

INFORMATION AND INSTRUCTIONS COMMUNITY RESEARCH COLLABORATION (CRC) PILOT AND FULL AWARDS OPTIONAL PRE-APPLICATION RESEARCH PLAN REVIEW

Optional Research Plans Due: October 24, 2016

Deadlines:

Research Plan submission: October 24, 2016 Critiques returned to applicants: December 15, 2016 Full application submission deadline: March 2017

Submission guidelines and procedure:

- Read the guidelines contained in this document for what is included in a CRC research plan.
- Download the template form for your research plan submission: research plan template form (doc)
- Two components in the template that you must submit:
 - Cover page that must include:
 - The title of your project
 - The full names, titles, mailing addresses, phone numbers and email addresses of all of the principle investigators on the project
 - Any specific questions about the research plan that the reviewers should consider
 - Research plan, that:
 - Must be written in English
 - Is single spaced
 - Has page margins of at least ½ inch
 - Cannot have font size smaller than 11 point
 - Cannot be longer than 10 pages for a Pilot Award and 15 pages for a Full Award (references are not included in the page limit)
- The cover page and research plan must be converted into a single pdf file before submitting
- To submit your research plan for review, please send an email to <u>Senaida Poole</u>, Ph.D., with a copy of your pdf file that includes the cover page and research plan.

Please note: The critiques should be taken as **technical advice only** and will not be considered in the formal review of the application.

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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 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 \$7 million for breast cancer research and funded more than 45 grants
- Ninety-five percent of our revenue goes directly to funding research and education efforts
- The revenue is used to make grants for California scientists and community researchers to find better ways to prevent, treat and cure breast cancer
- The CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, the CBCRP has awarded 939 grants to 107 scientific institutions and community entities, totaling \$230 million for research in California to prevent, treat, and cure breast cancer.

Our Community Research Collaboration (CRC) awards bring community members and experienced research scientists together to study breast cancer-related issues that are of interest to both. The CRC award, developed in 1997, requires a partnership between community members (such as a breast cancer advocacy organization, a community clinic or organization serving women with breast cancer, or a member of a California community affected by breast cancer) and experienced research scientists. The partnership works together to identify the research question, develop the research plan, carry out the research, interpret the results, and disseminate information to the community.

CBCRP PRIORITY AREAS

The following four CBCRP priority areas define our critical research needs. CRC award applications must identify a priority issue addressed by the study. Detailed explanations of these areas can be found in the "CBCRP Call for Applications".

1. The Community Impact of Breast Cancer: The Social Context

- Health Policy and Health Services: Better Serving Women's Needs
- Socio cultural, Behavioral, and Psychological Issues Relevant to Breast Cancer: The Human Side
- Disparities: Eliminating the Unequal Burden of Breast Cancer

2. Etiology and Prevention: Finding the Underlying Causes

- Etiology: The Role of Environment and Lifestyle
- Prevention and Risk Reduction: Ending the Danger of Breast Cancer

3. Biology of the Breast Cell: The Basic Science of the Disease

- Biology of the Normal Breast: The Starting Point
- Pathogenesis: Understanding the Disease

4. Detection, Prognosis, and Treatment: Delivering Clinical Solutions

- Imaging, Biomarkers, and Molecular Pathology: Improving Detection and Diagnosis
- Innovative Treatment Modalities: Search for a Cure

AVAILABLE FUNDING

The CBCRP has set aside \$2 million to fund two types of CRC awards:

- The **CRC Pilot award** is for a maximum of \$150,000 in direct costs for an 18month project. Indirect costs, over the direct cost limit, are also available. The Pilot award supports the initial phase of the project, including feasibility of methods, strengthening collaborations, development of tools and methods, and collecting pilot data. Budgets will be carefully scrutinized for appropriateness to the work proposed.
- The **CRC Full award** is for a maximum of \$600,000 in direct costs for a threeyear project. Indirect costs, over the direct cost limit, are also available. The Full award is for projects with a fully developed research plan with supporting preliminary data, carried out by a well integrated team of scientific and community members with a previous work relationship. Typically, the application is to support the completion of the research plan developed and initiated during the Pilot award. Although a previous Pilot award is not a requirement for the Full award application, based on our experience, a Pilot project is strongly recommended as preparation for the Full award. Budgets will be carefully scrutinized for appropriateness to the work proposed.

