COMMUNITY RESEARCH COLLABORATION (CRC) INFORMATION AND APPLICATION INSTRUCTIONS
PILOT AND FULL AWARDS

Applications Due: March 12, 2015, at 12 Noon Pacific Standard Time

Deadline #1: Electronic submission: the deadline for the complete application (all required uploaded PDF and other forms and the required data (web page) information is Thursday **March 12, 2015** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL's Web site)

Deadline #2: Face Page submission with signatures:

- Print your application's Face Page from proposalCENTRAL and obtain the necessary signatures (PI and institutional signing official are required).
- E-mail a scanned copy as a PDF attachment to: rgpogrants@ucop.edu before 5 pm (Pacific Standard Time) by Thursday March 19, 2015.

Funded Project Start Date: September 1, 2015

Note:

1. **Other key information**: refer to CBCRP's Call for Applications PDF document (also downloadable from proposalCENTRAL).
2. **Submission of Additional Materials.** No supplemental application materials (e.g., manuscripts or publications) will be accepted after the March 12 deadline, unless explicitly requested and approved in advance by the CBCRP.

Table of Contents

ABOUT CBCRP AND CRC AWARDS

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 18-month 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 three-year 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.

RESUBMISSION GUIDELINES

Teams are eligible to submit revised applications from any previous grant cycle. Teams can make any changes in their resubmission that they see fit (including changing one or both co-PI's, the title, or the aims). Resubmissions should include a two page form that includes 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. We also recommend emphasizing in the Research Plan any relevant work done since the previous application.

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.

Following is a list of items to consider for conducting community-based participatory research (CBPR). Please note that these are items for your team to consider and do not have to be explicitly addressed in the application instructions.

- 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?
- 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?

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

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).

REVIEWING CRC APPLICATIONS

Please review the section "Application Evaluation" in the CBCRP General Application Requirements & Award Conditions for changes in the review process.

It is a combination of, (i) the average and individual components of the scientific and collaboration ratings in the peer review, (ii) the programmatic rating, and (iii) available funding, that determines a decision to recommend funding.

Peer Review

All CRC applications are evaluated by a peer-review committee of individuals from outside of California. The committee is comprised of scientists from relevant disciplines, including scientists who are experts in community-based or participatory research and breast cancer advocates and other community representatives.

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

The review committee evaluates each application using the four criteria: Quality of the Research, Feasibility, Partnership, and 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 dissemination of the results • The potential for capacity building for any or all of the partners. • *For Full awards*: Demonstrated successful collaboration in previous research projects	Community Benefit (Collaboration Element) • 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 conceptualize the research question through dissemination of results • The potential importance and benefit to the broader lay community of the research question and expected outcomes • The potential for the research project to facilitate learning and further collaboration. • *For Full awards*: The plan for translating the results into tangible benefits for the community and for informing the community of the results of the research.

Some applications with low preliminary scientific merit scores will be "triaged" and not receive a full committee discussion and final scores. However, all applications will receive written feedback from the peer review via a detailed "evaluation summary" document. The CBCRP staff is available to discuss the evaluation summary.

Programmatic Review

This independent review is conducted by the Breast Cancer Research Council and involves reviewing and scoring applications with sufficient scientific and collaborative 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 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:

- **Response to priorities.** How responsive is the proposed research to CBCRP priority issues? [The Council will compare the co-PI's statements on Program Responsiveness, top section) and the content of the abstracts to the CBCRP priority issues and examples.]
- **Response to award type.** How responsive is the project to the stated intent of the selected award type? [The Council will compare the co-PI's statements on Program

Responsiveness, bottom section, to the CBCRP award type criteria.]

- **Dissemination and Translation Potential.** The degree to which the research and community collaboration, if successful, have the potential to be more broadly distributed and applicable to other communities and the general California population. [The Council will inspect the Additional Criteria form.]
- **Underfunded.** The degree to which the PI on Distinction from Other Funding has highlighted the unique aspects of the proposed research from their own projects (past and present) and the research by others. Is the research relatively underfunded by other agencies, or not funded?
- **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 breast cancer understandable?
- **Addressing the needs of the underserved.** Do the project and the co-PI's statements on Additional Criteria demonstrate how this research will address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive limitations, age, occupation and/or other factors)?
- **Advocacy inclusion.** Do the co-PIs express sensitivity to and awareness of the existing and potential human issues involved in the research and the concerns of breast cancer advocates? More specifically, have advocates from the appropriate community been engaged and involved in the development of the research questions, design of the project, and/or plans for conducting the research? Have the co-PIs committed themselves to be proactive in disseminating the research to the lay audience? [The Council will examine the co-PI's statements on the Additional Criteria form.]

