CALIFORNIA Breast Cancer Research Program

Request for Proposals (RFP)
Community-Driven Pilot Studies To Explore Racial/Ethnic Disparities In Consumer Product Availability And Use

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to apply
February 16, 2017

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California Breast Cancer Research Program &
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 over $267 million in 1006 grants to over 130 institutions across the state. With continued investment, the CBCRP will work to find better ways to prevent, treat and cure breast cancer.

CBCPI Priority Areas

In 2004, the CBCRP launched its Special Research Initiatives. 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 (RFQ) 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.

Community-Driven Pilot Studies To Explore Racial/Ethnic Disparities In Consumer Product Availability And Use

Available Funding

This initiative aims to advance our understanding of racial/ethnic disparities in consumer product availability, access, and use among California women and girls, through two community-driven pilot projects.

It is anticipated that funding will be available for this initiative to support two types of projects (Project I and Project II) for up to $250,000 direct costs for Project I and up to $350,000 direct costs for Project II. Maximum duration of Projects I and II is 3 years.

Completed responses to this RFP are due by the deadline: noon, February 16, 2017. Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm, February 23, 2017. The project start date is June 1, 2017.

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

Consumer products is a broad term that includes cosmetics and personal care products, household cleaning products, gardening products, and other products used on a regular basis by consumers. Chemicals used in consumer products can mimic naturally-occurring hormones in some cases, and in other cases can be carcinogenic. Emerging data indicate that there may be different patterns of use among various ethnic groups, and by extension, varying degrees of exposure to chemicals. Given the ethnic diversity of the California population, our conceptualization of factors related to breast cancer disparities could be significantly improved through an understanding of (1) what consumer products are marketed, available in stores, purchased and used by consumers, (2) how patterns vary by ethnicity, and (3) what chemical ingredients are in these consumer products.

Chemical Exposures via Consumer Products

Women in California and the U.S. are exposed to a myriad of chemicals from consumer products. Data from the Environmental Working Group indicate that each day women are exposed to an average of 126 unique chemicals through their use of personal care products alone.[1]

Chemicals in Consumer Products: Screening for Use and/or Safety

Of the 10,500 chemical ingredients used in the personal care products, just 11% have been assessed for health and safety.[2] Often, chemicals of concern such as those that are hormone mimicking or disrupting are neither regulated nor classified by governmental agencies. This lack of

regulation occurs despite data linking such chemicals to growth of breast cancer cells in laboratory studies.[3-4] Chemicals found in consumer products can include groups of chemicals such as parabens, phthalates, bisphenol A (BPA), antimicrobials, cyclosiloxanes, fragrances, and glycol ethers.[3-4] Further, racial or ethnic disparities in consumer product marketing and use may be a factor in differential exposures to potentially toxic chemicals known or suspected of being associated with breast cancer risk.

Relying on product labels to inform consumers of concerning ingredients has significant flaws. For example, in a 2009 study conducted by The Campaign for Safe Cosmetics, 28 children's bath products (e.g. shampoos, bubble baths, lotions) were tested for both 1,4-dioxane and formaldehyde.[5] Results indicated that 61% of products tested contained both formaldehyde and 1,4-dioxane. However, the chemicals were not disclosed on product labels because they were contaminants, rather than intentional ingredients, and therefore are exempt from labeling laws. Additional policy issues identified in a study by Dodson and colleagues[6] include the limitations of rating the safety of consumer products based on the product label and unsafe product substitutions of better recognized endocrine disrupting chemicals (EDCs) with other, less recognized EDCs.

Links Between Chemicals and Health

There has been a groundswell of concern over chemicals used in consumer products, and their potential links to breast cancer. Mechanisms through which chemicals can impact breast cancer development are varied, and include:

- Changing how mammary glands develop
- Changing how cells grow and function
- Mimicking hormones
- Changing how and when hormones act in the body (endocrine disruption)

Personal care products such as hair products, skin creams, and make-up can contain parabens, placenta, mercury, and other chemicals of concern for their carcinogenic activity or potential for hormone disruption.[3, 7-8] For example, studies by James-Todd and colleagues[7, 9] found that some hair care products used by African American girls and women have endocrine disrupting ingredients, such as mono-ethyl phthalate or methylparaben. Data from Wu and colleagues indicated that shampoo and hair conditioner were used less frequently among African Americans, who were more likely to have used chemical straighteners and relaxers on their hair.[10] The data also suggested that Asian women were more likely to use skin care products, and less likely to use make-up and deodorant when compared to other groups. Other studies have found that African American and Afro-Carribbean women are more likely to use leave-in conditioners, root-stimulators, perms, and hair oils compared to white women.[7]

