Request for Qualifications (RFQ)
Science Convener for Program Initiatives

University of California
California Breast Cancer Research Program (CBCRP)

Deadline to apply
March 1, 2016

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California Breast Cancer Research Program
and
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 $262 million in 1,006 projects to over 100 academic institutions and community organizations across the state. With continued investment, the CBCRP will work to find better ways to prevent, treat and cure breast cancer.

CBCPI Priority Areas

In 2004, the CBCRP launched its Special Research Initiatives (SRI). The CBCRP's Breast Cancer Research Council devoted 30 percent of CBCRP research funds to support coordinated, directed, and collaborative research strategies that increase knowledge about and create solutions to both the environmental causes of breast cancer and the unequal burden of the disease.

In March 2010, CBCRP's Council decided to build on the existing Program-Directed Initiative, 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.

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. At the same time, the Council also decided to continue to devote 50% set-aside funds to coordinated, directed and collaborative research strategies over a five-year period (2016-2021) in three topical areas:

1. Identification and elimination of environmental contributors to breast cancer.
2. Identification and elimination of fundamental causes of health disparities, with a focus on breast cancer in California.
3. Development and testing of population-level prevention interventions that incorporate approaches that address the needs of the underserved and/or populations experiencing disparities in the burden of breast cancer.

Science Convener for Program Initiatives

Available Funding

CBCRP is issuing an open Request for Qualifications (RFQ) to fund a PI and her/his team to collaborate with CBCRP to coordinate and implement a planning process for the third phase of the CBCRP's Program Initiatives. This process will build on and be informed by the previous two strategy development processes (SRI and CBCPI). The goal is to provide sound and innovative recommendations to the CBCRP's Breast Cancer Research Council for a new strategy for researching breast cancer disparities and prevention in California.

Up to $1,150,000 in direct costs over five years will be available for this project. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses, which receive indirect costs at a rate of 25%.

Completed responses to this RFQ are due by **March 1, 2016**. The anticipated award period is **June 1, 2016.**

For more information and technical assistance:
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CBCRP Toll free: (888) 313-2277

Project Aims

The aim of this project is to coordinate and support the implementation of CBCRP's strategic planning process that will lead to recommendations for innovative breast cancer prevention research priorities.

Specific questions to be addressed include:

1. What are the most compelling strategies for research into identifying and eliminating environmental causes or exacerbations of breast cancer?
2. What are the most promising research opportunities for identifying and eliminating disparities/inequities in the burden of breast cancer in California?
3. What are the gaps and opportunities for high-impact research on population-level interventions on the prevention of breast cancer?
4. What impacts have the projects from the two previous strategy development efforts had and what opportunities have they created?

5. How can California resources be best used to advance progress in the primary prevention of breast cancer?

Methods and Activities

We anticipate that the PI and his/her team selected through this RFQ will partner with the CBCRP team to coordinate and document a detailed strategy development plan that incorporates the seven (7) activities below.

1. Convene and Support Steering Committee

The awardee will coordinate and support the Initiative's Steering Committee. The Steering Committee will consist of scientists, advocates, and impacted individuals from outside of California, and will be chaired by the CBCRP Director. We expect the committee will include both members of the two previous initiatives' (SRI and CBCPI) Steering Committees and new members.

Minimally, the awardee will support the CBCRP Director and staff to:

- Engage 6-8 Steering Committee members;
- Arrange and coordinate all seven in-person meetings (one per year of the project and an additional two meetings attended by both steering committee members and strategy advisors) and bimonthly teleconference meetings each year, including scheduling, facilitation, setting agendas with CBCRP staff, and recording minutes;
- Coordinate and document all meetings and provide supporting materials for their deliberations and decision-making;
- Coordinate and document strategic planning process infrastructure and logistics (calendar, communications, travel, honoraria, online project management platform e.g. basecamp or sharepoint);
- Assist with the development of the strategy development plan;
- Gather information or data as requested;
- Draft, edit, and produce progress reports and other products determined by the Steering Committee; and
- Coordinate interim materials and work.

