individually-oriented (even though some of its activities may involve individual contacts).

2. must have an impact on the distribution of health within populations, ensuring equitable opportunities for improving overall health throughout and within populations.

3. must have a before-the-fact quality, i.e., be targeted to groups not yet experiencing breast cancer (even though they may, because of their life situations or recent experiences, be at risk).

[3] Excerpted and expanded from Cowen 1982.

V. *Develop a report outlining these components of the Breast Cancer Primary Prevention Plan to be made available and disseminated to various California constituencies.*

A draft of the report should be developed using the work generated from Aims 2-4 and in close consultation with the advisory committee. The draft should also contain an implementation plan with dissemination strategies tailored to the key stakeholders that can act on the report components. The draft must be shared and refined with the advisory committee during an invitation-only two-day in-person meeting to discuss the report and to solicit feedback for revisions. During this two-day meeting, the advisory committee should also contribute to the implementation plan by identifying existing efforts in each of the strategy areas of the Plan. The draft report should be finished no later than end of the first project year. After revisions have been implemented, the report must be reviewed and approved by the advisory committee and CBCRP staff before it is considered final.

The final report will move into production to prepare for its dissemination at the conclusion of the project period. Upon competition of the production-ready comprehensive Breast Cancer Primary Prevention Plan for California, the research team, in partnership with CBCRP, will release the report in a public forum, such as a briefing for a California State Legislator or other decision-making bodies in Sacramento where the advisory committee and other stakeholders will be invited to attend. It is expected that the report will be disseminated widely to encourage innovative and effective interventions to reduce breast cancer risk through California.

Who May Apply (Eligibility)

The eligibility for this RFQ includes:

1. Any individual or organization in California may submit an application in response to this RFQ. We welcome investigator(s) from community organizations, public or privately owned corporations and other businesses, volunteer health organizations, health maintenance organizations, hospitals, laboratories, research institutions, colleges, and universities.
2. The research must be conducted in California.
3. The application for qualifications must identify a principal investigator and at least two co-investigators to comprise the transdisciplinary cross-sector team to lead and coordinate this effort. Each team member must represent and demonstrate at least one of the three required areas of expertise in breast cancer prevention: research, policy development and advocacy.

Budget

One award of up to **$300,000** direct costs for 2 years will be awarded. 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 25% indirect costs

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

- Principal Investigator(s)
- Co-Investigators and other Key Personnel
- Study Coordinator
- Honoraria for Advisory Committee members
- Travel and housing for Advisory Committee members

- Communication costs
- Meeting space and food
- Report design and production
- Postage, printing, materials development

References

Adami HO, NE Dayb, D Trichopolosc, WC Willette. 2001. Primary and secondary prevention in the reduction of cancer morbidity and mortality. H.-O. Adamia, N.E. Dayb, D. Trichopoulosc, W.C. Willette. European Journal of Cancer 37 (2001) S118–S127.

American Cancer Society. Breast Cancer Facts & Figures 2013-2014. Atlanta:
American Cancer Society, Inc. 2013.

Brody, JG, KP Moysich, O Humblet, KR Attfield, GB Beehler, RA Rudel. 2007. Environmental Pollutants and Breast Cancer: Epidemiologic Studies. Cancer, 109 (S12): 2667–2712.

Brophy, James et al. Breast cancer risk in relation to occupations with exposure to carcinogens and endocrine disruptors: a Canadian case--control study. Environmental Health 2012, 11:87.

California Breast Cancer Research Program (CBCRP). Gaps Supplement: Targeted Scans of the 2007 "Gaps" Document "Identifying Gaps in Breast Cancer Research: Addressing Disparities and the Roles of the Physical and Social Environment." September 2013.

California Breast Cancer Research Program (CBCRP). Identifying gaps in breast cancer research: Addressing disparities and the roles of the physical and social environment. August 2007.

California Cancer Registry (November 2014), Cancer Surveillance Section, California Department of Public Health.