CRC AWARDS

About the Community Partner

For the purposes of the CRC application, "community" is defined as a group of people who share some common element – such as geography, age, gender, culture, disease status or risk, race, ethnicity, sexual orientation, disability or socio-economic status. In traditional community/researcher collaborations the individuals who will be the "research participants" are included as partners in planning and conducting the research. Therefore, for the CRC Awards those individuals who will be "researched" must be included on the research team or community-advisory board for the purposes of developing, conducting, analyzing, and reporting on the research and research results. A formal or informal community group must be named as either the applicant/PI or Collaborating Institution on ProposalCENTRAL. The community organization is required to appoint a co-principal investigator ("co-PI") for CRC awards. This individual represents the community organization and acts as the lead community researcher. If the Community co-PI leaves the community agency he/she is representing, the research project will remain the responsibility of the community organization. The community group would then work with the Scientific Researcher co-PI and CBCRP to replace the person designated as Community co-PI.

Award Purpose

The CBCRP believes that communities should actively participate in research about issues that concern them. They should take part in deciding which issues are important and how to study them, in gathering and interpreting data, and in communicating findings with other community members, the scientific community and the public at large. The CBCRP also recognizes that sound research needs the expertise of well-trained and experienced research scientists for the results to be reliable and applicable to other communities. By combining the knowledge and interest of communities with the expertise and resources of research scientists, we aim to fund innovative and important research that will reduce the impact of breast cancer.

Who can Apply

A team consists of individuals representing at least one California-based community organization (formal or informal), lay community members (including patients, clients, or interested persons), and at least one experienced scientific researcher (working in an appropriate discipline or setting). The community organization must identify one member who will act as the community "Co-Principal Investigator" for the purposes of the study. This partnership must work together in all phases of the collaborative research project, including:

- identifying the problem and formulating the research questions
- writing and submitting the application
- designing and carrying out the research
- analyzing the research findings
- preparing reports to the CBCRP
- disseminating the results to both community and scientific audiences

Evidence of the participation of broad community involvement throughout the entire proposal and proposed project MUST be present.

Kinds of Projects we Fund

You may apply for an award addressing any breast cancer issue that has been identified by your community as important, that is consistent with CBCRP priorities, and will add to our knowledge about how to have an impact on the problem of breast cancer. You must be able to express the issue you have identified as a well-defined research question. For example, you could test whether a certain health service improves a woman's quality of life, but we would not fund research to simply evaluate whether you provided that service in a timely, efficient manner. Research in any of CBCRP priority areas is appropriate for a CRC award. Examples of recent funding include:

New methods of dissemination of information about breast cancer (including state-of-the-art technologies).

• The Northern Sierra Rural Health Network and Stanford University are testing the use of videoconferencing to improve psychosocial support for women with breast cancer.

New methods to improve patient support at diagnosis, treatment, recurrence, and in clinical trials (such as psychosocial support, provider networks, etc.).

• Santa Cruz's WomenCARE and Stanford University are evaluating whether peer

CRC Optional Pre-Application Research Plan Review Information navigators improve quality of life at diagnosis.

- The San Joaquin Valley Health Consortium and California State University, Fresno are identifying barriers faced in going from abnormal screening to treatment.
- The Mendocino Cancer Resource Center, the Humboldt Community Breast Health Project, and the University of California, San Francisco, are studying whether a treatment decision-making aid previously used in an urban hospital setting among a mostly white population can be successfully used as a telephone intervention for a diverse rural community.

Note: the CBCRP does not generally encourage proposals that solely focus on increasing primary screening (i.e., mammography).

Considerations in Community Based Participatory Research (CBPR)

Following is a list of items to consider for conducting community-based participatory research. Please note that these are items for your team to consider and discuss with each other.

- Who/what is the "community"? How is it defined? An ideal model is CBPR which involves all levels of the organizational staff, as well as representatives of the clientele served and the community from which the clientele come. Community can be defined as any group of individuals sharing a cultural, racial, ethnic, social, [political, health interest, distinct geographical locations, or other aspect of community life]. Community can also be entities such as health care providers, services agencies, businesses, churches, etc.
- Did the community identify the research issue? If not (and it was identified by the research partner), it is crucial for the team to demonstrate strong community interest and participation in all other phases of the research.
- How is the community involved in all stages of the research process (conceptualization, development, implementation, analysis, dissemination, mentorship, and training)? It may not be possible for the community to be involved in all phases but it is important to note reasons and justification for this lack of involvement.
- Has (or how will) both the research and community partners' knowledge been integrated into planning the research?
- Is there mutually beneficial learning for the community and academic partners? Identify specific areas of such learning.
- Is there community empowerment and capacity enhancement through the research process? Identify specific areas of such empowerment and capacity enhancement.
- Is there a Community Advisory Committee/Board, especially chaired by a community member, and with participation of the academic partner?
- Is there equity in budget distribution between the academic partner and community partner?
- Is there equity of control and participation by the community and research partners?
- Is there equity in roles and responsibilities for the community and academic partner?
- Is there a conflict resolution mechanism in place to resolve disagreements?

