Request for Qualifications (RFQ)
The Impact of Proposition 65 to Reduce or Eliminate Exposures Linked to Breast Cancer

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to apply
February 23, 2017

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California Breast Cancer Research Program &
California Breast Cancer Preventions 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, CBCRP has awarded over $267 million in 1,006 projects to over 130 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.

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 to fund a team to collaborate with the CBCRP to develop and implement the CBCPI 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.

The Impact of Proposition 65 to Reduce or Eliminate Exposures Linked to Breast Cancer

Available Funding

This initiative aims to identify whether Proposition 65 (Safe Water and Toxic Enforcement Act) has been effective in reducing exposure to chemicals that may cause or contribute to breast cancer including known and suspected mammary gland carcinogens, mammary gland toxicants, endocrine disruptors, and/or chemicals with similar properties or similar mechanisms of action.

Funding for this initiative is anticipated to be available to support one project for up to **$600,000** in direct costs for up to three years. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for non-UC Institutions and at 25% for University of California campuses.

Completed responses to this RFQ are due by the deadline: noon, February 23, 2017. Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by **5pm PT on March 2, 2017**. The project start date is June 2017.

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

Since the 1970s there have been numerous regulatory and legislative efforts to protect public health by restricting exposure to a wide range of chemicals and heavy metals. These efforts, including landmark legislation such as the Clean Water Act, the Clean Air Act and The Toxics Substance Control Act set the stage for federal guidelines. In the wake of these efforts, states, counties and municipalities have taken leadership to add more protective measures. These efforts have gained momentum, especially in California, but there is little clarity on the actual impacts these efforts have on reducing chemical exposures. Many questions remain unanswered. What is the best prevention-oriented approach to reducing chemical exposure? Is it through policy? Is it through market pressure? Importantly, to what extent do policies actually reduce exposures to chemicals that may cause or contribute to breast cancer?

In 2014, CBCRP commissioned a review of policy interventions intended to reduce exposures to environmental hazards (Apollonio et al, 2016). This review contains several important findings:

1. There is a significant need for more investigation into the efficacy of different interventions to reduce chemical exposure;
2. The context in which an intervention policy is embedded is important to its effectiveness but is often afforded little attention;

3. Of the policies considered, bans or restrictions were more effective than voluntary programs (though the review did not consider market-based campaigns that successfully resulted in companies agreeing to reformulate or replace products); and
4. Better monitoring of human exposures to banned or restricted chemicals is needed to understand how effective interventions really are.

Historically, chemical reduction policies have usually been information disclosure programs or "right-to-know" programs (Bennear and Olmstead, 2008). In the United States, right-to-know programs proliferated in an attempt to inform individuals and communities about the chemical exposures in their everyday lives. These programs situate the reduction of chemical exposures within the choices and actions of individuals once they receive and understand chemical risk information (Pease 1991). The Environmental Protections Agency's Toxic Release Inventory (TRI) is one of the most recognized information disclosure programs in the United States (Hearn, 1996; Konart and Cohen 1997). TRI is a resource for learning about toxic chemical releases and pollution prevention activities reported by industrial and federal facilities, with the intent of informing decision-making by communities, government agencies, companies, and others.

In 1986, California enacted its own right-to-know program, California's Safe Drinking Water and Toxic Enforcement Act of 1986, known to most as Proposition 65. The intention of Proposition 65 is to help Californians make informed decisions about their exposure to chemicals known to cause cancer, birth defects and other reproductive-related harms. The state of California is required, because of Proposition 65, to publish a list of chemicals determined to cause increased risk for these harms. The list currently has over 900 chemicals. Companies cannot knowingly release significant concentrations of these chemicals in sources of California's drinking water and should any manufactured product sold in California contain any of these chemicals, the public must be notified, usually in the form of a warning label. Finally, if an individual or groups of individuals believe there is a product available in California containing a toxic chemical with no warning label, they can sue the manufacturer if the chemical is present (Trager 2016).

Right-to-know programs should communicate to the public the information necessary to promote informed decision-making and early on, Proposition 65 was criticized for being ineffective in promoting informed choice (Rechtschaffen, 1996). It has also been suggested that Proposition 65's "compliance with the reporting requirements has been poor, and efficient use of the information has been hindered by confused and conflicting implementation of the right-to-know rules" (Black 1989, pg. 1021).The context and implementation of Proposition 65, coupled with the inherent difficulties in evaluating the effect of policy on population-level chemical exposures and market responses, have resulted in very few attempts to evaluate the effectiveness of Proposition 65 as a whole (Pease, 1991). Key questions remain, including: Has Proposition 65 resulted in useful, meaningful consumer-friendly disclosure? Has Proposition 65 resulted in meaningful changes in product formulations and uses? Has Proposition 65 resulted in meaningful reductions in these exposures? Have consumers changed their behavior as a result of any labeling efforts?