The awardee will be responsible for all meeting costs and for compensation (travel and honoraria) of Steering Committee members.

2. Convene and Support Strategy Advisors

The Steering Committee, led by the CBCRP Director, will identify topic area experts, advocates and impacted individuals from both outside and inside of California to serve as advisors. Some members of the previous Strategy Advisors will be invited along with new members, depending upon the expertise, experience, and perspectives needed in the planning process or for a given task. The final selection of the advisors will be determined by the CBCRP Director and staff.

The role(s) and scope of work of the Advisors will be determined and overseen by the Steering Committee. The PI and her/his team will be responsible for supporting the work of the advisors.

Minimally, the awardee will work collaboratively with the Steering Committee (including the CBCRP Director) and the CBCRP staff to:

- Assist in the identification, recruitment and engagement of 30-35 advisors;
- Arrange and coordinate at least five in-person meetings for strategy advisors (three meetings for strategy advisors and an additional two meetings with steering committee members and strategy advisors combined) and any teleconferences, including scheduling, facilitation, setting agendas with CBCRP staff, and recording minutes;
- Document all meetings and provide supporting materials for their deliberations and decision-making;
- Coordinate and document strategic planning process infrastructure and logistics (calendar, communications, travel, honoraria, online project management platform e.g. basecamp or sharepoint);
- Gather information or data as requested;
- Draft, edit, and produce reports and other products on behalf of the Strategy Advisors determined by the Steering Committee; and
- Coordinate interim work.

The awardee will be responsible for meeting costs and for compensation (travel and honoraria) for the Strategy Advisors.

3. Support SRI and CBCPI Projects' Review

The Steering Committee will analyze the preliminary and final results and impacts of the previous two initiatives (SRI and CBCPI) to identify successes and opportunities to continue or build on research efforts. This analysis will be guided by the Steering Committee, which will review the results, identify potential projects, and consult with Advisors to determine how these data will inform future funding.

Minimally, the awardee will support the CBCRP staff to:

- Coordinate and document (through basecamp, sharepoint or similar online project management platform) the work of the Steering Committee and Strategy Advisors in their review of the SRI and CBCPI projects; and
- Coordinate interim work.

4. Assist in Review and Synthesis of Scientific Reviews within the CBCRP Portfolio and within Targeted Scientific Areas

The Steering Committee, in collaboration with CBCRP, will take the lead in gathering and synthesizing recent research findings to update the data that informed the first two phases of the CBCRP's Program-Directed Initiatives (SRI and CBCPI).

Minimally, the awardee will support the Steering Committee (including the CBCRP Director) and the CBCRP staff to:

- Coordinate and document (through basecamp, sharepoint or similar online project management platform) any working groups that are formed; and
- Coordinate interim work.

5. Develop and Implement Community Stakeholder Engagement Plan

The awardee will work with CBCRP staff to ensure that stakeholders and interested communities are informed about the planning process, and have opportunities to provide input. The awardee will assist in the development of the Community Stakeholder Engagement Plan with CBCRP staff to be reviewed by

the Steering Committee. This plan will form the basis of the methods to engage and include stakeholders in the planning process.

Minimally, the awardee will work collaboratively with the CBCRP staff to:

- Support and coordinate a Community Stakeholder Engagement Plan for statewide outreach to scientists, advocates, community members;
- Create collateral materials to engage stakeholders;
- Establish a web-based mechanism for ongoing stakeholder input for periodic review by the Steering Committee members;
- Coordinate and document (through basecamp, sharepoint or similar online project management system) the community stakeholder engagement work;
- Collect and review stakeholder input; and
- Disseminate stakeholder input to CBCRP staff, Steering Committee, Advisors, and other applicable CBCRP stakeholders.

