CALIFORNIA
Breast Cancer
Research Program

Request for Proposals
Animal studies to investigate concurrent effects of environmental chemicals and stress factors on mammary cancer

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to apply
Thursday, October 6, 2016

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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, the CBCRP has awarded over $262 million in 994 grants to over 120 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. Approximately $24 million will be dedicated to directed, coordinated, and collaborative research to pursue the most compelling and promising approaches to:

1. Identify and eliminate environmental causes of breast cancer.
2. Identify and eliminate disparities/inequities in the burden of breast cancer in California.
3. Population level interventions (including policy research) on known or suspected breast cancer risk factors and protective measures.
4. Targeted interventions for high-risk individuals, including new methods for identifying or assessing risk.

To focus these research efforts, the CBCRP issued a Request for Qualifications to fund a team to collaborate with the CBCRP to develop and implement the California Breast Cancer Prevention Initiatives planning process. In 2010, the grant was awarded to Tracey Woodruff, PhD, MPH, Professor and Director of the University of California, San Francisco, Program on Reproductive Health and the Environment (PRHE).

In March 2015, CBCRP's Council approved fifteen (15) concept proposals to stimulate compelling and innovative research in all four topical areas of the CBCPI (environmental causes, health disparities, population-level interventions and targeted interventions for high risk individuals). A series of funding opportunities will be released over the next two years reflecting these concepts.

Animal studies to investigate concurrent effects of environmental chemicals and stress factors on mammary cancer

Available Funding

This initiative aims to investigate the combined effect of environmental chemicals and stress factors on the development of mammary cancer using animal models.

Up to two research projects capped at $625,000 in direct costs each and a duration of up to four years will be funded in this initiative. 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 RFP are due by the deadline: noon, October 6, 2016. Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm **October 13, 2016**. The project start date is **February 1, 2017**.

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

Exposures to environmental chemicals (e.g., estrogen disruptors, pesticides, metals) and psychosocial stressors (e.g. social isolation, lack of social support) are both thought to impact breast cancer in humans. Rarely have both environmental chemicals and psychosocial factors been studied concurrently in human studies; however, the growing regulatory interest in cumulative risk assessment methodology and application has focused attention on the need for better experimental models for understanding the intersection of chemical and non-chemical stressors on adverse health outcomes (Payne-Sturges and Martin, 2015; Rider et al., 2014). Studying key risk factors concurrently could make important advances in our knowledge of breast cancer etiology, prevention, and disparities.

Animal studies could significantly advance our understanding of concurrent exposure to environmental chemicals and psychosocial stress. They can contribute important information because of the ability to apply selected exposures at different developmental stages to investigate critical windows of vulnerability – to individual and combinations of exposures. Because each of the various identified breast cancer risk factors by themselves is modestly associated with breast cancer risk, it is important at this stage to investigate combinations of factors. Women are exposed to a combination of risk factors in their lives, yet rarely are the combined exposures investigated, nor are they followed over time.

Contributions of psychosocial factors to mammary cancer development in animals have been studied sporadically since the 1970's and have primarily consisted of investigations of exposures to stressors. Stressors can have beneficial effects as well as long-term adverse consequences for disease outcomes (Kubala, et al., 2012; Rozeske et al., 2011). The impact of stressors may be determined by the type of stressor as well as the timing and extent of exposure. Early studies involved the use of very intense stressors (such as foot shock, electroconvulsive shock and sound) applied over extended periods of time, which generally produced inhibition of 1,12-dimethylbenz[a]anthracene (DMBA)-induced tumors (Newberry et al., 1972; Pradhan and Ray, 1974; Bhattacharyya and Pradhan, 1979). Later investigators questioned the relevance of these models because the stressors were applied over a prolonged period and could constitute extreme exposure, not to the scale that a person would experience (Trainor et al., 2009).Some hypothesized that due to the long duration of the studies, the stressor became predictable to the animal and became a stressor that built up resistance rather than causing damage (Cory-Slechta, 2015). In virtually all of these studies, animals were individually housed, which is itself a known stressor and therefore stressor stimuli applied experimentally were superimposed upon a physiological state already altered as a consequence of individual housing of the rodents (Ros-Simo and Valverde, 2012; Weintraub, et al, 2010).