There are limitations to assessing the impact of right to know programs; including conceptual problems in defining and operationalizing appropriate measures and having access to good data (Pease, 1991). By putting the responsibility for change within the domain of citizens writ large, right-to-know programs' effectiveness are more unpredictable and harder to measure. It is difficult to capture empirically linear effects of a policy when it occurs in the context of other

legislation, trends and inconsistent implementation. Given the aim of Proposition 65 is to inform the public of their exposures, determining how knowledge leads to change and what kind of change is also not an easy exercise. Finally, understanding the linkage between the policy, public knowledge and any changes in market behavior is wrought with challenges.

Despite these challenges, Proposition 65 exists. It is untested for its overall effectiveness and its impact on reducing breast cancer risk is largely unknown. We do know through a preliminary survey by Silent Spring Institute that more than 100 chemicals regulated under Proposition 65 are chemicals that may cause or contribute to breast cancer, with studies documenting successes in reducing emissions and reformulations of products to remove certain substances (Freund 2012). Studies have also documented that taking away certain exposures can quickly reduce body burden. For example, one study found that when people stopped consuming packaged food for three days they had a 66 percent reduction in an endocrine disruptor, Bisphenol A levels (found in the food packaging) and when people returned to the normal habits of eating packaged food their BPA levels returned to the same level as before the intervention (Rudel et al., 2011).

Examples do exist of assessments or studies that look at the impact of Proposition 65 on the levels of chemical exposures. Through the use of linear modeling, Konart and Cohen (1997) examined air emissions with companies recorded emission levels, violations and trends over time to determine the likelihood of Proposition 65 causing any change. Through this methodology, the authors concluded that required disclosure may change business practices in response to potential financial threats (Konart and Cohen, 1997). Indoor dust in child care facilities was the focus of another examination of how Proposition 65 determined benchmark levels of phlalates in dust, through exposure estimates, and led to a probabilistic health risk assessment (Gaspar et. al., 2014). Gaspar and colleagues found, through the risk assessment results, that California children are exposed to phthalates that exceed benchmarks for both reproductive health (between 82-89% of children in child care facilities) and cancer (between 8-11% of children younger than 2 in these same facilities).

Lowe and Jamall (1994) assessed DDT levels in soil modeled after the Environmental Protection Agency's Risk Assessment Guidance for Superfund, and found Proposition 65 may lead to a business assessing chemical risk in response to perception of risk and not the actual risk itself. These authors, however, were unable to ascertain how the warning labels help inform the public of their chemical exposure (Lowe and Jamall, 1994). Another examination, this time of the levels of formaldehyde emanating from furniture, set out to develop a methodology for measuring exposure over time, modeled on user-scenarios of product use. Molhave, Dueholm and Jensen (1995) were able to extrapolate over time, at the population level, an assessment of health risks with Proposition 65 estimated exposure levels and found that the exposure limits for formaldehyde set by Proposition 65 would not cause significant risk to develop cancer.

Most of these studies focused on assessing whether the established risk levels identified by Proposition 65 were sufficient enough to decrease the risk of these chemicals. These studies did not focus on the effectiveness of the policy in total, although for some, the investigators were able to find evidence to suggest business practices and behaviors may be influenced by Proposition 65 through the threat or perception of risk (Konart and Cohen 1997; Lowe and Jamall 1994). None of these studies examined the effects of informing the public of these exposure levels on changes in knowledge or behaviors and there has not been a focus on

products that contained endocrine disruptors or other chemicals that are known or suspected mammary carcinogens.

Almost thirty years post enactment, the examination of Proposition 65 impact on individual's knowledge about chemical exposures and the actual reduction of exposures in California's communities remains largely missing in the literature. CBCRP seeks to support research to broaden and deepen our understanding of the effectiveness of Proposition 65 to increase public knowledge and informed decision-making to reduce chemical exposure and to reduce population-wide exposure to chemicals that may cause or contribute to breast cancer.

Research Aims

This RFQ seeks an investigative team to undertake an evaluation to determine how effective California's Safe Drinking Water and Toxic Enforcement Act of 1986 (better known as Proposition 65) has been at reducing exposure to breast carcinogens.

The research aims for the initiative are to identify measurable changes caused by Proposition 65 in three key areas:

- the public exposure to chemicals that may cause or contribute to breast cancer, including known and suspected mammary gland carcinogens, mammary gland toxicants, endocrine disruptors, and/or chemicals with similar properties or similar mechanisms of action;
- consumer perception and behavior regarding their chemical exposure risk based on labeling or public education campaigns; and
- business practices such as reformulating products, utilizing informed substitution that leads to safer alternatives, offering more complete ingredient disclosure, adopting company-wide voluntary restricted substance lists, and/or chemical ban policies.