6. Develop and Implement Evaluation Plan

The awardee will work with CBCRP staff to develop an evaluation research design with both process and outcomes measures for this planning process. The awardee will produce an Evaluation Plan with CBCRP staff to be reviewed and approved by the CBCRP Council. Expected elements include, but are not limited to:

- A qualified and experienced evaluation team (either in-house or through subcontract) with at least two individuals designated to collect, analyze and present evaluation progress and findings;
- Detailed evaluation research design;
- Continuous data collection built in;
- Mixed methods approach including surveys, document/portfolio analyses, focus groups and/or one-to-one interviews;
- Appropriate process and outcome metrics for both the strategic planning process and subsequent research projects; and
- Peer review of concept proposals.

Minimally, the awardee will work collaboratively with the CBCRP staff to:

- Create an evaluation plan with an appropriate research design incorporating both process and outcome measures;
- Develop data collection methods and analytic plan to document both process and outcome measures;
- Collect and analyze data;
- Coordinate and document (through basecamp, sharepoint or some other online project management system) the evaluation work;
- Provide quarterly progress reports on evaluation efforts; and
- Develop final report and presentation to Council.

7. Provide Periodic Progress Reports and Decision Documents for CBCRP and Its Council

Beginning in the second year, the Steering Committee, assisted by Strategy Advisors as appropriate, will generate *concept proposals*. These concept proposals will detail focused, innovative ideas for coordinated, directed, and collaborative research projects that address the specific aims of this

initiative. Concept proposals will be presented to the CBCRP Council for their consideration annually, individually or as a package of recommendations from the Steering Committee.

Minimally, the awardee will support the Steering Committee (including the CBCRP Director) and the CBCRP staff to:

- Coordinate and document (through basecamp, sharepoint or similar online project management system) the development of the concept proposals;
- Assist in and coordinate the Steering Committee presentation of the concept proposals to the CBCRP Council; and
- Coordinate interim work.

Terms of Award

This award is being made as a cooperative agreement, an instrument establishing a "collaborative" relationship (in contrast to an "acquisition" relationship) between the CBCRP and the awardee. In this cooperative agreement, CBCRP staff is substantially involved in the program activities, above and beyond routine grant monitoring. Specifically, the CBCRP Director and staff will be active in both scientific and programmatic aspects of the award to facilitate the successful conduct and completion of this project. At the termination of this award, the CBCRP shall retain all products and materials produced under this award.

Awardee Responsibilities

The awardee (PI) will coordinate project activities at the awardee institution and at the other sites that may be supported by sub-contractors to this award. The awardee and her/his staff retain the primary responsibility and dominant role for coordinating and implementing the proposed initiative. The awardee will agree to accept close management and direction of the initiative from the CBCRP as described under “CBCRP Responsibilities.”

Specifically, the awardee will:

1. Coordinate, facilitate, document and convene strategic planning activities for the Steering Committee, Strategy Advisors, advocates and other key CBCRP stakeholders through at least 10 in-person meetings and consistent teleconference calls.
2. Support CBCRP’s scientific and programmatic leadership for the project;
3. Arrange logistics, travel and honoraria for Steering Committee, Strategy Advisors, advocates and other CBCRP stakeholders involved in key strategic planning activities or in-person meetings;
4. Coordinate, facilitate and document activities and other planning processes to develop and finalize the strategic development and community stakeholder engagement plans;
5. Develop and implement an evaluation plan using a mixed methods design, process and outcome metrics to measure success; and
6. Protect the confidentiality and intellectual property rights of any and all research concepts explored during the this strategic planning process; hold confidential the names and institutional affiliations of CBCRP grant applicants and the information contained in grant applications, and otherwise respect intellectual property rights during this project; maintain confidentiality of Steering Committee and review committee deliberations.

CBCRP Responsibilities
The CBCRP will have substantial and active scientific and programmatic leadership and involvement throughout this project. The CBCRP role is to provide scientific direction and guidance, general direction, specific input and be involved in all substantive aspects of the project.