Note:

1. **Basis for funding decisions.** It is a combination of, (i) the programmatic rating, and (ii) strengths and weaknesses in both the average scientific merit and individual components.
2. **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 CBCRP Program Officer (with whom the applicant is encouraged to discuss his/her concerns), the CBCRP Director, or by contacting us through the CBCRP Web site: www.cbcrp.org/. All appeals must be put in writing to the Executive Director of the UCOP's Research Grants Program Office, Dr. Mary Croughan, **within 30 days of receipt of the application evaluation** from the Program office (see Section 5 (Dispute Resolution) of our Grants Administration Manual for more information). Final decisions on application funding appeals will be made by the Vice President of Research and Graduate Studies of 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.

CRC FORMATTING REQUIREMENTS AND IMPORTANT REMINDERS

Formatting Requirements

All application contents must be in **English**. Follow these format requirements for submitted written text, which are consistent with the NIH's 398 form instructions:

- 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, and must no more than 6 lines of type within a vertical inch.
- Type density, including characters and spaces, must be no more than 15 characters per inch (cpi)
- Page margins, in all directions, must be at least ½ inch.

Deviations from the page format, font size, specifications and page limitations, especially the page limit for the Research Plan, will be grounds for the CBCRP to reject and return the entire application without peer review.

Important Reminders

- When preparing your application on proposalCENTRAL be sure to use the "validate" function early and often to see whether all required submission items are entered.
- Each co-PI must be registered with proposalCENTRAL (see Application Template and Form instructions) and must select an institution with a tax ID (EIN) number in the Proposal Section called "Institution & Contacts." In addition, the "signing official", "contracts & grants official", and "fiscal contact" must be registered with proposalCENTRAL prior to submission so they can be selected from the pull down menu for each institution.
- Other Documents Necessary to Review Prior to Submission: CBCRP Call for Applications– – pertains to all award types
- In the fall of each year (September-October), we offer an optional pre-application review of the research plan for those teams wishing to receive feedback prior to the actual application submission. Please email *CRCinfo@cabreastcancer.org* for more information about this optional review.
- Technical Assistance is Available: For many community groups and scientific researchers, collaborations of this type are new and a bit confusing. Community groups may also be unfamiliar with the scientific research award process and the online application submission system. Please feel free to contact Senaida Poole, Ph.D., at (510) 987-0491 or Toll Free (888) 313-2277 or email at CRCinfo@cabreastcancer.org 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.

CRC APPLICATION TEMPLATE AND FORM INSTRUCTIONS

There are two types of forms on ProposalCENTRAL for the CRC applications –

- **Templates and Data Fields.** These are the pre-formatted data (Web) pages on the proposalCENTRAL website that are listed in the application section in a column called "Proposal Sections." See "Templates and Data Fields" section below.
- **Downloadable Forms.** These are the individual forms that you must download to your computer, complete, and then upload back to your application in PDF format. They are available to download on the proposalCENTRAL website in Proposal Sections #2 and #10 (see "Templates and Data Fields" section below) .

INSTRUCTIONS: Templates and Data Fields

Once you open your application on proposalCentral you will see a grey box on the left side of

the screen with items (corresponding to items described below). These template pages will walk you through your application process.

1) Title Page

Each team will submit a single JOINT application. Your partnership should discuss and decide together which of the co-PIs will formally submit the application via proposalCENTRAL. This person will be designated as the Applicant/PI for the purposes of submission of the application. However, both co-PIs will be equally acknowledged throughout the review and feedback process.

The individual being designated as the Applicant/PI should log onto proposalCENTRAL first to begin the submission process.