Research Questions

The following research questions should be answered with this evaluation:

Overall Effectiveness

- What does the public think about Proposition 65?
- What are the significant evidence-based accomplishments of Proposition 65?
- Has Proposition 65 been aided by other California or federal policies? If so, which ones and how? How has Proposition 65 aided other policies?

For the reduction of chemical exposures

- Is there a discernible change in chemical (those known and suspected mammary gland carcinogens, mammary gland toxicants, endocrine disruptors, and/or chemicals with similar properties or similar mechanisms of action) levels in products that can be attributable in part to Proposition 65? Can these changes be applied to population-level risk exposure differences?

For consumer perception and behavior

- Do people use the disclosure and action methods available through Proposition 65?
- What do people do with the information about chemical exposure levels?

- Do warnings effectively reduce exposures to toxic chemicals? Do they effectively communicate information about toxic chemical exposure to promote meaningful choice and promote better-informed decision making?
- Early on, Proposition 65 was criticized for being ineffective in promoting informed choice for Californians (Rechtschaffen, 1996). Has that changed 20 years later?

For business behavior and practices

- What is the behavior of the companies or organizations that have a chemical (those known and suspected mammary gland carcinogens, mammary gland toxicants, endocrine disruptors, and/or chemicals with similar properties or similar mechanisms of action) on the list?
- Does having a Proposition 65 chemical in a product change business practices?
- Does the threat of or actual litigation change business behavior? Or is it the threat of market valuation?

Project Requirements and Methods

Proposals should be developed with consideration for the following project requirements and guidelines.

Project requirements

- Proposals must be grounded in a clear scientific rationale and must be linked to chemicals that may contribute to breast cancer (known and suspected mammary gland carcinogens, mammary gland toxicants, endocrine disruptors, and/or chemicals with similar properties or similar mechanisms of action).
- The evaluation should include analyses of how the use of warning labels lead to informed choice and decision-making (e.g. whether the warnings are read; whether the warnings communicate adequate and accurate information that is understandable) (Rechtschaffen 1996). The collaborating advocacy group could be particularly helpful in gathering information and interpreting findings for how effective Proposition 65 is to communicating risk to lay audiences. An analysis of the public perception of risk would be a valuable contribution to our understanding of the effectiveness of Proposition 65 (Dunsby 2004).
- The evaluation will fill an important void in our information about Proposition 65 and should include a representative sample for California on consumer knowledge/attitude or changes in consumer purchases.
- Projects must include strategies for effectively disseminating and communicating research findings and translating them into guidance for regulatory, public health and individual decision-making.
- Projects should integrate expertise in relevant disciplines including, but not limited to toxicology, communications, behavior change, epidemiology, and legal and regulatory assessment, and to include advocates, regulators and community members.
- The final report of the evaluation must include
    - information on the legal and regulatory context and landscape in which Proposition 65 is situated in California and nationally
    - description and implication for how Proposition 65 was and is implemented
    - description and implications for enhancements made to the Proposition over its lifespan

- aims and methods that address the three key areas of the policy (public exposure to chemicals, consumer perception and behavior in response to the Proposition 65 warnings, and business practices and behavior);
- evaluation results;
- identification of accomplishments (if found); and
- recommendations based on the findings to increase or strengthen the effectiveness of Proposition 65. These recommendations should not only be legislative or regulatory in nature. They should also include grassroots, advocacy, research and organizational recommendations.

Project methods

- The study design should have both qualitative and quantitative methods; self-report methodology (e.g. surveys) is allowed but the design should also include independent assessment.
- The proposed study design must measure changes in public exposure (e.g. body burden), in consumer knowledge and behavior, reformulation of products, company commitments or business practices that demonstrate the impact of Proposition 65.
- The proposed research design should be creative in developing or identifying measurement proxies to determine Proposition 65's effectiveness especially in the areas of reduction of chemical exposures at a population-level and how market behaviors have changed due to the Proposition 65 (reduction of chemicals in products, etc.). These measurements should still be justifiable, grounded in the evidence and if successful, can be used as examples for how to examine or measure effectiveness of policies and programs like Proposition 65.