The stressors that seem to best replicate the factors affecting cancer risk are those restricted to an independent variable determined to be an aversive stimulus that is both uncontrollable and unpredictable from the organism's point of view. Comparisons of uncontrollable/unpredictable stress to controllable/predictable stressors are not systematically incorporated into stress studies. In order to successfully interpret these studies, it is critical to evaluate the extent to which the stressor remains chronic, uncontrollable/unpredictable from the animal's point of view, or whether it eventually becomes predictable/controllable (Cory-Slechta, 2015).

Animal models have also been designed to study the physiology of stress using primarily two types of stressors – restraint and social isolation. Models of restraint stress (e.g., placing the animal in a supine position and taping down all of its extremities to prevent movement or escape) are the best physiologically characterized models. However, some argue that they do not represent a relevant model for human stress in breast cancer studies (Trainor et al., 2009). The majority of recent groups studying stressors and cancer risk have adopted the use of isolation vs. group housing (social isolation), which operationalizes a psychosocial concept. Both rodents and primates are social species and thus live in group situations, making the stressor somewhat more relevant. Social isolation is considered to be an analogue of deprivation of a social support structure that has been shown to be critical to stress mitigation in humans. However, the physiological responses to stress using social isolation have been harder to characterize than with the restraint models (Cory-Slechta, 2015).

The physiological response to stress activates pathways shown to be involved in the initiation and progression of cancer (Williams et al., 2009). Stressors early in life can permanently alter the hypothalamic-pituitary-adrenal (HPA) axis that influences mammogenic reproductive hormones through interactions with both the limbic-hypothalamic-pituitary-adrenal axis and the hypothalamic-pituitary-gonadal axis (Gavrilovic and Dronjak, 2005; Ros-Simo and Valverde, 2012). Such disruptions can lead to abnormal sex hormone levels (e.g., estrogen) and to altered mammary gland development. Animal studies of stressors and mammary tumor development suggest that stressors can cause glucocorticoid receptors to increase as tumors became more invasive, hampering the body's ability to respond or cope with the stressor and shutting down

expression of estrogen and progesterone (Hermes GL et al., 2009; Volden and Conzen, 2013). Breast cancer and the physiological reaction to stressors are potentially connected through their mutual relationship to inflammatory processes (Clougherty, J.E., et al., 2010).

Environmental chemical exposures such as some endocrine disrupting chemicals, are also known to cause mammary cancer in animals (Rudel, et al., 2014). In contrast to controlled, animal bioassays, epidemiological studies to quantify breast cancer risk related to exposure to just a single given chemical, or chemical class, remains difficult not only due to resource and methodological constraints, but timing of exposure considerations. Prospective cohorts with the ability to assess lifelong and/or life-cycle specific exposures (via survey, observation, biomonitoring, etc.) are prohibitively expensive, resource intensive and long-term (i.e. decades). Capturing exposure data from multiple and non-chemical stressors (such as psychosocial stress) magnifies this difficulty. Therefore, the development of an animal model, capable of integrating stressors with suspected or known breast carcinogens, could better inform the scientific understanding of breast cancer development and provide avenues for strategizing/prioritizing targets for intervention.

Animal studies have yet to study concurrently environmental chemicals and psychosocial factors and the potential for cumulative or synergistic influence on mammary cancer development; however, joint chemical:non-chemical models have been developed for respiratory diseases and other end-points (Clougherty, J.E., et al., 2010; Hassan, S et al., 2013). The majority of the recent studies on the effect of stressors on mammary cancer causation have been conducted in spontaneous rat tumor models by the Conzen and McClintock laboratories. These studies have examined stressor exposures early in development, which may have a different pattern of effect on sex hormones than those applied during adulthood or later (Hermes and McClintock, 2008, Hermes et al, 2009). All of the studies by Conzen's group implicate the period of puberty in rats (from mammary gland development to ovulation). Additionally, timing of stressor in relation to the period of mammary gland development may also be critical in terms of potential changes in mammary morphology and function and associated estrogen function since many breast tumors are estrogen dependent (Hermes, et al., 2009; Volden.,et al., 2013; Volden and Conzen, 2013). The effects of social isolation observed in rats have been supported by limited studies using the C3(1)/SV40 T-antigen transgenic mouse model (Williams et al., 2009) and adult administration of DMBA to mice that were exposed to neonatal stressors (Boyd et al., 2010).