California's Comprehensive Cancer Control Plan 2011-2015. Sacramento, CA: California Dialogue on Cancer, July 2011.

Clarke AR, AP Goddu, RS Nocon, NW Stock, LC Chyr, JAS Akuoko, MH Chin. 2013. Thirty years of disparities intervention research: What are we doing to close racial and ethnic gaps in health care? Med Care, 51(11).

Comprehensive Cancer Control in California, 2004. Oakland, CA: California Dialogue on Cancer, April 2004.

Cowen EL. 1982. Primary Prevention Research: Barriers, Needs and Opportunities. J Primary Prevention, 213 (Spring): 131-137.

Daly B and OI Olopade. 2015. A Perfect Storm: How tumor biology, genomics, and health care delivery patterns collide to create a racial survival disparity in breast cancer and proposed interventions for change. Ca Cancer J Clin, 65 (3): 221-238.

DuPont WD, DL Page, 1985. Risk Factors for Women with Proliferative Breast Disease. NEJM 312(3): 146-151.

Gullotta T. 1994. The What, Who, Why, Where, When, and How of Primary Prevention. J Primary Prevention, 15 (1): 5-14.

Hiatt RA, TC. Porco1. F Liu, K Balke, A Balmain, J Barlow, D Braithwaite, AV Diez-Roux, LH Kushi, MM Moasser, Z Werb, GC Windham, and DH Rehkopf. 2014. A multi-level model of postmenopausal breast cancer incidence. 2014. Cancer Epidemiology, Biomakers and Prevention. Published OnlineFirst July 13. doi: 10.1158/1055-9965.EPI-14-0403.

Institute of Medicine (IOM). 2012. Breast cancer and the environment: A life course approach. Washington, DC: The National Academies Press.

Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC). 2013. Breast Cancer and the Environment Prioritizing Prevention.

Kothari AS, Fentiman IS (2002). Breast cancer in young women. Int J Clin Pract 56(3): 184-187.

President's Cancer Panel (PCP). 2010. Reducing Environmental Cancer Risk: What We Can Do Now. U.S. Department Of Health And Human Services, National Institutes of Health, National Cancer Institute.

Rudel RA, Fenton SE, Ackerman JM, Euling SY, Makris SL. Environmental Exposures and Mammary Gland Development: State of the Science, Public Health Implications, and Research Recommendations, Environmental Health Perspectives, Vol. 119, No. 8 (AUGUST 2011), pp. 1053-1061. See supplemental materials for a list of chemicals.

Rudel, RA, KR Attfield, J Schifano, JG Brody. 2007. Chemicals Causing Mammary Gland Tumors in Animals Signal New Directions for Epidemiology, Chemicals Testing, and Risk Assessment for Breast Cancer Prevention. Cancer, 109 (S12): 2635–2667.

Siegel RL, Miller KD, Jemal A, 2015. Cancer Statistics 2015. Ca Cancer J Clin, 65: 5-29.

Starfield B, J Hyde, J Gervas. 2008. The Concept of Prevention: a Good Idea Gone Astray? Heath. J Epidemiol Community Health, 62: 580-583

How We Evaluate RFQs

Scientific Review

The CBCRP will convene a peer review panel of experts from outside California to evaluate applications based on the following criteria:

1. Feasibility: Has the investigator(s) identified a transdisciplinary cross-sector team with the expertise and leadership in research, policy development and advocacy to undertake the project? Does the team have existing relationships or sufficient networks to identify key stakeholders that can meaningfully advise on the primary prevention of breast cancer in California that incorporates environmental exposures, regulatory concerns, health equity, population-based prevention strategies with the more common lifestyle choices and personal habits? Does the team have demonstrated experience and ability to facilitate diverse, high working groups in the successful completion of similar initiatives? Does the team have diverse scientific expertise including but not limited to environmental health, health equities, population-based prevention and communications? Has the investigator(s) demonstrated the capacity of resources and staff to undertake the project within the timeframe?