A line of investigation that merits consideration is whether marketing and use of hair products that contain hormonally active chemicals such as EDCs may differentially affect racial and ethnic populations. As noted above, there are racial differences in the use of products with EDC's, and use of products with EDCs has been associated with more rapid appearance of sex characteristics and an earlier reported menarche.[9, 11, 14] Currently, data suggest that African American girls go through puberty at younger ages than White girls.[12-13]

In addition to personal care products, there are concerns around household cleaning products. These include the exposures to potential carcinogens and compounds with endocrine-disrupting properties via chemicals in the products (e.g. synthetic musks, antimicrobials, phthalates, and alkylphenolic surfectants),[14] and exposures to secondary pollutants that are toxic and produced when chemicals (unsaturated terpenes used for scents such as pine [alpha-pinine], and lemon [*d*-limonene]) mix with home environment. Recent data indicate that women with the highest exposure levels to cleaning products have a two-fold higher risk of developing breast cancer.[14] Another study found that Latina women have higher exposure to home products that contain volatile organic compounds such as p-dicholorobenzene, (a carcinogen) found in indoor air fresheners, toilet deodorizers, and moth repellent products.[15]

Efforts to build a data base of usage data, and identify usage patterns of household cleaning products have yielded a few striking findings.[16] First, most frequently used products included all-purpose cleaners, and glass cleaners. Second, the use of specific types of products varied by gender and ethnicity. For example women were more likely to use all-purpose cleaners when compared to men, and of the eight products for which participants were surveyed, Latinos used the following six products more often than non-Latinos: car cleaner, floor cleaner, glass cleaner, oven cleaner, and polish. And third, a statistical exploration of the stability of the classification system used by the authors indicated that people can be accurately and reliably categorized into three groups of users based on a single time-point of assessment.

Empirical data demonstrate that avoidance of phthalate exposure through avoidance of fragrances and hair gels, and careful selection of personal care products and changes in diet can reduce one's daily exposure to these compounds.[17-18] While these data indicate there is promise in individual behavior change to reduce exposure, there are limitations with relying on individual-level interventions alone. For example, the Environmental Working Group's (EWG) "Skin Deep" database, which lists the ingredients of over 66,000 products, documents widespread use of toxic chemicals in personal care products even though it is limited to information on products obtained from online retailers, manufacturers, and product packaging. Further, information on consumer product packaging is not a fully reliable source of chemical information, and products sold in small neighborhood "ethnic" markets may also not be included in the EWG database.

Need for Improved Understanding: Availability, Access and Use of Consumer Products

With all this information, however, little has been done to incorporate the impact of these chemicals into risk assessments for breast cancer. And the cumulative risk of these exposures has yet to be assessed. In order to move to this point in the scientific trajectory, we need to know more about any racial or ethnic disparities in consumer product availability, access, and use among California women and girls.

Our understanding of disparities in breast cancer will be advanced through answers to questions such as:

- What consumer products are marketed, available in stores, purchased and used by consumers?
- How do these patterns vary by ethnicity?
- What chemicals ingredients are in these consumer products?

In the next section, we describe two types of pilot studies to explore these questions. For each study type, we propose that one or more community organizations form a consortium with scientist(s) to conduct the project.

Research Questions

Projects I and II will provide opportunities for formal establishment of collaborations across a number of active communities and identification of appropriate scientific partners. It is our expectation that the partnerships built among community-based organizations and scientists in this initiative will poise teams to apply for future research grants that explore questions inspired from the results of Projects I and II.

If more than one project is funded, we expect that the grantees will meet periodically during their project periods to exchange information and preliminary findings. Applicants may apply for one of these projects.

PROJECT I

Minimum length of Project I: 1 year
Maximum length of Project I: 3 years
Maximum direct cost of Project I: $250,000

Objective: to identify and analyze existing marketing data to document the types of consumer products used by women and girls in California, including at least three racial/ethnic groups. Potential products to explore include but are not limited to: skin and hair products, fragrances, household-cleaning products, pesticides, and garden supplies.

PROJECT II

Minimum length of Project II: 1 year
Maximum length of Project II: 3 years
Maximum direct cost of Project II: $350,000

Objective: to document the range of products used by one or more racial/ethnic group in California and where these products are purchased, for example, in ethnic markets or other local venues.