Once logged on, that person should select the "Grant Opportunities" (gray) tab on the top of the page. Open up the filter, scroll down to California Breast Cancer Research Program, and sort the application by that funder. All of the funding opportunities for CBCRP will be showing. Choose the application (Pilot or Full) you are intending to submit to and click on the "Apply Now" link at the far right of the line.

On the "Title Page" enter the name of your application in the space "Project Title" and click "Save". Once saved, click "Next".

Enter the appropriate "Application History" category "No" or "Yes" from the drop-down menu and put the year of prior submission if this is a reapplication.

Enter the appropriate "Award Budget Option" from the drop-down menu.

The Award Budget Option should be used to identify whether a single institution will receive the full award (and pay directly or subcontract to others) or whether multiple institutions will receive awards.

2) Download Templates & Instructions

All Instructions and downloadable forms are available on this page.

3) Enable Other Users to Access this Proposal

Click on "Enable Other Users to Access this Proposal" (#3 on the left side in the gray box). Read this page thoroughly to understand the different levels of access you can grant others to your application.
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 application (they should all have completed the registration process prior to being enabled) and then click "Find User."

Select "View," "Edit," or "Administrator" for the level of access they will have.

You must include your Collaborating Investigator (co-PI) as "Enabled" to access the proposal.

Click "Accept Changes" to save this page.

4) Applicant/PI

Click on "Applicant" (#4 on the left side in the gray box) and make sure that all required fields are complete. Click "Edit Professional Profile" to enter any missing data.

Not all blank data fields are required to submit your application. Use the "Validate" function (described below), which will show you which, if any, fields are missing that are required.

Click "Return to LOI/Proposal" after entering missing data.

Click "save."

5) Applicant Institution and Other Contacts

Click on "Applicant Institution" (#5 on the left side in the gray box) and make sure that all required fields (identified with a red asterisk) are complete, including the Signing Official and Fiscal Contact for the applicant institution.

To complete Signing Official and Fiscal Contact fields enter the email address of the individuals in those roles and click "Add."

Review the "Contact Screen - Applicant Institution" page to make sure that all required fields (identified with a red asterisk) are completed.

Click "Save".

Then click "Close Window".

If you click "Edit Institution Profile" to complete any blank fields, you do not have to complete any fields below the line "Please provide the following institution information, if applicable." at this time.

Click "save" then "Return to LOI/Proposal" at the top of the page.

Then click "save" on the Applicant Institution page.

6) Collaborating Investigator & Contacts

Now click on "Collaborating Investigator(s) & Contacts" (#6 in the gray box on the left side of the page.)

On this page you MUST add the Collaborating Investigator (whichever co-PI is not listed as the Applicant/PI.) You must also add the Signing Official and the Fiscal Contact for the Collaborating Investigator's Institution (even if they are the same person or the same person as the Collaborating Investigator). These are the individuals who are authorized to sign contracts on behalf of their institution and can be contacted regarding fiscal matters on behalf of their institution. In a nonprofit agency the co-PI, Signing Official, and Fiscal Contact may be the same person (i.e., the executive director). You must still list that person three times and identify all three of those roles.

When you are adding the co-PI, Signing Official, and Fiscal Contact for the Collaborating Investigator(s) you will need to follow these steps:

Type in the email address (twice) for one of the individuals at the bottom of the form and click "Add".

The "Contact Screen – Collaborating Institution(s) & Contacts" screen will open. If they have already registered with proposalCENTRAL, their information will be listed. If they are not already registered with proposalCENTRAL, complete as much information as you know. ProposalCENTRAL will send them an email with information on how they can complete their registration and Professional Profiles. Choose their role with your project: Collaborating Investigator, Signing Official, or Fiscal Contact. Any field marked with a red asterisk "*" is required. Make sure those fields are filled in. Confirm the information and hit "Save" then "Close Window."

If you will have more than two co-PI's, repeat this step for the additional co-PI's.

DO NOT add others who will be working on your project (research staff, support personnel, etc.). Instead, list other project personnel on forms available in the Proposal Section.

7) Abstracts

Copy both Lay and Scientific abstracts for your project from the corresponding forms shown in "Research Plan and Other Attachments." Add three (3) key words to describe your project. Then, select the CBCRP priority issue that best matches your project from the menu.