2. 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 and stated milestones of the project? Does the investigator or the team have a mastery of the concepts inherent in the RFQ's definition of primary prevention and expectations for the comprehensiveness of the strategies expected within the report? Will the approach yield the desired outcomes that reflect the goals and objectives of the RFQ?

3. Impact: Is there appropriate inclusion of community members and advocates from throughout the state that represent a range of communities, issues and approaches in their work? Does the investigator or team have experience disseminating to audiences relevant to this initiative? Will the investigator or team be able to develop an appropriate action plans with high impact potential?

4. Innovation: Has the investigator(s) used creative approaches to utilize key stakeholders and the project's advisory committee? Are the proposed approaches to the specified steps/activities innovative? Are methods novel and original?

Programmatic Review

This review is conducted by the 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 Other Review Criteria form and the content of the Lay and Scientific abstracts to the CBCPI topic area. (A score of "0" for Responsiveness is an automatic disqualification.)

- **Dissemination and translation potential.** The degree to which the applicant's statements on the Other Review Critiera form provides a convincing argument that the proposed research has the potential to inform the development and/or implementation of a comprehensive Breast Cancer Primary Prevention Plan for California.

- **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?

- **Advocacy Involvement.** Are the named advocate(s) and advocacy organization appropriate for the proposed research project? Were they engaged in the application development process? Are meetings and other communications sufficient for substantive engagement? Are the roles and responsibilities of the PI and the advocate(s) clearly outlined and is the agreement for advocate compensation and reimbursement clear? The Advisory Council will examine the PI's statements on the Lay and Scientific Abstracts and Advocacy Involvement forms.

Submission of Application

Submission Deadline: Applications must be submitted through proposalCENTRAL (https://proposalcentral.altum.com/) by Tuesday, March 1, 2016 at 12:00 noon PT.

Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm on Tuesday, March 1, 2016.

proposalCENTRAL Online Submission Instructions

Formatting Instructions

All submissions must be in **English**.

Follow these format requirements for written text (consistent with NIH/PHS 398 form):

- The height of the letters must not be smaller than 11 point. Times New Roman or Arial are the suggested fonts.
- Type density must be no more than 15 characters per inch (cpi).
- Page margins, in all directions, must be at least 1/2 inch.
- PI(s) last names and first initials must be in a header, on each page, flush right.

Deviations from the page format, font size, specifications and page limitations are grounds for the CBCRP to reject and return the submission without peer review.

Online Application (Proposal) Management

The CBCRP requires applications be submitted via an online system: proposalCentral. Following are instructions on how to register and how to submit your response to the RFP. The submission deadline is **12 noon Pacific Time on Tuesday, March 1, 2016.** *Note*: the proposalCENTRAL site shows East Coast times. Do NOT wait until the deadline to submit your application; if you miss the deadline, the system will not allow you to submit.

If you have any problems using proposalCENTRAL, please contact the proposalCENTRAL help line at (800) 875-2562.

Online Registration

The PI as well as the institution's signing official, contracts & grants manager and fiscal contact must be registered in proposalCENTRAL: https://proposalcentral.altum.com/. Start with "Click here to register". Fill out all the necessary fields on the registration page: First Name, Last Name, Email Address, User ID (can be your name), Password (case-sensitive), Challenge Question, and Answer.

Click BOTH BOXES on the bottom of the page to confirm your agreement with their "Terms of Service" and "Acceptable Use Policy." Click on the "Register" button. ProposalCENTRAL will send you an email with your username, password and a confirmation number. Once confirmed, you can login and the first time you enter the system, it will ask you to enter the confirmation number. You won't need that number again.

Online Forms and Fields

Once logged on, select the "Grant Opportunities" (gray) tab on the top of the page. Open up the filter and scroll down to California Breast Cancer Research Program. Sort the available funding by CBCRP and all of the funding opportunities for CBCRP will be showing. Choose the California's Comprehensive Breast Cancer Primary Prevention Initiative and click on "Apply Now" at the far right of the line.