Specifically, the CBCRP will:

1. Have the Director serve as chair of the Steering Committee;
2. Identify and recruit Steering Committee members and Strategy Advisors;
3. Lead, coordinate and approve strategic development, community stakeholder engagement and evaluation plans;
4. Lead and develop concept proposals with Steering Committee, Strategy Advisors and other key advocate and scientific personnel;
5. Coordinate and lead the collection, analysis, and interpretation of data on past SRI/CBCPI grants and activities;
6. Closely monitor project processes, progress and timelines, providing constructive feedback and suggestions as possible;
7. Facilitate communication with the CBCRP Council and provide periodic updates or guidance on Program priorities and their impact on this project; and
8. Provide final approval of all published documents and materials for distribution.

Collaborative Responsibilities
Close interaction between the awardee and the CBCRP will be required. It is anticipated that decisions in all activities will be reached jointly by the awardee and the CBCRP Director, with final recommendations on research strategies to be reached by the consensus of the Steering Committee for review and approval by the Council.

Jointly, the awardee and the Director of CBCRP will:

1. Determine appropriate processes for carrying out the project;
2. Support Steering Committee members and Strategy Advisors; and
3. Set procedures and guidelines for program operations, develop plans for handling all disagreements, and address any issues that arise during the course of the grant.

Budget

It is anticipated that up to $1,150,000 in direct costs is available for this RFQ. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses.

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

- Principal Investigator(s) time
- Project coordinator
- Staffing with evaluation and community engagement expertise
- Staffing with scientific research familiarity
- Meeting and travel expenses (Total amount across five years should be at least $200,000)
- Compensation/honoraria for Steering Committee and Strategy Advisors (Total amount for five years should be at least $300,000)

- Infrastructure expenses (e.g. basecamp or sharepoint) to share and coordinate the work done under this initiative
- Teleconference costs
- Postage, printing, and materials development

NOTE: The successful applicant will not be eligible to apply for awards, receive subcontracts or otherwise be funded under the grants resulting from this process. In addition, the PI will need to make adequate provisions to ensure against real or perceived conflict of interest for their institution and collaborators.

How We Evaluate RFQs

Scientific Review

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

1. Feasibility: Has the investigator(s) identified a project team with the expertise and leadership in coordination, facilitation and evaluation of larger or similar strategic planning and funding priority efforts? Does the team have demonstrated experience and ability to convene and facilitate diverse, high working groups in the successful completion of similar initiatives? Does the team have scientific experience including environmental health, health equities, population-based prevention and communications? Does the team have evaluation and community engagement experience? Does their evaluation plan illustrate their expertise in assessing process and outcome measurements? Has the investigator demonstrated the capacity of resources and staff to undertake the project within the timeframe? Can the team accomplish the identified aims and activities within their proposed timeline and deliverable schedule?

2. Approach: Does the implementation plan demonstrate a clear understanding of the scope of the initiative including specific steps/activities and experts to address each of the Aims for the project? Are the design, methods and analyses well-developed, integrated and appropriate to the aims of the project? Will the approach yield the desired outcomes that reflect the goals and objectives of the RFQ?

3. Impact: Does the investigator or team have experience engaging and disseminating to audiences relevant to this initiative? Will the investigator or team be able to develop an appropriate evaluation plan with high impact potential?

4. Innovation: Are the proposed approaches to the specified steps/activities innovative? Are methods novel and original?

Programmatic Review

This review is conducted by the Breast Cancer Research Council and involves reviewing and scoring applications with sufficient scores from the peer review process based on the criteria listed below. The individuals on the Council performing this review include advocates, clinicians, and scientists from a variety of disciplines. In performing the Programmatic Review the advisory Council evaluates **only a**

portion of the application materials (exact forms are underlined). Pay careful attention to the instructions for each form. The Programmatic criteria include:

- **Responsiveness.** How responsive are the approach and PI to the stated intent of the selected Initiative? Compare the PI's statements on the Responsiveness 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.)

- **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?

Application Process and Instructions

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

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

The application materials will be available on proposalCENTRAL by **December 18, 2016**.

proposalCENTRAL Online Submission Instructions

Formatting Instructions

All submissions must be in **English**.