Finally, add the CSO coding. The CSO coding scheme is presented in the Web site: www.cancerportfolio.org/cso.jsp. There are seven major CSO categories, and each of these is divided into 4-9 sub-categories. Choose a major heading under which you think your research belongs. There may not be an exact CSO and CBCRP topic correspondence, but the bullets on the CSO Web site and those under our priority issues listings in the "CBCRP General Application Information" download should allow you to make a rational selection. Next, you can use either one or two CSO codes to best categorize your application:

- Use a single CSO code if it best describes the total topic area of the application. **Many applications are adequately characterized by one code.**
- If your project fits under more than one CSO category, then add a second code. The second code should represent a different, but integral part of the research, not a contingency aim, and represent some minimum of the total effort.

8) Combined Project Budget Summary

All applicants MUST provide the total costs for the entire funding request for each grant year on this Combine Project Budget Summary template. Each institution requesting a direct award or subcontract must complete the "Budget – Each Institution" download form as well. See the directions for "Budget – Each Institution" in the section below.

9) Organization Assurances

Provide the required information for Human Subjects and Vertebrate Animals. If applications

have not been submitted prior to submission of the CRC Application, mark "pending" and put the proposed date of submission in the "Approved or Pending Date" The DNA and biohazard items can be checked "no."

10) Research Plan and Other Attachments

Here you will find a duplicate list of all Application Forms and the downloadable instructions (the same that were in Download Templates and Instructions above). This is also the area where you will "Upload Attachments" to your proposal. The required upload items are listed as you upload them so you can track the progress towards completion.

When Uploading Attachments you should:

Describe Attachment: Please provide a meaningful description for what you are uploading, especially if it is an appendix item it would be better to describe the item then to just say "appendix."

Select Appropriate Attachment Type: From the drop down menu, select the type of form that is being attached. Note that "appendix" should be chosen for all appendix items (except the appendix cover sheet which has its own category).

Allowable File Type: All attachments must be in Adobe PDF. Suggestions about how to convert files to PDF can also be found on the proposalCentral site. **Select File From Your Computer to Attach:** This section has a browse button that will allow you to find the correct pdf file on your computer and attach it to your application.

11) 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 working on the application so you have time to address missing items.

12) Print Pace Page When Application Complete

On this page use the "Print Signature Pages and and Attached PDF Files" to print out a copy of your face/signatures page(s). You may also choose to make a copy of your entire proposal for your records.

Print an original of the face page, gather the required signatures, and send a pdf copy to the Research Grants Program Office by the deadline listed on page 1 of these instructions.

The required signatures are:

- **Applicant co-PI** (person who initiated the application in proposalCENTRAL)
- **Signing Official from the Applicant co-PI's institution.**
- **Collaborating co-PI** (equal partner with the applicant co-PI).
- **Signing Official from the Collaborating co-PI's institution.**

If there is more than one Collaborating co-PI, then either print additional copies of the face page with signatures or just sign at the bottom on the first page.

13) Submit

Submission is only possible when all required items have been completed and all required forms have been attached.

INSTRUCTIONS: Downloadable Forms

These are the individual forms you download, complete on your computer, and then upload in PDF format. They are available on the proposalCENTRAL website in Proposal Sections #2 and #10 (see "Templates and Data Fields" section above).

Upload Item (Template/Form)	Page limit	Required or optional	Peer Review?	Programmatic Review?
Lay Abstract	1	Required	Yes	Yes
Scientific Abstract	1	Required	Yes	Yes
Program Responsiveness	2	Required	Yes	Yes
Additional Criteria	2	Required	Yes	Yes
Collaborative Agreements	2	Required	Yes	Yes
Distinction from Other Funding	1	Required	Yes	Yes
Biosketches & Other Support (All Personnel listed on Key Personnel form)	4 (each biosketch)	Required	Yes	Yes
Budget Summary – Each Institution	1	Required	Yes	No
Budget Justification & Facilities	2	Required	Yes	No
Key Personnel	1	Required	Yes	No
Previous Submission Review Response	2	Required (when application is resubmission)	Yes	No
Research Plan	10 (Pilot Award) + references Or 15 (Full Award) + references	Required	Yes	No
Human Subjects	No limit	Required	Yes	No
Vertebrate Animals	No limit	Optional	Yes	No
Appendix List	1	Required	Yes	No
Appendix uploads	30	Optional	Yes	No

FORMS REVIEWED IN BOTH PEER REVIEW AND PROGRAMMATIC REVIEW

Instructions – LAY ABSTRACT (required)

This form is included in the Peer review and Programmatic Review.