Portions of the application are prepared using pre-formatted web pages in proposalCENTRAL (Proposal Sections 1 and 3-8). To move from section to section you can click the "Next" button to both save your work and go to the next section, or click "Save" and then click on the next section.

Proposal Section 2 allows you to download the Templates and Instructions for the CBCRP forms. After completing the forms on your computer, Proposal Section 9 allows you upload each one as PDF to attach it to your application.

❒ Title Page

On the "Title Page" enter the Project Title in the space provided (do not exceed 60 characters). Enter the total budget amount requested for the project, including indirect costs, if eligible. The projected start date for this project is June 1, 2016. Enter the end date of the project (up to 2 years).

❒ Download Templates & Instructions

This section includes these instructions as well as the relevant application forms. You will need these forms in order to respond to this RFQ.

❒ Enable Other Users to Access this Proposal

Note: A person must be registered in proposalCentral before s/he can be given access.
Read the instructions on this page thoroughly to understand the different levels of access. At the bottom of that page, in "Proposal Access User Selection," type in the email address of other individuals who will be working on the RFP, then click "Find User." Select the desired level of access and Click "Accept Changes" to save.

❒ **Applicant/PI**

Click on "Applicant/PI" and make sure that all required fields (identified with a red asterisk) are complete. (Click "Edit Professional Profile" to enter any missing data.)

Click "Return to Proposal" after entering missing data. Enter the % effort that the PI will devote to this project. The minimum effort is 10% FTE. Click "Save."

A required field entitled "ORCID ID" has been added to Professional Profile Page, at the bottom of Section 4: Personal Data for Applications. 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 here: 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.

❒ **Institution & Contacts**

On the "Institution & Contacts" page, make sure that all required fields (identified with a red asterisk) are complete, including the Signing Official, Contracts and Grants Official, and Fiscal (Accounting) Contact for the applicant institution. To complete these fields select the name or enter the email address of the individual in each of those roles and click "Add."

If you add someone, the "Contact Screen - Applicant Institution" screen will open. Make sure that all required fields (identified with a red asterisk) are completed. Click "Save", then click "Close Window". Then click "Save" on the Institution & Contacts page.

❒ **Abstracts**

Copy each the Lay Abstract and the Scientific Abstract from the CBCRP templates into the appropriate boxes on the proposalCENTRAL page. ***Note***: symbols or other special text will not copy.

On this page you should also select and add CSO codes. At https://www.icrpartnership.org/CSO.cfm you will find the seven major CSO categories, each with 4-9 sub-categories. Choose a major heading for your research and read the subcategory description. Choose the one that most closely fits. If your project fits under more than one CSO category, add a second code. The second code should represent a different, but integral, part of the research and about half of the total effort.

❒ **Budget**

Provide the total costs for the entire funding request for each grant year on this page. Make sure the budget numbers are exactly the same as those in the provided Excel Budget Summary form that you upload.

❒ **Organization Assurances**

Provide any required information for Human Subjects. If assurances will be required and have not yet been received, mark "pending" and enter the (proposed) date of submission in the "Approved or Pending Date".

❒ **Upload RESEARCH PLAN and Other Attachments**

This page contains a duplicate list of the forms and instructions that are in Download Templates and Instructions (above and Proposal Section 2). This is where you will upload the CBCRP forms and any other attachments to your proposal; the required items are listed.

To upload attachments, fill in the fields at the top of the page:

- **Describe Attachment:** Provide a meaningful description, such as Jones CV.
- **Select Attachment Type:** From the drop down menu, select the type of form that is being attached.
- **Allowable File Type:** Only Adobe PDF document may be uploaded. Do not Password Protect your documents. Help on converting files to PDF can be found on the proposalCentral site at https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp.
- **Select File From Your Computer to attach:** The Browse button allows you to search for the PDF on your computer; click Open to select the file.