The goals of Project II are:

1) Conduct a pilot survey of one or more groups of racial/ethnic minority girls and women with regard to the consumer products that they use regularly (i.e. hair, skin, pesticides, etc.);
2) Ascertain where these products are purchased;
3) Conduct a product inventory in the neighborhoods where the populations being surveyed live, work, and shop by visiting the stores that sell consumer products; and
4) Purchase and test a sample of products based on criteria including but not limited to the most commonly mentioned products and products that are likely to have high breast

cancer-related toxicity. Selected products will be tested for chemicals of relevance to breast cancer toxicity, defined for the purpose of this project as: known and suspected mammary gland carcinogens,[1] mammary gland toxicants[2,3] and/or endocrine disrupting chemicals.[4]

Projects I and II will answer the following questions:

1. What consumer products are being purchased by women and girls of at least three different race/ethnic backgrounds in California? Examples of the sorts of products to be identified include hair, skin, household cleaning, and home garden.

2. What consumer products are sold at, for example, hardware stores, gardening stores, bodegas, salons, and beauty supply stores in and/or serving these populations?

3. What chemicals are in the products used by these populations? Based on the results of the survey of product use, select the products of highest interest, for example, the most commonly named products and/or the products with the highest likelihood of toxicity. Conduct a label review for chemicals of relevance to breast cancer toxicity and test products for the presence of chemicals of relevance to breast cancer toxicity. Consider other sources of chemicals in consumer products, for example, from packaging or contaminants from the production facility.

Budget

CBCRP intends to fund two projects that are community-driven pilot studies. Maximum duration for each type of project is 3 years. Each project will establish formal research collaborations between a consortium of two or more community organizations, and scientists.

- Project I: Use existing marketing data to document the sort of consumer products women and girls in California are using.
- Project II: The collaboration will conduct a pilot survey to gather data on consumer product use, and take store inventory to gather data on availability and access. Pilot project outcomes could lead to a larger scale research project.

It is anticipated that up to $600,000 direct costs is available for this initiative. Allowable direct costs per project are as follows:

Maximum direct cost of Project I: $250,000
Maximum direct cost of Project II: $350,000

[1] Rudel et al have identified 216 chemicals that have been associated with increases in mammary gland tumors in at least 1 animal study. See: Rudel RA, Attfield KR, Schifano JN, Brody JG. Chemicals causing mammary gland tumors in animals signal new directions for epidemiology, chemicals testing, and risk assessment for breast cancer prevention. Cancer. 2007 Jun 15; 109 (12 Suppl):2635-66.

[2] Mammary gland toxicants include commercial chemicals or pharmaceuticals reported to induce morphological or functional change in the mammary gland, including but not limited to: high production/exposure chemicals such as chlorotriazine metabolites, perfluorinated compounds, parabens and BPA replacements.

[3] 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.

[4] http://www.endocrinedisruption.com/endocrine.TEDXList.overview.php

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for non-UC institutions,. Indirect costs are capped for the University of California campuses at 25% F&A.

Applicants should consider the following elements when constructing their budgets:

- Expertise: Proposals must involve researchers with appropriate proficiency for the research questions (e.g. epidemiologist, breast cancer biologist, statistician, toxicologist)
- Capacity: Applicants should demonstrate possession of or access to appropriate tools and technologies (e.g. laboratory facilities and equipment, animal facilities, etc.)

Details on allowable costs can be found in section *Budget Summary* section on page 20-21 of this RFP.

References

[1]Exposures add up – Survey results. *EWG's Skin Deep Cosmetics Database*. Available at: http://www.ewg.org/skindeep/2004/06/15/exposures-add-up-survey-results/.

[2]Food and Drug Administration (FDA). 2000. Center for Food Safety Applied Nutrition. Cosmetics Compliance Program. Domestic Cosmetics Program. Issued July 31, 2000. Accessed online March 1, 2005 at http://www.cfsan.fda.gov/~comm/cp29001.html.

[3]New Study: Consumer Products Contain Potentially Harmful Chemicals Not Listed on Labels. *Silent Spring Institute*. 8 March 2012. Available at: http://www.silentspring.org/press-releases/new-study-consumer-products-contain-potentially-harmful-chemicals-not-listed-labels.

[4]Common Chemicals of Concern. *Massachusetts Breast Cancer Coalition*. Available at: http://mbcc.org/breast-cancer-prevention/chemicals-of-concern/.