Project guidelines

When developing a research design in response to this RFQ, the following guidelines should be considered:

1. This is considered an independent evaluation of Proposition 65. However, the Office of Environmental Health Hazard Assessment (OEHHA) should be consulted regarding the evaluation to learn of particular areas of interest to them as the oversight agency and to query about sources of reliable data to inform the evaluation.
2. The evaluation of Proposition 65 must be done within the context or landscape both in California and nationally in terms of chemical exposure trends or other regulatory efforts, to situate how findings related to any change in exposure can be attributable to Proposition 65 or other market factors and/or policies.
3. The applicants should demonstrate their understanding of the literature related to conveying knowledge to the general public including where the public are likely to get their information, the sources they trust and what types of information is either useful or influential to them as well as how knowledge is retained, internalized and turned into action. This understanding will be useful when evaluating how chemical exposure risk, through Proposition 65, is communicated and used by the public.
4. Although not central to the research design, there should be a component that provides legal analyses of Proposition 65 in three core areas: the implementation of the Proposition; the enhancements since its enactment; and pending the findings of the evaluation, recommended changes or enhancements to the legislation to address any gaps (Pease, 1991).

5. Modeling methods should be considered to illustrate how risk to chemical exposure has changed since Proposition 65. Models can focus on one chemical, family of chemicals or product with a rationale in the chemical's relationship to breast cancer risk.
6. Risk and risk assessment concepts should be part of the evaluation of Proposition 65. This can take on many forms including the strengths and weaknesses of how risk is measured and/or communicated in the implementation of Proposition 65.
7. Applicants should consider using the California Office of the Attorney General's reporting system database of legal cases (https://oag.ca.gov/prop65/60-day-notice-search) as one potential method to identify case studies for understanding how business practices or market change and consumer activation of the legislation occurs.
8. Unintended consequences of policy interventions can also be assessed. For example, there has been great success moving the market away from using BPA in baby products, however the alternatives may not be an improvement (Colliver, 2014).

Budget

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, risk assessment, modeling, communication, 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 21-22 of this RFQ.

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How We Evaluate RFQs

CBCRP uses a two-tier evaluation process: peer review and programmatic review. It is a combination of, (i) the peer review rating, (ii) the programmatic rating, and (iii) available funding that determines a decision to recommend funding.

Peer Review
All applications are evaluated by a peer-review committee of individuals from outside of California. The committee is comprised of scientists from relevant disciplines and breast cancer advocates and other community representatives. The Peer Review criteria include:

- **Innovation.** Extent to which the project explores new and potentially useful information. Are the concepts and hypotheses speculative and exploratory? Are methods novel and original? Has(ve) the investigator(s) thought creatively about how to measure the effectiveness of the three components of the Proposition 65 (public exposure to chemicals, consumer perception and behavior regarding their chemical exposure risk and business practices)?

- **Impact.** Potential for the project, if successful, to identify and/or validate outcomes and recommendations for enhancements to strengthen Proposition 65. Will the research generate new information that can be used effectively by policy makers and advocates? Will the research generate new information about methodology to aid in future similar policy evaluations?

- **Approach.** 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 questions and requirements for the evaluation?

- **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. Does the investigator (and do 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 PI to the stated intent of the selected Initiative? Compare the PI's statements on the Other Review 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.)

- **Dissemination and translation potential.** The degree to which the applicant's statements on the Other Review Criteria template provides a convincing argument that the proposed research has the potential to inform the development and/or implementation of California chemicals policy.

- **Addressing the Needs of the Underserved.** Do the project and the PI's statements on the Other Review 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 limitations, age, occupation and/or other factors)?

- **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 advocate(s) and advocacy organization named in the Advocacy Involvement form and the Advocate Letter of Commitment 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?

Application Process and Instructions

Submission Deadline: Applications must be submitted through proposalCENTRAL (https://proposalcentral.altum.com/) by **Thursday, February 23, 2017 at 12 noon Pacific Standard Time.**

Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm on **March 2, 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 on February 23, 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 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 Proposition 65 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, 2017. Enter the end date of the project (up to 3 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 RFQ, 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. **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."

❒ 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 **March 2, 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 your 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 (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).

CBCPI Focus: Provide a clear, brief summary for the CBCRP Council (1 or 2 paragraphs) 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 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 etc.). Describe the

potential for how the research findings can be translated into interventions, policy and/or other practice.

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 limitations, age, occupation and/or other factors)?

Advocacy Involvement (REQUIRED)

This item is evaluated in the programmatic review. 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). 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. Explain how this proposal shows awareness and inclusion of breast cancer advocacy concerns involved in the proposed research.

Letter(s) of Commitment (REQUIRED)

This item is evaluated in the programmatic review. Please use the template as a basis for commitment letters from the advocate(s). 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 3 Years & $600,000

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 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).
>
> **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, 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. 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 & 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 CBCPI 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: 12 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.

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 expectations outlined within the RFQ 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 and qualifications of the PI and her/his investigative team relevant to the proposed project. Emphasize work by the PI and data specific to breast cancer and policy analysis.

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 PI 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 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, 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 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, 2017**. 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 not be more than 30 pages in length.**

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

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.