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

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

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

Online Application (Proposal) Management

The CBCRP requires applications be submitted via an online system: proposalCentral. Following are instructions on how to register and how to submit your response to the RFP. The submission deadline is **12 noon Pacific Time on Tuesday, March 1, 2016.** *Note*: the proposalCENTRAL site

shows East Coast times. Do NOT wait until the deadline to submit your application; if you miss the deadline, the system will not allow you to submit.

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

Online Registration

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

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

Online Forms and Fields

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

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

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

❒ Title Page

On the "Title Page" enter the Project Title in the space provided (do not exceed 60 characters). Enter the total budget amount requested for the project, including indirect costs, if eligible. The projected start date for this project is June 1, 2016. Enter the end date of the project (up to 5 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 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 Tuesday, March 1, 2016.

CBCRP Uploaded Form Instructions

Lay Abstract (REQUIRED)

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

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

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

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.

Responsiveness (REQUIRED)

This item is evaluated in the programmatic review. Limit the text to one page. The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan. The information on this template allows the CBCRP Research Council to rate the application for adherence to the objectives of the CBCPI research area as outlined in the specific RFQ.

Provide a clear, brief summary for the CBCRP Council of how your proposed approach addresses the specific RFQ topic area, by increasing or building on previous strategic development processes; by engaging community stakeholders and by facilitating high impact research strategies.

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, scientific and/or subcontracting individuals/institutions. Limit the text to two pages.

Budget Summary (REQUIRED)

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

The maximum duration and direct costs may not exceed 5 Years and $1,150,000.

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 or Annual meeting (years 1 and 4 only). In addition, meeting-related expenses (including travel expenses for the Steering Committee members and Strategy Advisors) should be at least $200,000 over 5 years.

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). Compensation/honoraria for Steering Committee and Strategy Advisors should be at least $300,000 over 5 years.

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* four (4) pages.

Research Plan (REQUIRED)

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

Page limit: 10 pages
An additional 3 pages is allowed for References.

Format issues: Begin this section of the application using the template. Subsequent pages of the Research Plan and References should include the principal investigator's name (last, first, middle initial) placed in the upper right corner of each continuation page.

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:

I. Preliminary Work

Describe the qualifications for the PI and his/her team in the areas of expertise listed in the Evaluation criteria. Provide details about work conducted by the investigator and key staff that is similar and relevant to this initiative. Elaborate on PI and staff experience facilitating processes that include a wide variety of collaborators, particularly scientists, clinicians, advocates and affected communities.

II. Initiative Plan

Provide an overview of your understanding of the initiative and research questions, and your plan to carry out the activities detailed in the Methods and Activities section above. Describe in detail your approach and steps to coordinate a complex strategic planning process, including who would coordinate and complete the methods and activities.

Be sure to discuss in detail your ideas for the evaluation plan, including how you would propose to develop and implement the evaluation plan.

Discuss potential obstacles in your approach and which methods will be used to overcome them.

III. Community Involvement and Communication

Provide a detailed description of how you will contribute to the engagement of advocates and other stakeholders to ensure their input into the development of new research strategies.

IV. Resources and Facilities

Briefly describe the resources, systems and facilities to be used at the applicant organization. Indicate the range of staff expertise to be utilized: their capacities, relative proximity and availability. Describe any external resources to be drawn on, including any contractual or other arrangements regarding these resources or facilities.

Human Subjects (OPTIONAL)

This item is evaluated in the peer review. **This form is required only for applications that use Human Subjects, including those in the "Exempt" category. Use additional pages, if necessary. For applications requesting "Exemption"** from regular IRB review and approval please provide sufficient information in response to item #1 below to confirm there has been a determination that the designated exemptions are appropriate. The final approval of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB).

Documentation must be provided before an award is made. Research designated exempt is discussed in the NIH PHS Grant Application #398 http://grants2.nih.gov/grants/peer/tree_glossary.pdf. Most research projects funded by the CBCRP falls into Exemption category #4. Although a grant application is exempt from these regulations, it must, nevertheless, *indicate the parameters of the subject population* as requested on the form.