[5]The Campaign for Safe Cosmetics. 2009. No More Toxic Tub. Accessed online October 10, 2016 at http://static.ewg.org/reports/2009/Campaign-for-Safe-Cosmetics-Report-No-More-Toxic-Tub.pdf?_ga=1.69768720.1253896802.1476212267.

[6]Dodson, R.E., et al., Endocrine Disruptors and Asthma-Associated Chemicals in Consumer Products. *Environmental Health Perspectives*, 2012.

[7]James-Todd, T., Senie, R., and Terry, M. Racial/Ethnic Differences in Hormonally-Active Hair Product Use: A Plausible Risk Factor for Health Disparities. *Journal of Immigrant and Minority Health* (2012) 14: 506-511.

[8]Dickenson, C., Woodruff T.J., Stotland N.A., Dobraca D., and Das R. Elevated mercury levels in pregnant woman linked to skin cream from Mexico. American Journal of Obstetricians & Gynecology. August 2013.

[9]James-Todd, T., Terry, M.B., Rich-Edwards, J., Deierlein, A., and Senie, R. Childhood Hair Product Use and Earlier Age at Menarche in a Racially Diverse Study Population: A Pilot Study. *Ann Epidemiol* 2011; 6: 461-465.

[10]Wu, X.M., Bennett, D.H., Ritz, B., Cassady, D.L., Lee, K., and Hertz-Picciotto, I. (2010). Usage pattern of personal care product in California households. Food and Chemical Toxicology, 48: 3109-3119.

[11]Tiwary, C.M. (1998). Premature sexual development in children following the use of estrogen- or placenta-containing hair products. Clinical Pediatrics 27: 733-739.

[12]W. C. Chumlea, C. M. Schubert, A. F. Roche et al., "Age at menarche and racial comparisons in US girls," Pediatrics, vol. 111, no. 1, pp. 110–113, 2003.

[13] P. B. Reagan, P. J. Salsberry, M. Z. Fang, W. P. Gardner, and K. Pajer, "African-American/white differences in the age of menarche: accounting for the difference," Social Science and Medicine, vol. 75, no. 7, pp. 1263–1270, 2012.

[14]D.E. Buttke, and C. Martin, "Exposures to Endocrine-Disrupting Chemicals and Age of Menarche in Adolescent Girls in NHANES (2003-2008)" Environmental Health Perspectives, 11: 1613-1618.

[14]Zota, Ami, et al. Self-reported chemicals exposure, beliefs about disease causation, and risk of breast cancer in the Cape Cod Breast Cancer and Environment Study: as case-control study. Environmental Health. 2010.

[15]Hun, D., Morandi, M.T., Stock, T.H., and Corsi, R.L. Cancer Risk Disparities between Hispanic and Non-Hispanic White Populations: The Role of Exposure to Indoor Air Pollution. *Environmental Health Perspectives*. Dec 2009;117(12):1925-1931.

[16]Moran, R.E., Bennett, D.H., Tancredi, D.J., Wu, X.M., Ritz, B., Hertz-Picciotto, I. Frequencyand longitudinal trends of household care product use. Atmospheric Environment. 2012; 55:417-424.

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[18]Harley, K.G., Kogut, K., Madrigal, D.S., Cardenas, M., Vera, I.A., Meza-Alfaro, G., She, J., Gavin, Q., Zahedi, R., Bradman, A., Eskenazi, B., Parra, K.L. Reducing Phthalate, Paraben, and Phenol Exposure from Personal Care Products in Adolescent Girls: Findings from the HERMOSA Intervention Study. Environ Health Perspect. 2016 Oct;124(10):1600-1607.

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 comprised of scientists from relevant disciplines and breast cancer advocates and other community representatives.

All applicants will receive the reviewer's evaluations, with suggestions for improvement. The CBCRP staff is available to explain the evaluation and assist applicants in understanding how to use the evaluation to improve their research project or for future applications.

The review committee evaluates each application using the four criteria: Quality of the Research, Feasibility, Partnership, and Impact. All elements are weighted equally.

- **Quality of the Research:** The quality, organization, and presentation of the research plan, including methods and analysis plan. Will the research planned answer the research questions? Are the design, methods and analyses well-developed, integrated and appropriate to the aims and stated milestones of the project? Does the application demonstrate an understanding of the research question and aims?