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- How will the community participating in the project and the larger community (as represented by those participating in the project) benefit from the research outcomes?
- How long has there been partnership between the academic and community partners? Is this a new partnership or an existing partnership? Is the partnership stable, interactive, and balanced?
- What are the existing skills and experience (research for community partner and community for research partner) and resources (community and academic) available for the project?

REVIEW OF CRC RESEARCH PLANS SUBMITTED FOR OPTIONAL REVIEW

Those who submit research plans will receive up to two reviewer's comments, with suggestions for improvement. Reviewers for this optional exercise are individuals from outside of California, and are scientists from relevant disciplines, including scientists who are experts in community-based or participatory research. The CBCRP staff is available to explain the feedback and assist applicants in understanding how to in improving their research project or for future applications.

The reviewers evaluate each research plan using four criteria: Quality of the Research, Feasibility, Partnership, and Community Benefit. Scientific Merit and Collaboration Elements are weighted equally.

Scientific Merit for CRC Applications		
 Quality of the Research The scientific importance of the research questions, including consideration of the most relevant literature and whether results with the population being researched will apply to other populations The appropriateness and integration of the conceptual framework, research methods, and data analysis plan to the research question and aims The strength of the research plan to answer the research questions. 	 Feasibility The extent to which the project can be successful given the partners knowledge, skills, resources, and experience The likelihood of completing the project as proposed given the available funding and time frame For Full awards: The usefulness (validity and/or importance) of data from previous research for the proposed research plan 	
 Partnership (Collaboration Element) Plans for the equality of control and participation by both partners in all phases of the research project The level to which both partners' knowledge is integrated into planning the research The extent to which agreements have been reached regarding procedures for resolving disagreements among collaborators, ownership of data, and 	 <u>Community Benefit (Collaboration</u> <u>Element)</u> The clarity of definition of the target community for the research How the community has been involved in the development of the research idea and the writing of the application Plans for how the broader lay community will be involved in the research project during the course of the research, from helping to 	

CRC FORMATTING REQUIREMENTS AND IMPORTANT REMINDERS

Formatting Requirements

All application contents must be in English.

Follow these format requirements for submitted written text:

- The height of the letters must not be smaller than 11 point. Times New Roman or Arial are the suggested fonts.
- Line spacing is single spaced.
- Page margins, in all directions, must be at least ½ inch.

Important Reminders

Technical Assistance is Available: For many community groups and scientists, collaborations of this type are new and a bit confusing. Community groups may also be unfamiliar with the scientific research award process. Please feel free to contact Senaida Poole, Ph.D., at (510) 987-0491 or Toll Free (888) 313-2277 or email at <u>CRCinfo@cabreastcancer.org</u> to request technical assistance. Our staff is not involved in the scoring process; any questions you ask will not affect the evaluation of your application in any way.

RESEARCH PLAN: INSTRUCTIONS

Principal Investigators

Both co-principal investigators' names (last name, first name, middle initial) must be printed in the upper right-hand corner of every page.

Page Limits

For CRC research plans, limit the pages to:

- Pilot Award: Ten Pages
- Full Award: Fifteen Pages

Page limits are exclusive of bibliographical references, which should follow the research plan.

Concise and Focused Research Plan

We ask that you describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and collaboration elements (see content in "Recommended Format" below). If you don't use all the pages to describe your research plan, it might be best to review what you have written and explain in more detail anything not fully explained. However, note that a concise, focused research plan of less than the maximum number of pages is preferable to one less concise and made longer by overly elaborate or unimportant details.

In the actual application (but not in the research plan submitted for this exercise) supporting materials (such as questionnaires, consent forms, interview questions, letters of collaboration) that are directly relevant to the proposal may be included in the Appendix. Remember that the research plan must be self-contained and understandable without having to refer extensively to supporting materials.