The goal of this initiative is to fill the knowledge gaps about the interaction of environmental chemicals and psychosocial stressors on breast cancer causation by developing new animal models that incorporate the relevant levels and biological windows of exposure to explain how they contribute to human risk.

Project Guidelines

Studies that fulfill this RFP will investigate the influence of concurrent exposure to one or more chemicals (e.g. endocrine disruptor) and unpredictable and uncontrollable stressors on mammary cancer in animal models. The objective is to develop new animal studies testing the effects of concurrent exposure to environmental chemical(s) and social stressors on the development of mammary cancer, with consideration of the timing of exposure/impact risk, and the duration of exposure/impact risk.

Successful applicants will construct their research plans to address two or more of the following questions:

1. What are the effects of concurrent exposure to environmental chemical(s) and social stressors on the development of mammary cancer? Do concurrent exposures have multiplicative, additive or other impacts on the development of mammary cancer that differ from the impact of exposure to a chemical or psychosocial stress alone?

2. Does the timing of exposure impact risk? For example, does concurrent exposure to environmental chemicals and stress during specific windows of vulnerability affect the risk of developing mammary tumors or the type or size of the tumor(s)?

3. Does the duration of exposure to environmental chemicals or stress and/or concurrent exposure to both impact risk? Does a prolonged exposure affect the risk of developing mammary tumors or the type and the size of the tumors? Are the effects of exposure cumulative over time or must the exposures be constant to generate an impact?

Studies that address these questions should be proposed with a list of proposed endpoints (e.g. tumor development, tumor size, biomarkers of carcinogenesis) and a map of how the exposure type (e.g. duration, intensity) and animal endpoints map onto analogous human exposures (e.g. acute or chronic stressor) and endpoints.

All studies should adhere to IACUC guidelines.

Budget

Up to two research projects capped at $625,000 in direct costs each and durations of up to four years will be funded in this initiative.

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses. UC campuses institutional F&A is capped at 25% Modified Total Direct Costs (MTDC) including up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract).

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How We Evaluate RFPs

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

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

- **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 the investigator thought creatively about how to measure the effects of exposure to environmental chemical(s) and social stressor(s) on mammary gland?

- **Impact:** Potential for the project, if successful, to answer to at least two of the questions posed in the RFP. Has the investigator chosen appropriate environmental chemicals and animal models for extrapolation to humans?

- **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 question and aims?

- **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 identified in the description). Pay careful attention to the instructions for each form. The Programmatic criteria include:

- **Responsiveness.** How responsive are the project and PI to the stated intent of the selected Initiative? Compare the PI's statements on the Other Review Criteria form and the content of the Lay and Scientific abstracts to the CBCPI topic area. (A score of "0" for Responsiveness is an automatic disqualification.)

- **Dissemination and translation potential.** The degree to which the applicant's statements on the Other Review Criteria template provides a convincing argument that the proposed research has the potential to develop models that will provide relevant information about the effects of concurrent exposure to environmental chemical(s) and social stressors on the development of mammary cancer.

- **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 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 Forms Instructions

Submission Deadline: Applications must be submitted through proposalCENTRAL (https://proposalcentral.altum.com/) by **Thursday, October 6, 2016** at 12 noon Pacific Standard Time.

Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm **Thursday, October 13, 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 **Thursday October 6, 2016.** *Note*: the proposalCENTRAL site shows East Coast times. Do NOT wait until the deadline to submit your application; if you miss the deadline, the system will not allow you to submit.

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

Online Registration

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

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

Online Forms and Fields

Once logged on, select the "Grant Opportunities" (gray) tab on the top of the page. Open up the filter and scroll down to California Breast Cancer Research Program. Sort the available funding by CBCRP and all of the funding opportunities for CBCRP will be showing. Choose the "Concurrent Environmental and Psychosocial Animal Models 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 February 1, 2017. Enter the end date of the project (up to 4 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 RFP.