The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan and Collaboration Plan. Thus, it is important to ensure that essential parts of your research and collaboration plans are reflected in the lay abstract and other forms as noted. This form is important as one of the places where the Council will understand the impact of your collaboration.
The text is also entered in the appropriate box in the "abstracts" page of the Templates and Data Fields section. Do not use symbols or other special text, as these will not transfer to the box in the "abstracts" template.

The Lay Abstract is limited to 5000 characters, including spaces and subtitles.

The **Lay Abstract** must include the following sections:

- The **project title**
- A non-technical **introduction** to the research topics
- The **question(s) or hypotheses** of the research in lay terms
- The **general methodology** in lay terms
- **Innovative elements** of the project in lay terms
- The **community involvement** of those addressed in the research
- The **future plans** for the research team and use of the research results

The Lay Abstract is prepared for a general description of CBCRP-funded projects. It is placed on the CBCRP Web site and included in a Compendium book of funded projects. The abstract should be written using a style and language comprehensible to the general public. The scientific level should be comparable to either a newspaper or magazine article, such as might appear in *Time* or *Newsweek*. Avoid the use of technical terms and jargon not a part of general usage.

The CBCRP reserves the right to edit abstracts before a grant is funded.

Instructions - SCIENTIFIC ABSTRACT (required)

This form is included in the Peer review and Programmatic Review.

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

The text is also entered in the appropriate box in the "abstracts" page of the Templates and Data Fields section. Do not use symbols or other special text, as these will not transfer to the box in the "abstracts" template.

The Scientific Abstract is limited to 5000 characters, including spaces and subtitles.

The Scientific Abstract should include:

- The **project title**
- 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 **specific aims** or objectives 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.
- The **community involvement** of those addressed in the research
- The **future plans** for the research team and use of the research results

The Scientific Abstract is used by the CBCRP in assigning reviewers to the application and by Review Committee members in their evaluation of the application. 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 in the space allotted. Emphasize the unique, innovative, and exciting approaches and the community involvement as well as relevant community goals of the project. Make the abstract understandable without a need to reference the detailed research plan.

Instructions – PROGRAM RESPONSIVENESS (required)

This form is included in the Peer and Programmatic review.

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

Limit the text to two pages.
Address, in detail, how the proposed project relates to the CBCRP Priority Issues and the CRC award requirements as described in the *CBCRP's Call for Applications (see pages 5-6 of the PDF document for their full description)*. This will be *the* major piece of the application used by reviewers to evaluate responsiveness, which is the first step in the evaluation process.

Part I. Responsiveness to Priority Issues: Please explain how the proposed research addresses the CBCRP Priority Issue you have chosen as well as to other priority issues as appropriate. Make your case clear and compelling.

Part II. Responsiveness to CRC Mechanism and Award Type: Please explain how the proposed research is responsive to the intent of the CRC mechanism (collaborative research) and the award type (Pilot or Full study). Please carefully review the community collaboration elements in the application instructions as well as the intent of the CRC awards.

You may add one continuation sheet to complete this form.

Instructions – ADDITIONAL CRITERIA (required)

This form is included in the Peer and Programmatic review.

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

Limit the text to two pages.

Dissemination and Translation Potential: Explain how the research findings will be returned to the community of interest. Describe how research findings will be shared with other stakeholder audiences beyond the project's community of interest (i.e., health care providers, funders, policymakers etc.). Explain the strategies the project team have planned to encourage the community to use the knowledge generated by the research findings (i.e., language translation; plain language formatting, ownership of the data, output of the research results etc).

Addressing the Needs of the Underserved: Explain how the proposed research project has the potential to reduce differences in the impact of breast cancer on the underserved. Take the time to study the human issues of breast cancer and the extra burden the disease places on different communities, and consider how your project might address the needs of the underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive limitations, age, occupation and/or other factors in prevention, detection, prognosis, and treatment.