Note: Explicit instructions on the content of the documents to be uploaded follow in the "Instructions for CBCRP Forms" section.

❒ **ORCID ID number**

This section is a reminder to returning investigators to obtain and enter an ORCID ID number by editing your professional profile using the link that appears here. At the bottom of Section 4 in your profile (Personal Data for Applications), you will find the space to enter your 16 digit ORCID ID number and a link to obtain one if necessary. Please enter the information in the following format: xxxx-xxxx-xxxx-xxxx.

❒ **Validate**

This function allows you to check whether all required items have been completed and attached. Don't wait until the last minute to check! Validate often during the course of completing your application so you have time to address missing items. Clicking the "Validate" button will either result in a link to missing items so you can easily go to the page and complete them, or a message at the top of the page "Has been validated and is ready to submit."

❒ **Print Face Page When Application Complete**

Applicants must print application's Face Page and obtain the necessary PI and institutional signing official signatures within a week of the electronic submission (see below).

❒ **Submit**

Submission is only possible when all required items have been completed and all required forms have been attached. Once an applicant hits "Submit," the application cannot be recalled.

❒ **Email Face Page Submission**

The PI, institution's signing official, Contract and Grants official and Fiscal (or Accounting) official all must sign the printed Face Page. Scan the signed form as a PDF and email to RGPOGrants@ucop.edu before 5 pm (Pacific Time) by Tuesday, March 1, 2016.

CBCRP Uploaded Form Instructions

Lay Abstract (REQUIRED)

This item is evaluated mainly in the programmatic review. The Lay Abstract is limited to one page and 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 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 you advocate partner to read this abstract and provide feedback.

Scientific Abstract (REQUIRED)

This item is evaluated mainly in the peer review. The Scientific Abstract is limited to one page and 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.

Other Review Criteria Form (REQUIRED)

This item is evaluated in the 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.

CBCPI Program Responsiveness: Provide a clear, brief summary for the CBCRP Council of how your proposed research addresses the specific RFQ 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 primary prevention strategies.

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 and the general California population, etc.). Describe the potential for how the research findings will be translated into policy and/or other practice.

Advocacy Involvement Form (REQUIRED)

This item is evaluated in the programmatic review. Limit the text to one page.

Discuss what involvement, if any, advocates had in the development of this proposal and will have in the project, if funded. Describe applicant's awareness of and sensitivity to breast cancer advocacy concerns involved in the proposed project. Explain how this proposal shows that awareness and inclusion of breast cancer advocacy concerns involved in the proposed research.

Follow the instructions on the form, and address the requested three items (Advocacy Organization/Advocate(s) Selection and Engagement to Date, Advocate(s) Role in Proposed Research and Meeting and Payment Plans).

Collaborative Agreement (REQUIRED)

This document is used by the peer reviewers and text is limited to two pages. At minimum, the agreement should cover:

> Roles and Responsibilities: Describe what decisions have been made about how the effort will be coordinated among the team members. Discuss responsibilities of the team members as they related to the aims of the initiative. Illustrate how the team can collaboratively bring their expertise, networks and resources to bear on completing the aims.
>
> Handling Disagreements: Describe what procedures collaborators will use to handle disagreements during the course of the project and afterwards. Potential issues include conduct and direction of the implementation of the project, dissemination and other outreach for the final Plan, administrative and budget conflicts.

Letter(s) of Commitment (REQUIRED)

Please use the template as a basis for commitment letters from the other members of the team coordinating the effort as well as any advocate, scientific and/or subcontracting individuals/institutions. Limit the text to two pages.

Budget Summary (REQUIRED)

Please enter the budget for the presented categories by year into the summary sheet (Excel format). Additional instructions are presented on the form.

The maximum duration and direct costs may not exceed the following for the RFQ *California's Comprehensive Breast Cancer Primary Prevention Plan*:

Project:	2 Years & $300,000

Note: The amount of the 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 cap by the amount of the F&A costs to the subcontracted partner's institution.