❒ Enable Other Users to Access this Proposal

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

❒ Applicant/PI

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

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

❒ 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 www.cancerportfolio.org/cso.jsp 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.

❒ **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 **Thursday, October 13, 2016.**

CBCRP Uploaded Form Instructions

Lay Abstract (REQUIRED)

This item is evaluated mainly in the programmatic review. The Lay Abstract is limited to one page and must include the following sections:

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

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

CBCPI Focus: 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.

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 policy and/or other practice.

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. Limit the text to two pages.

Budget Summary (REQUIRED)

This item is evaluated in the scientific review. Please enter the budget for the presented categories by year into the summary sheet (Excel format). Additional instructions are presented on the form.

The direct costs of an individual award are capped at $625,000. The maximum duration may not exceed 4 years.

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 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 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 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 Form (REQUIRED)

This item is evaluated in the peer review. Use the current 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
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.

Applicants should be clear in describing how their proposed research project adheres to, and/or builds on, approaches/methods described in the RFP. A proposed research project should include at least two of the research questions.

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 PI and data specific to breast cancer. Describe any models that are currently in use and how quickly they can be adapted to the proposal.

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 each of the Specific Aims above in sufficient detail in terms of design and methods. Provide a description of the work to be conducted during the award period, exactly how it will be done, and by whom. 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 that will be applied to this project and the site(s) where the research will be performed. Describe the resources that are immediately available to the investigators. If resources will need to be acquired during the conduct of the study, describe how they will be procured.

Vertebrate Animals (REQUIRED)

This item is evaluated in the peer review. **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 February 1, 2017**. Funds will not be released until all assurances are received by the CBCRP.

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 February 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.

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

Who May Apply

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.

Note: 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 an CBCPI 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.

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:

- Up-to-date human IRB and animal assurance documents from a federally licensed review board must be on file for each grant.
- Modify the title and lay abstract, if requested.
- Agree to any changes in specific aims, award budget, or duration as recommended by the Review Committee and Program.
- Resolve overlap with other grant support and any issues with PI percent effort.
- Supply any missing application forms or materials.
- 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.

Conditions of Awards

Details concerning the requirements for funding recipients are available in a separate Program publication, the University of California, Office of the President, "***Grant Administration Manual 2011-2012***." It is sent to every funding recipient principal investigator, contracts and grants official, and the accounting contact. The Manual can be obtained from the Program's office or viewed on our Web site: www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf.

Awardees are expected to account for the expenditure of funds and for the performance of work as agreed upon in a timely manner, so that the CBCRP may file reports and answer

inquiries from the legislature and the public. They are also expected to adhere to the stated goals of the legislation, which include the systematic dissemination of research results to the public and to the healthcare community and the facilitation of translation of research results into commercial, alternate technological and other applications. The Institutional Official's and Principal Investigator's **signatures on the Face Page of the application signify that the individuals are aware of the conditions for receiving funding** from the Program.

To ensure the proper management of these public funds, a prospective funding recipient must satisfy the **following standard requirements** before an award will be made:

- Have adequate organizational and fiscal management, and accounting systems to administer the award and assure compliance with award terms and conditions.
- Have adequate liability insurance and bonding, including indemnification of the UC Regents.
- Ensure nondiscrimination in employment, and assurances regarding the treatment of animal or human subjects and research safety and ethics.
- Have adequate financial resources, equipment, facilities, and technical skills to perform the proposed work, or the ability to obtain them.
- Be able to perform the proposed work within the approved time frame, taking into consideration all existing commitments.
- Have a satisfactory record of integrity and business ethics.
- Maintain mechanisms to assure integrity and honesty in the conduct of research, safe conduct of research, and fair practice for all employees and research subjects.
- Certify that none of the key personnel on the initiative are barred by the U.S. Public Health Services Office on Research Integrity from performing comparable roles on federally funded grants.