Advocacy inclusion: Explain how this proposal shows awareness and inclusion of breast cancer advocacy concerns involved in the proposed research. Describe the interest, support, potential benefits to, and involvement of, the community of interest in the research—from developing the research question, through designing, carrying out, and analyzing the research, to disseminating the results. Include information about how this proposal fits into the breast cancer advocacy concerns.

Examples of advocacy concerns/human issues can be sourced through web sites, such as:

- http://www.y-me.org/ Y-ME National Breast Cancer Organization
- http://www.natlbcc.org/ National Breast Cancer Coalition
- http://www.bcaction.org/ Breast Cancer Action
- http://www.breastcancerfund.org The Breast Cancer Fund
- http://www.komen.org The Susan G. Komen Breast Cancer Foundation

Instructions – COLLABORATIVE AGREEMENTS (required)

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

total score.

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

Ownership of Data: Describe what decision you made about who will own the data and intellectual property rights AND why you came to that decision (i.e. what factors you considered, what was important to you in making this decision). If you decide that the data will be owned by only one of the collaborators please consider that the need to continue to work together will likely extend well beyond the grant period. Will the partner who owns the data be willing to volunteer his/her time well after the grant period to provide access to the data for the other partner? Be sure to discuss ownership of identified and de-identified data, including arrangements both partners have agreed to ensure access to that data by the other partner (including beyond the study period).

Handling Disagreements: Describe what decision you made about the procedures you will go through to handle disagreements during the course of the study and afterwards. Past teams have had to resolve issues around data ownership, conduct of the research, dissemination of data and publications, administrative and budget issues, etc. Describe why you believe your decision on handling disagreements will work for you.

Recipient of Grant Award: Describe what decision you made about whether the grant award will be contracted directly to one partner or to both partners and why you came to that decision. CBCRP suggests that if both applicant agencies have the administrative capacity to manage grant awards, that each agency receives a separate award.

Plans for Broader Community Involvement: Describe how individual community members not on the research team (including staff and board of the community agency applicant as well as community members outside of the organization) will be involved in the planning, conducting, and dissemination of research. Describe how the community co-PI will be overseen by the community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).

Plans for Dissemination of Findings: Dissemination of research findings to both the lay community and the scientific community is important to this research award. This is sometimes a difficult issue as scientific dissemination is often a lengthy process and may impede community dissemination. Please describe how research findings will be disseminated to both the community of interest and the scientific community and what agreements have been made about the timing of dissemination.

Plans for Turn-over of Personnel: Describe how the turn-over of personnel will be handled (who will hire, fire, etc.) Describe how the community co-PI, specifically, will be overseen by the

community applicant and what steps will be taken to select a replacement community co-PI if that were to be needed (please keep in mind that the community co-PI replacement will need to be approved by CBCRP in accordance with the Grants Administration Manual available on the CBCRP website).

Instructions – DISTINCTION FROM OTHER FUNDING (required)

This form is included in the Peer review and Programmatic review.

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

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

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

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

Instructions – BIOGRAPHICAL SKETCH AND OTHER SUPPORT (required)

These forms are included in the Peer review and Programmatic Review.

Limit the text to four pages.
Complete a biographical sketch for each person listed in the Key Personnel section only, beginning with the co-principal investigators. Limit each sketch to four pages. Do not send reprints or manuscripts as part of this form. Corresponding NIH forms are acceptable (NIH Form 398).

Bio Sketch Includes:

- **Personal Statement:** Briefly describe why you are a good fit for the project team, based on your experience and qualifications. Describe in a few paragraphs what specific strengths you bring to the project, that are relevant to the collaboration, community-connectedness, scope, aims and methods of your application.
- **Positions & Honors**

  - **Education/Training:** Begin with baccalaureate and end with the most recent, including postdoctoral training.
  - **Research and/or Professional Experience:** List positions in chronological order.
  - **Honors:** List awards or honors received in chronological order. This can include awards for community based or academic efforts that are relevant to the current application. You can include membership in advisory committees (including those for the federal government).
- **Selected Publications:** List your most recent publications first. For academics, list your most significant peer-reviewed publications in breast cancer first, then other publications in either cancer research or on a topic associated with a specific aim in this application, and then other relevant publications for this application. Explain any gaps in the publication history of the academic co-PI. For community members, list your most significant publications in breast cancer first (if peer-reviewed list those first), then other publications in either cancer research or on a topic associated with a specific aim in this application, and then other relevant publications for this application. Do not include items 'submitted' or 'in preparation'.
- **Research Support:** List all active and pending grants. Include: (1) grant title, (2) active or pending & period of support, (3) funding agency/grant number, (4) role in grant & percent effort, (5) one sentence that describes the aims of the grant, and (6) description of the overlap issues and possible resolution with the present proposal. See examples in CRC Dissemination Application Form Instructions.