> **Personnel**. List the PI for the application and "individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested" (NIH definition). Include those at the level of postdoctoral fellow and higher. Upload a NIH "Biographical Sketch and Other Support" form for each individual listed. The minimum "Months Devoted to Project" required for each Project 1 PI is 1.2 months (= 10% FTE) and .6 months (= 5% FTE) for Project 2.
>
> **Other Project Expenses**. Enter the costs associated with each category presented on the template (description to be provided in Budget Justification).
>
> **Advocate(s) Expenses.** Include any travel, meeting, and consultation costs/fees associated with advocate engagement.

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 above.

Travel Expenses. Requested travel costs must be broken down and justified as Project-related.

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. Both categories require additional description (Budget Justification) and documentation (Appendix).

Service Agreements and Consultants. Both categories require additional description (Budget Justification) and documentation (Appendix).

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 25% MTDC*

> **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.*

Please see the RFQ under **Allowable Indirect (F&A) Costs** for more information.

Budget Justification Form (REQUIRED)

This item is evaluated in the peer review. Limit the text to two pages. Follow the instructions on the template. The minimum "Months Devoted to Project" required for the PI is 1.2 months (= 10% FTE).

Please put considerable thought into this section. Relate each item explicitly to the research plan. Items not well justified are likely to be deleted or reduced. Provide special justification for any unusual expenses.

Personnel

Provide a detailed justification of the budget. Describe the duties of each participant and the specific role each will perform in this project, and justify by category all requested expenditures. List by name and job title all personnel who will participate in the project, if known; if not known, use the position title.

For each position, include:

- The percent FTE (full time equivalent) appointment at the applicant institution
- The percent time devoted to this project
- The percent salary requested (which cannot exceed the percent time devoted to this project)

Subcontracts and Consultants

For each subcontract and consultant, please do the following:

- Enter the name(s), role(s), and total annual costs
- Itemize the direct, Indirect/Facilities & Administration (F & A), and total costs.

Subcontract or consultant arrangements may involve costs such as personnel, supplies, and other allowable expenses, including indirect or Facilities and Administration (F & A) costs at the federally approved MDRC (include a copy of the agreement), for the relatively independent conduct of part of the work described in the research plan. Contractual agreements for major support services, such as the laboratory testing of biological materials, clinical services, etc. may be of sufficient scope to warrant a similar categorical breakdown of costs.

Supplies and Expenses
Itemize supplies and expenses in separate categories, such as glassware, chemicals, radioisotopes, publication costs, computer charges, rental agreements (e.g. meeting space), etc.

Equipment
Individual equipment items that are listed must be in excess of the NIH threshold of $5,000. The maximum equipment costs cannot exceed $10,000. Justify each item of equipment on the Budget Justification form. Any items less than $5,000 (e.g. most computers and small lab items) are now budgeted under the "Supplies and Expenses" category.

Travel
Initiative-related travel must be separately described and justified.

Indirect/Facilities & Administration (F&A)
Indicate the F&A rate chosen, whether the rate is a DHHS negotiated rate, a rate established by some other means or authority, or the default rate of 25%. Indicate whether the CBCRP base was used or another base. For more information about allowable F&A costs please consult the CBCRP General Application Requirements and Conditions of Awards.

Key Personnel (REQUIRED)

This item is evaluated in the peer review. Limit the text to one page. Follow the instructions on the template.

List the individuals, including collaborators and consultants, who will have significant intellectual input into the scientific development and execution of the project, regardless of whether they will be paid with funds from this grant. For each individual, include advanced degrees, position title, department and institution, percent FTE on project, as well as role in project. Include a biographical sketch for each individual listed.

Biographical Sketch & Other Support (REQUIRED)

This item is evaluated in the peer review. Use the NIH form. Limit the length of each biosketch to *no more than* four (4) pages.