For applications needing full IRB approval: If you have answered **"YES"** on the Organization Assurances section of the CBCPI Application Face Page and designated no exemptions from the regulations, the following **seven points** must be addressed. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s), provide this information before discussing the seven points. Although no specific page limitation applies to this section, be succinct.

1. Provide a detailed description of the proposed involvement of human subjects in the project.
2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of

California, and the CBCRP that research involving human subjects must include members of underserved groups in study populations. Applicants must describe how minorities will be included and define the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated.

3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.
4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent.
5. Describe any potential risks —physical, psychological, social, legal, or other. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
6. Describe the procedures for protecting against, or minimizing, any potential risks (including risks to confidentiality), and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also, where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.
7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects, and in relation to the importance of knowledge that may be reasonably expected to result.

Documentation of Assurances for Human Subjects

In the appendix, if available at the time of submission, include official documentation of the approval by the IRB, showing the title of this application, the principal investigator's name, and the approval date. Do not include supporting protocols. Approvals obtained under a different title, investigator or organization are *not* acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, an USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible, but **no later than June 1, 2016.** Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

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

Vertebrate Animals (OPTIONAL)

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

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

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

Documentation of Assurances for Vertebrate Animals

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

Appendix List (OPTIONAL)

Follow the instructions and items list on the template. **The appendix may 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 30, 2016. The written application critique from the review committee, the merit score average, component scores, percentile ranking, and programmatic evaluation are provided at a later time. Some applications could be placed on a 'waiting list' for possible later funding.

Appeals of Funding Decisions

An appeal regarding the funding decision of a grant application may be made only on the basis of an alleged error in, or deviation from, a stated procedure (e.g., undeclared reviewer conflict of interest or mishandling of an application). Details concerning the appeals procedure may be obtained from the appropriate Research Administrator (with whom the applicant is encouraged to discuss his/her concerns), the CBCRP Director, or by contacting us through the CBCRP Web site: www.cabreastcancer.org/. The period open for the appeal process is within 30 days of receipt of the application evaluation from the Program office. Contact the CBCRP to obtain full information on the appeals process.

Final decisions on application funding appeals will be made by the UCOP Research Grant Program Office (RGPO) Executive Director Dr. Mary Croughan. Applicants who disagree with the scientific review evaluation are invited to submit revised applications in a subsequent grant cycle with a detailed response to the review.

Pre-funding Requirements

Following notification by the CBCRP of an offer of funding, the PI and applicant organization must accept and satisfy normal funding requirements in a timely manner. Common pre-funding items include:

- Verification of Principal Investigator status from an appropriate institutional official.
- Documentation of 501(c)(3) non-profit organization status for the organizations.
- Documentation of the DHHS-negotiated (or equivalent) indirect cost rate for non-U.C. institutions.

- Supply up-to-date documentation for approved indirect rate (F&A costs) agreements as of the grant's start date and any derived calculations, if applicable.
- Supply any missing application forms or materials, including detailed budgets and justifications for any subcontract(s).
- IRB applications or approvals pertaining to the award.
- Resolution of any scientific overlap issues with other grants or pending applications.
- Resolution of any Review Committee and Program recommendations, including specific aims, award budget, or duration.
- Modify the title and lay abstract, if requested.

Open Access Policy

As a recipient of a California Breast Cancer Research Program (CBCRP) grant award, you will be required to make all resulting research findings publicly available in accordance with the terms of the Open Access Policy of the Research Grants Program Office (RGPO) of the University of California, Office of the President (UCOP). This policy, which went into effect on April 22, 2014, is available below:

RGPO Open Access Policy

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

Scope and Waiver (Opt-Out)

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

Deposit of Articles

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

Grant Management Procedures and Policies

Details concerning the requirements for grant recipients are available in a separate publication, the University of California, Office of the President, "RGPO Grant Administration Manual." The latest version of the Manual and programmatic updates can be obtained from the Program's office or viewed on our Web site: http://www.ucop.edu/research-grants-program/grant-administration/index.html.