- **Partnership:** Have the partners created a comprehensive and clear plan for the community to drive the project and for equal control and participation by all partners in all phases of the project? Have the partners demonstrated that all partners' knowledge has been integrated into planning the research? Has the team adequately described the potential for capacity building for any or all of the partners to participate in future community-driven research projects? Have appropriate agreements been reached regarding: procedures for resolving disagreements among collaborators, ownership of data, and dissemination of the results?

- **Impact:** The extent to which the project, if successfully carried out, would make an original and important contribution to advancing our understanding of racial/ethnic disparities in consumer product availability and use? Does the project address relevant products that are likely to have high breast cancer-related toxicity? Will the pilot data yielded by the research advance our understanding of racial/ ethnic disparities in consumer product availability and use?

- **Feasibility:** The extent to which the aims are realistic for the scope and duration of the project; adequacy of investigator's expertise and experience, and institutional resources; and availability of additional expertise and integration of multiple disciplines. Do the principal investigators and co-investigators have demonstrated connections to the

communities of interest? Do the principal investigators and co-investigators have demonstrated expertise and experience working in the topic area? Can the project be completed as proposed given the available funding, time frame and the staff knowledge, skills, experience, and institutional resources?

Programmatic Review
This review is conducted by the 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 PIs to the stated intent of the selected Initiative? Compare the PIs' statements on the Other Criteria template and the content of the Lay and Scientific abstracts to the CBCPI topic area. (A score of "0" for Responsiveness is an automatic disqualification.)

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

- **Underfunded.** On the Distinction from Other Funding form, have the PIs highlighted the unique aspects of the proposed research from their own projects (past and present) and the research by others. Is the research relatively underfunded by other agencies, or not funded?

- **Addressing the Needs of the Underserved.** Do the project and the PIs' statements on the Other Criteria template demonstrate how this research will address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors)?

- **Advocacy Involvement.** Are the named community PIs and community organizations clearly driving the proposed research project? Were they engaged 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 PIs' statements on the Lay and Scientific Abstracts and Other Criteria forms.]

Application Process and Instructions

Submission Deadline: Applications must be submitted through proposalCENTRAL (https://proposalcentral.altum.com/) by **February 16, 2017 at 12 noon** Pacific Standard Time.

Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm, **February 23, 2017**. The project start date is June 1, 2017.

The application materials will be available on proposalCENTRAL by December 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, February 16, 2017. *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 PIs 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 Fields and Forms

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 Consumer Products Initiative and click on "Apply Now" at the far right of the line.

Proposal Sections 1 and 3-9, 11, 12 are prepared using pre-formatted web pages in proposalCENTRAL. 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.

Proposal Section 10 allows you upload each template as a PDF (in order to attach it to your application) after completing the template on your computer.

❒ Section 1: 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, 2017**. Enter the end date of the project (up to 3 years).

❒ Section 2: 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 RFP.

❒ Section 3: 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.

❒ Section 4: 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. **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.

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."

❒ Sections 5 & 6: 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.

❒ Section 7: 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.

❒ Section 8: 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.

❒ Section 9: 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".

❒ Section 10: 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.

❒ **Section 11: 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.

❒ **Section 12: 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."

❒ **Section 13: Print Face Page When Application Complete**

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

❒ **Section 14: 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.

❒ **Outside of proposalCENTRAL: Email Face Page Submission**

The PIs, 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 **Thursday February 10, 2017.**

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 Criteria (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 RFP and by the CBCRP Council/SRI Steering Committee (see www.cabreastcancer.org/funding-opportunities/sri/index.html).

CBCPI Focus (Responsiveness): Provide a clear, brief summary for the CBCRP Council (1 or 2 paragraphs) of how your proposed research addresses the specific RFP topic area, by increasing or building on specific scientific knowledge; by pointing to additional solutions to identify and eliminate environmental causes, and or disparities in, breast cancer; and/or, by helping identify or translate into potential prevention strategies.

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

Advocacy Involvement: Discuss the involvement community PIs, community organizations, and the broader community had in the development of this proposal and will have in the project, if funded. Describe the interest, support, potential benefits to, and involvement of, the community of interest in the research—from developing the research question, through designing, carrying out, and analyzing the research, to disseminating the results. Explain how this proposal shows awareness and inclusion of community concerns involved in the proposed research.

Collaborative Agreements (REQUIRED)

This form is used in Peer Review in part to score the "Partnership" criteria and is included in Programmatic Review as well. Applicants should remember that a fully collaborative and power-sharing partnership is an equally weighted criterion, making up ¼ of each application's total score. Limit the text to two pages.