Examples:
Increasing Adherence to Follow-up of Breast Abnormalities in Low-income Chinese American Women: A Randomized Controlled Trial.
Active 6/1/03-11/30-06 Department of Defense, DAMD17-05-1-0876 (PI, B. Smith) Co-investigator, 5% We will design a culturally tailored intervention and evaluate it in a randomized design in Chinese American women who have a potential breast abnormality and have missed their first follow-up appointment. No overlap.

Psychological Well-being in Long-Term Adult Cancer Survivors
Active, 8/99-7/04 Cancer Institute-CA 21972 (PI, S. Klein) Co-investigator, 5% This two-phase study will identify the unique aspects of psychological well-being associated with LTS and to document the long-term impact of cancer and its treatment over the adult lifespan. No overlap.

FORMS REVIEWED IN PEER REVIEW, BUT NOT PROGRAMMATIC REVIEW

Instructions – BUDGET SUMMARY – EACH INSTITUTION (required)

This form is included in both the Peer review.

Limit the text to one page per institution.
Each institution that is requesting a direct award or will receive a subcontract must complete a budget form.

Applicants should ensure that the separate budget summary forms add up to the total on the

Combined Project Budget Summary template.

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 type cap by the amount of the F&A costs to the subcontracted partner's institution.

Instructions – BUDGET JUSTIFICATION AND FACILITIES (required)

This form is evaluated in the Peer review.

Each institution requesting a separate award or a subcontract must complete a budget justification and facilities form.

Limit the text to two pages per institution.

Budget Justification: Complete the Budget Justification and Facilities Form. Separate the budget justification by each institution which will receive a direct award or subcontract. Peer reviewers examine the budget and budget justification carefully. Please put considerable thought into this section. Relate each item explicitly to the research plan. Provide a detailed justification of the budget. Items not well justified are likely to be deleted or reduced. Provide special justification for any unusual expenses.

Personnel

Describe the duties of each participant and the specific role each will perform in this project, and justify by category all requested expenditures. List by name and job title all personnel who will participate in the project, if known; if not known, use the position title. For each position, include:

- The percent FTE (full time equivalent) appointment at the applicant institution
- The percent time devoted to this project
- The base salary at the applicant organization for each person (do not include supplementary income)
- The percent salary requested (which cannot exceed the percent time devoted to this project)
- **The minimum required time commitment for all co-principal investigators is 10% FTE**

When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income. Graduate students may be paid as personnel and may also receive tuition remission from awards. Tuition remission in this circumstance, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition) allowable will be $35,568 per year per FTE. There are no constraints on how this amount is divided between salary and tuition.

Subcontracted Collaborative Partners, Consultants, and Contractual Costs

For each subcontracted collaborative partner, consultant, and/or consortium/contractual organization listed on the Budget Summary, include a separate detailed budget summary including itemized direct, F & A, and total costs.

For each subcontracted collaborative partner, consultant and/or consortium/contractual organization:

- Enter the name(s), role(s), and total annual costs
- Complete a "Budget Summary" form for each subcontract.
- Itemize the direct, Facilities & Administrative (F & A), and total costs.

Consortium arrangements may involve costs such as personnel, supplies, and other allowable expenses, including F & A costs at the federally approved ICR rate (include a copy of the agreement), for the relatively independent conduct of part of the work described in the research plan. Contractual agreements for major support services, such as the laboratory testing of biological materials, clinical services, etc., may be of sufficient scope to warrant a similar categorical breakdown of costs.

Supplies and Expenses

Itemize supplies and expenses in separate categories, such as glassware, chemicals, radioisotopes, publication costs, computer charges, rental agreements, etc.