Individuals who are to be awarded funds may meet these requirements directly or by making arrangements with a research organization that does. A funding recipient may satisfy modified requirements, if this is determined to be appropriate upon review by the University of California's Office of Research Administration, Office of Risk Management and General Counsel.

Though the research must be conducted primarily in California by California investigators, part of the work may be done outside California if the need to do so is well justified (i.e., it is integral to the achievement of a specific aim and cannot reasonably be performed in California) and the results of such work may be applied to furthering the achievement of the Program's goals.

Grant awardees must agree to:

- Use award funds only as approved by the CBCRP. The Program must approve changes in the specific aims of an initiative.
- Maintain accounts, records and other evidence pertaining to work performed and costs incurred.
- A final scientific report and any interim reports as specified in this announcement.
- File annual fiscal reports and a final fiscal report.
- Participate in CBCRP sponsored activities to disseminate research results as able and as requested.

- Ensure the timely translation of research results into commercial applications, public policy, and public communications as appropriate and/or required by this announcement.
- Attend CBCRP research symposiums, if scheduled during the award period, or forfeit budget amounts assigned to this item.

Award Period and Indirect (F&A) Costs

If a multiple year award, continuation funding for additional years is released upon receipt of an Annual Progress Report showing research effort/progress, no overlap with other support, maintenance of sufficient FTE percentage by the PI, continuing approval of Human and Animal subjects use, submission of publication copies, and reporting any changes in Key Personnel. If funding is delayed, or if all funds are not expended in the normal award period, then the investigator(s) may request a no-cost time extension for a maximum of one year in order to complete the work.

The CBCRP encumbers the funds for all approved years of an award from the appropriation in the year the funds are awarded; thus full funding of a multi-year initiative is assured, dependent only on timely submission of the required reports. Funds will be disbursed annually, contingent on receipt of required progress and fiscal reports.

For one-year initiatives, and for the final budget year of multiyear initiatives, 20% of the approved budget is withheld (except for UC institutions) and paid in arrears upon receipt and acceptance by the Program of all required final reports.

Direct Costs

CBCRP award funds may be used only for expenditures necessary to carry out the approved initiative, as specified in the approved budget. Significant changes in proposed expenditures must be approved in advance by a CBCRP Research Administrator. Please follow the policies in the "SRP Grant Administration Manual" regarding allowable changes in expenditures and the guidelines for submitting a formal request form to change initiative budgets.

Allowable direct cost expenditures may include administrative costs only if the following two conditions are satisfied: (a) the services, functions, or activities are directly necessary for the conduct of the initiative; and, (b) these administrative costs have not been included in the calculation of the recipient institution's indirect cost rate agreement approved by the Federal government. In other words, the Program policy does not prohibit administrative costs, but it is careful to ensure that costs meet both conditions (a) and (b).

Cost Base for Determining Indirect Cost Allocations for UCOP RGPO Awards

The "cost base" for determining the indirect cost (IDC)[1] recovery for RGPO awards will consist of: salaries and wages, fringe benefits, materials and supplies, services, travel, and sub grants and subcontracts to an outside institution up to the first $25,000 of the initial sub-award budget (excluding renewals or extensions). This base is called the Modified Total Direct Cost, or MDTC

[1] IDC is also commonly referred to as Overhead or Facilities and Administrative costs, or F&A.

base. Equipment or other capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, as well as the portion of each sub grant and subcontract *in excess* of the first $25,000, and the total cost of any subcontract from one UC to another UC campus, are **excluded** from this MTDC base. Any questions about interpretation of the MTDC base can be directed to the CBCRP Program Officer, and/or the RGPO Contracts and Grants Analyst assigned to an awarded grant.

Allowable Indirect (F&A) Costs
For primary grantees the following conditions apply regarding recovery of indirect costs:

- For awards to UC Campuses, a cap of no more than 25% MTDC is allowable on grant awards. See below for additional discussion on indirect on subcontracts.
- For awards to Non-UC institutions, the CBCRP awards allow F&A cost recovery utilizing the MTDC base, at the applicable federally approved F&A rate for the Non-UC Institution. (The rate approved by a federal cognizant agency must be used if available). In the absence of a federally negotiated rate agreement, an equivalently documented F&A rate for the institution may be used (upon approval of UCOP RGPO).