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

these agreements.

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: CBCRP suggests that if both applicant agencies have the administrative capacity to manage grant awards, that each agency receives a separate award. Confirm that your organizations in your partnership will receive separate awards.

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 Turn-over of Personnel: Describe how the turn-over 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).

Distinction From Other Funding (REQUIRED)

Limit the text to one page. The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan. Thus, it is important to ensure that essential parts of your research and collaboration plans are reflected in this form and other forms as noted. This form is important as one of the only places where the Council will understand the impact of your collaboration.

Applicants should highlight the unique aspects of the proposed research compared to their other current and previously funded projects. The peer review committee considers this information when evaluating the quality of the research. For the programmatic review the information is used to rate the criteria "Underfunded."

Discuss the unique properties of the current application from, (i) other current and past grant support to the PI, (ii) the current CBCRP portfolio as shown on our Web site (http://www.cabreastcancer.org/) under the link "Research Portfolio", and (iii) general research in the topic under investigation on display on the International Cancer Research Portfolio (ICRP) Web site: http://www.icrpartnership.org/.

Describe the unique qualities of this research proposal and propose a resolution to any overlap with other research funding. If you think that your area of research is relatively underfunded, explain why. Explain why funding this research will fill a gap or underfunded area in the CBCRP's research portfolio.

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.

Maximum direct cost of Project I: $250,000
Maximum direct cost of Project II: $350,000
Maximum length of Project I or Project II is 3 years.

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions. Indirect costs are capped for the University of California campuses at 25% F&A.

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 CBCPI PI is 1.2 months (= 10% FTE).

Other Project Expenses. Enter the costs associated with each category presented on the template (description to be provided in Budget Justification).

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, Annual meeting (third year only) or Scientific meeting (PI only capped at $2,000 per year).

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).

Pooled Expenses. The RGPO takes a conservative budgeting approach to the allocation of pooled expenses. Pooled expenses such as insurance surcharges, system wide networking surcharges, and other pooled training and facilities expenses are generally disallowed as direct costs. Pooled expenses may be allowed at the discretion of the RGPO Program Director if the grantee can show that: 1) the project to be funded 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 (e.g. it is not allowable to charge a new indirect expense such as "facilities" as a direct line item in order to recoup funds lost due a poorly negotiated rate agreement). No indirect cost recovery will be allowed on pooled expenses.

Indirect (F&A) costs. For this initiative, non-UC institutions are entitled to 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 RFP under **Allowable Indirect (F&A) Costs** for more information.

Budget Justification & Facilities (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 each PI is 1.2 months (= 10% FTE).

Key Personnel (REQUIRED)

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

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* five (5) 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
References: 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.

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 at least ½ inch.

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

Suggested content:
Introduction and Hypotheses: Provide a brief introduction to the topic of the research and the hypotheses/questions to be addressed by the specific aims and research plan. The relationship of the project to the specific CBCPI Project Type and expectations outlined within the RFP should be clear.

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

Background and Significance: Make a case for your project in the context of the current body of relevant knowledge and the potential contribution of the research.

Preliminary Results: Describe the recent work relevant to the proposed project. Emphasize work by the PIs and data specific to breast cancer and consumer products.

Research Design and Methods: Provide an overview of the experimental design, the methods to be used, and how data is to be collected and analyzed. Describe the exact tasks related to the Specific Aims above. Provide a description of the work to be conducted during the award period, exactly how it will be done, and by whom. Include a letter of commitment if the applicant PIs will be using a data set that they do not control/own. 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. Explain the use of human subjects and vertebrate animals and show their relationship to the specific aims.

Resources and Facilities: Describe the resources and facilities to be used (e.g., laboratory space, core facilities, major equipment, access to populations, statistical resources, animal care, and clinical resources) and indicate their capacities, relative proximity and extent of availability. Include an explanation of any consortium/ contractual arrangements with other organizations regarding use of these resources or facilities. Describe resources supplied by subcontractors and those that

are external to the institution. Make sure all of the research needs described in the research plan are addressed in this section.

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 PIs are 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, 2017. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

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

Vertebrate Animals (OPTIONAL)

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

If you have answered *"YES"* to the Vertebrate Animals item on the Organizations Assurances 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, 2017. Funds will not be released until all assurances are received by the CBCRP.

Appendix List (OPTIONAL)

The appendix may <u>not</u> be more than 30 pages in length.

Follow the instructions and items list on the template. 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 1, 2017. 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.