Recommended Format

For both CRC Pilot and CRC Full research plans, the recommended format is as follows:

1. Statement of Goals, Research Questions, and Specific Aims

For Pilot applications: In a short paragraph, describe goals for the Pilot award in light of the long-term research goals. Describe how the Pilot, if awarded, will be used to prepare the collaborative team to pursue further research and to apply for a CRC Full Research award or funding from another agency. State the goals and research questions for the Pilot award. Follow with the Specific Aims—the specific tasks that will be undertaken to address the question(s). These should have a logical connection, and you need to make clear their relationship to the team's long-term research goals. Do not include tasks that you expect to undertake in the CRC Full Research award project or with future funding from another agency.

For Full Research applications: Briefly state the research question(s) and hypothesis for the Full Research award. Follow with the Specific Aims—the specific tasks that will be undertaken to address the question(s). These tasks should be very clearly defined and should not include exploratory or development undertakings. The research questions, hypothesis, and aims should have a logical connection.

2. Background and Significance

Concisely describe the rationale underlying the proposed research; the hypotheses to be investigated; the methodology to be employed; and the experience, knowledge, and skills of the research team. Emphasize positioning the research in the context of existing relevant scientific literature and preliminary data that the team may have collected in preparing for the research. Demonstrate a grasp of the current state of the knowledge relevant to the problem. Provide up-to-date references, acknowledge controversies and contradictory reports, and be comprehensive and accurate. If there is little literature on the topic, draw on information from related fields. Demonstrate the community interest, participation in the plan development from the beginning, and the potential contribution of the proposed research. Briefly state the long-term potential of the research: the problems, issues, or questions which, through the execution of this award, can be further developed, specified, and sharpened into testable hypotheses;

CRC Optional Pre-Application Research Plan Review Information and the methodologic approach (or possible approaches that seem at present most appropriate to be used). Keep discussion of the general problem of breast cancer brief; emphasize the specific problem addressed by your research proposal.

Preliminary Data (Required For Full Application)

Describe in detail the work you performed during the Pilot award, if any, or present relevant data or supporting information. Include a description of different approaches taken, and the results obtained with each approach to justify applying for the Full Research award. Present any data obtained in detail, with a description of how the data was obtained and analyzed. Describe any pitfalls or problems that arose, as well as how they were overcome. Provide justification and support for: (1) the hypothesis and assumptions; (2) the research design; (3) the potential for useful knowledge and/or products to result from the research.

3. Research Methodology: Research Design, Conceptual Framework, and Data Analysis

Describe in detail the exact tasks listed in the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. For instance, if women are to be surveyed, explain how many women will be surveyed; why you chose this number; how the women will be identified and recruited; why you believe you will be able to reach and recruit this many women; what questions you will ask them; whether you will use face-to-face or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline. Be sure to include a hypothesis and conceptual framework.

4. Partnership Collaboration Plan and Community Benefit

Begin this section by describing the community of interest for this study. Is the community distinct because of geography, age, gender, associated by disease status or risk, race, sexual orientation, or socio-economic status? Describe the interest of the community in the research question and how they have participated in identifying it. Discuss the importance and benefit to the community of the research question and expected outcome. Specifically answer how the broader community of interest was involved in developing the research proposal.

Describe the relationship between the community co-PI and their community organization and the community of interest. How will the community of interest be included on the research team? Discuss how the leadership of the community organization (the Executive Director, the Board of Directors, or the individuals of an informal organization) will ensure that the organization or group is committed to the research project? Describe how the Community Co-PI and the community organization will communicate with one another to facilitate input and decision-making.

Describe in detail the plan for carrying out the collaboration. Describe your specific collaboration plans, including how and when the partners will interact; what the specific roles and responsibilities of each partner will be through each step of the research process; how all members will be brought into the design, data analysis, and decision-

CRC Optional Pre-Application Research Plan Review Information making process. Briefly summarize collaborative agreements described in more detail in the Collaborative Agreements Form: ownership of data, handling disagreements, how grant funds will be handled; and plans for dissemination of results.

Discuss how participating in this research project will build capacity for the community organization (such as through developing research/evaluation skills, answering a question important to the organization, having policy impact, improving programs, etc).

5. Statement of Future Goals

For Pilot applications: Begin with a brief discussion of the long-term research goals of the team, as well as a description of the work the team would like to pursue with a CRC Full Research award or funding from another agency after completing the preliminary research funded by the Pilot award. Be as specific as possible about future research plans.

For Full Research applications: Begin with a brief discussion of the expected outcome of the proposed research. Describe how the research, if awarded, will result in benefit to the community and beyond— what new knowledge will be obtained and how will this knowledge reduce the human and economic costs of breast cancer?