For indirect costs for award subcontracts the following conditions apply:

- For subcontracts to UC Campuses, a cap of no more than 25% MTDC is allowable on subcontracts related to CBCRP awards.
- For awards to Non-UC institutions, the subcontractor F&A costs recovery utilizing the MTDC base is allowed at the appropriate federally approved F&A rate for the Non-UC Institution. (An approved Department of Health and Human Services (DHHS) rate must be used if available). In the absence of a federally negotiated rate agreement, an equivalently documented F&A rate for the institution may be used (upon approval of UCOP RGPO).
- For subcontracts awards to UC-managed National Labs (LBNL, LANL, LLNL) please contact the CBCRP Program Officer.

Individuals without an institutional affiliation will not be eligible for indirect costs.

Provisional or pending increases in indirect rates will be included in awards only if they are documented prior to execution of the award agreement and disbursement of year one funding. The maximum indirect costs which CBCRP pays is the lesser of: (a) the federally approved rate current for the budget year, or (b) the rate provided for in the final approved budget.

Under no circumstances will funded initiatives be supplemented to reflect an unanticipated increase in the F&A rate; nor can funds originally awarded as direct costs be shifted to cover increases in the F&A rate. If the F&A rate decreases below that provided for in the approved budget, the CBCRP will pay overhead at the new lower rate starting on the date of change, and will decrease the award to the institution by the difference between the originally approved amount and the amount to be accrued at the new rate.

Both to initiate funding and for continuation funding of existing awards, the Program requires a copy of the institution's current indirect cost agreement annually.

University of California Campuses

In accord with University of California policy, investigators who are University employees and who receive any part of their salary through the University must submit applications and proposals through their campus contracts and grants office ("Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University," Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the investigator is employed.

Fraud and Scientific Misconduct

Policy Regarding Scientific Misconduct

The University of California manages the California CBCRP, Tobacco-Related Disease Research Program (TRDRP), and the California HIV/AIDS Research Program (CHRP) within its Special Research Programs in general accord with the policies and procedures employed by the National Institutes of Health (NIH), including those that apply to scientific misconduct. The Department of Health and Human Services' (HHS) Office of Research Integrity is responsible for implementing HHS regulations regarding scientific misconduct in research conducted with NIH and other support from the US Public Health Service.

The administrative actions imposed by HHS include the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; prohibition against service on PHS advisory committees or as a consultant; and, debarment from receipt of Federal funds. These actions are for a specified duration, depending on the nature and seriousness of the misconduct.

Applicants for or recipients of funding from the Special Research Programs (SRP) must promptly inform the University of an administrative action for scientific misconduct that is imposed by HHS by providing a copy of the final notice of the administrative action (i.e., after the disposition of any appeal), either at the time of application or within 30 days of the imposition of the administrative action. In general, the University will apply the same administrative action. For example, if HHS has debarred an investigator from applying for or receiving NIH awards for a specified period of time, that investigator would also be excluded from applying for or receiving awards from any of the SRP programs. To take another example, if an investigator has entered into a voluntary agreement with HHS for special oversight and supervision of the investigator's applications, research, and publications, that agreement would apply to that investigator's applications to, or awards from, the SRP.

Applicants or recipients may request that HHS administrative actions be waived or modified with respect to an application or award from the SRP. In such case, the applicant must present a justification for the request.

Fraud or Misuse of CBCRP Funds

Report fraud or misuse of CBCRP funds to either the CBCRP Director, Dr. Marion Kavanaugh-Lynch, at (510) 987-9878, or to the Office of Audit Services, at (510) 987-0478 or www.ucop.edu/audit/.

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.

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, the costs (both direct and indirect), the initiative abstracts, and progress report abstracts. CBCRP uses a variety of media to communicate this information including (i) the "Compendium of research" for each funding cycle, (ii) CBCRP's "Advances" annual report, (iii) CBCRP's e-news, web site, and social media, and (iv) other special communication tools such as press releases. If the Program receives a request for additional information on a funded initiative, 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 application 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.