Research Plan (REQUIRED)

This section is the **most important** for the peer review. Note carefully the page limits, format requirements, and suggested format.

Page limit: 10 pages

An additional 3 pages is allowed for References.

Format issues: Begin this section of the application using the 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.

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

Applicants should be clear in describing how their proposed research project adheres to, and/or builds on, approaches/methods described in the RFQ. A proposed research project may include to one or more of these interest areas.

Suggested content:

Introduction: Provide a brief introduction to the topic of the research. The relationship of the project to the specific CBCPI Project Type and expectations outlined within the RFQ should be clear.

Background and Significance: Provide an overview of your understanding of the initiative. Make a case for your proposal in the context of the current body of relevant knowledge and the potential contribution of the research.

Preliminary Work: Describe the recent work relevant to the proposed project. Emphasize work by the PI, members of the coordinating team and data specific to primary prevention and breast cancer. Describe the team's qualifications in the area(s) of expertise listed; capacity related to areas of expertise, including access to relevant data, record of conducting similar work, and past performance of the investigator, specific staff and sub-awardees that demonstrate capability to successfully complete similar initiatives.

Specific Aims: List the specific aims, which are the steps or increments deemed necessary to address the objectives of the solicitation. The subsequent research plan will detail and provide the approach to achieving each of these aims.

Approach: Provide an overview of the approach to complete the Breast Cancer Primary Prevention Plan goals and objectives. Describe the exact tasks related to the Specific Aims above. Discuss in detail how you would propose identifying and utilizing key experts and developing and finalizing the report (Breast Cancer Primary Prevention Plan). Provide a description of the work to be conducted during the award period, exactly how it will be done, and by whom. Where possible, list specific individuals who have agreed to participate in the initiative and include a letter of agreement from them in the appendix. Where specific individuals have not been identified, list the expertise you will be seeking and the method for identifying them.

Recognition of potential pitfalls and possible alternative approaches is recommended. How will technical problems be overcome or mitigated? Cover all the specific aims of the project in sufficient detail. Identify the portions of the project to be performed by any collaborators. Match the amount of work to be performed with the budget/duration requested. A timeline at the end will demonstrate how the aims are interrelated, prioritized, and feasible.

Resources and Facilities: Describe the resources and facilities to be used at the applicant organization and indicate their capacities, relative proximity and extent of availability relevant to the area of expertise. Include an explanation of any consortium/contractual arrangements with other organizations regarding use of these resources or facilities.

Human Subjects (OPTIONAL)

This item is evaluated in the peer review. **This form is required only for applications that use Human Subjects, including those in the "Exempt" category. Use additional pages, if necessary. For applications requesting "Exemption"** from regular IRB review and approval please 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 CBCPI Application Face Page 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 appendix, 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 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, but **no later than June 1, 2016**. 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 NIH policy release, http://grants.nih.gov/grants/guide/notice-files/not98-084.html. This ensures patient safety, confidentiality, and guidelines for continuing or canceling a clinical trial based on data collected in the course of the studies. The CBCRP may require documentation that a DSMB is in place or planned prior to the onset of the trial.

Vertebrate Animals (OPTIONAL)

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

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

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

Documentation of Assurances for Vertebrate Animals

Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. In the appendix, if available at the time of submission, include official documentation of institutional review committee approval showing the title of this application, the principal investigator's name, and the inclusive approval dates. Do not include supporting protocols. Approvals obtained under a different title, investigator or institutions are not acceptable unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to the CBCRP as soon as possible, but **no later than June 1, 2016**. Funds will not be released until all assurances are received by the CBCRP.

Appendix List (OPTIONAL)

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

Note that the *research plan must be self-contained* and understandable without having to refer to the appendix. Only those materials necessary to facilitate the evaluation of the research plan or renewal report may be included.

General Funding Policies

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.
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 22 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 Research Initiative grants are not included in this limit. A PI may have more than one Research Initiative grant in a year.

Policy on Applications from PIs with Delinquent CBCRP Grant Reports

PIs with current CBCRP 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 a Cycle 22 application to possible 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 the CBCRP to allow an extension of any report deadlines.

Application Revision Guidelines

A revised application must have the same principal investigator as the original application. When possible it should have the same title as the original application. However, if the specific aims of the

project have changed sufficiently, then a modified title may be chosen. A revision submission for all eligible award types (except CRCs) must include a section of not more than 2 pages uploaded as a part of the Research Plan. This section is a summary of the substantial additions, deletions, and changes that have been made. It must also include responses to criticisms in the previous Review Committee evaluation. This material does not count towards the normal page limit for the Research Plan. We also recommend emphasizing in the Research Plan any relevant work done since the previous application. CRC applicants should follow the directions in the CRC application materials regarding resubmissions.

Confidentiality

The 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 the 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 the CBCRP's annual report, (iii) the project abstract and progress report abstracts on the CBCRP Web site. 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 June 30, 2016. The written application critique from the review committee, the merit score average, component scores, percentile ranking, 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). Details concerning the appeals procedure may be obtained from the appropriate Research Administrator (with whom the applicant is encouraged to discuss his/her concerns), the CBCRP Director, or by contacting us through the CBCRP Web site: www.cabreastcancer.org/. The period open for the appeal process is within 30 days of receipt of the

application evaluation from the Program office. Contact the CBCRP to obtain full information on the appeals process.

Final decisions on application funding appeals will be made by the UCOP Research Grant Program Office (RGPO) Executive Director Dr. Mary Croughan. 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.

Pre-funding Requirements

Following notification by the 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:

- Verification of Principal Investigator status from an appropriate institutional official.
- Documentation of 501(c)(3) non-profit organization status for the organizations.
- Documentation of the DHHS-negotiated (or equivalent) indirect cost rate for non-U.C. institutions.
- Supply up-to-date documentation for approved indirect rate (F&A costs) agreements as of the grant's start date and any derived calculations, if applicable.
- Supply any missing application forms or materials, including detailed budgets and justifications for any subcontract(s).
- IRB applications or approvals pertaining to the award.
- Resolution of any scientific overlap issues with other grants or pending applications.
- Resolution of any Review Committee and Program recommendations, including specific aims, award budget, or duration.
- Modify the title and lay abstract, if requested.

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 below:

RGPO Open Access Policy
The UCOP Research Grants Program Office (RGPO) is committed to disseminating research as widely as possible to promote the public benefit. To that end, all RGPO grantee institutions and researchers grant RGPO a nonexclusive, irrevocable, worldwide license to exercise any and all rights under copyright and in any medium for all scholarly articles and similar works generated as a result of an RGPO grant award, and agree to authorize others to do the same, for the purpose of making their articles widely and freely available in an open access repository. This policy does not transfer copyright ownership, which remains with the author(s) or copyright owners.

Scope and Waiver (Opt-Out)
The policy applies to all scholarly articles and similar works authored or co-authored as a result of research sponsored by an RGPO grant, except for any articles published before the adoption of this policy and any articles for which the grantee institution and/or researchers entered into an incompatible licensing or assignment agreement before the adoption of this policy. Upon express written request of the institutional grantee and/or researcher, RGPO will waive the license for a particular article or delay "open access" to the article for a specified period of time.

Deposit of Articles

To assist the RGPO in disseminating and archiving the articles, the grantee institution and all researchers to the grant award will commit to helping the RGPO to obtain copies of the articles that are published as a result of an RGPO sponsored grant award. Specifically, each author will provide an electronic copy of his or her final version of the article to the RGPO by the date of its publication for inclusion in an open access repository, subject to any applicable waiver or delay referenced above. Notwithstanding the above, this policy does not in any way prescribe or limit the venue of publication.

Grant Management Procedures and Policies

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 Web site: http://www.ucop.edu/research-grants-program/grant-administration/index.html.