Equipment

Individual **equipment items** that are listed must be in excess of the NIH threshold of $5,000. The maximum equipment costs cannot exceed $10,000. Justify each item of equipment on the Budget Justification form. Any items less than $5,000 (e.g. most computers and small lab items) are now budgeted under the "Supplies and Expenses" category.

Travel

- CBCRP Symposium: $400/year is recommended. Symposia take place on a tri-annual basis, and the next one is scheduled to take place in 2016.
- Project-Related: Must be separately justified and will be paid at the level approved by the review committee.
- Scientific Meetings: Is limited to $2,000 per year for each co-PI. Please list and explain.

Facilities & Administration (F&A)

Indicate the F&A rate chosen, whether the rate is a DHHS negotiated rate, a rate established by some other means or authority, or the default rate of 25%.

- **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* (not retroactive to prior grants).

  **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*

Facilities:

Please list the facilities available for each institution that will be used in the research project.

Briefly describe the facilities and resources that are needed and are available for successfully carrying out the proposed research. Make sure all of the requirements of the proposed research plan are addressed in this section. Justify any reliance on resources external to the institution and provide documentation of their availability to you (i.e. letters of collaboration in the appendix).

Instructions – KEY PERSONNEL (required)

This form is evaluated in the Peer review.

Limit the text to one page.

List the individuals, including collaborators and consultants, who will have significant intellectual input into the scientific and collaborative development and execution of the project, regardless of whether they will be paid with funds from this grant. For each individual, include advanced degrees, position title, department and institution, percent FTE on project, as well as role in project. Include a biographical sketch for each individual listed.

Instructions – PREVIOUS SUBMISSION REVIEW RESPONSE (required for resubmission applications)

This form is evaluated in the Peer review.

Limit the text to two pages

Follow the formatting instructions in "General Items" above.
This form is for the applicants to describe their response to the suggestions contained in previous submissions. Provide the page number of the research plan where the most salient changes can be found, if the changes are such that it they appear in a specific section or page of the plan (i.e., don't try to identify all the places where your responses are if they are scattered throughout the plan).

Instructions – RESEARCH PLAN (required)

This form is evaluated in the Peer review.

Limit the text to:
Pilot Award: Ten Pages
Full Award: Fifteen Pages

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

Follow the formatting instructions in "General Items" above.

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

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and collaboration elements, as described 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.**

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. **The research plan must be self-contained and understandable without having to refer extensively to supporting materials.**

Note: Recommended format for research plans is included below for the Pilot or Full Award.

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; 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-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?

Instructions – HUMAN SUBJECTS (required)

This form is required for all applications but only needs to be completed if the proposed study will involve human subjects.

Special Note to CRC Applicants: If you are planning on having data from your studies with individual identifiers being accessible and possibly even maintained by both the Community Research Partner and the Scientific Research Partner, please address this issue in your Human Subjects approval application. If you received Human Subjects approval through one partner's IRB, and you did not include in the IRB application that the other partner will receive a copy of the identified data during or after the study, you may be precluded from sharing the data.

Provide sufficient information in response to item (1) below to confirm there has been a determination that the designated exemptions are appropriate. Determination of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation of IRB review must be provided before an award is made. Research designated exempt is discussed in the U.S. Department of Health and Human Services, Public Health Service Grant Application #398 Part II Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Pages 4-5. Although a grant application is *exempt* from these regulations, it must, nevertheless, **address the issues of race/ethnic composition of the subject population**, as instructed in item (2) below.

If your proposal will involve human subjects, and you have not applied for or received an exemption, you must address the seven points below. 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 work outlined in the research plan.

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 males, females, and members of minority groups in study populations. Applicants must describe how minorities will be included as research participants and identify the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. For example, adequate inclusion of minorities as subjects in research studies may be impossible or

inappropriate with respect to the purpose of the research, due to the health of the subjects, or for other legitimate scientific reasons. 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. It is not necessary in this application to document inclusion of women.

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 and who will seek it, the nature of the information to be provided to the prospective subjects, and the method of documenting consent. State if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.

5. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. 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. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the IND has been obtained.

Documentation of Assurances for Human Subjects

In the Appendix to your application, include official documentation of the approval by the IRBs of all participating institutions, if available at the time of submission, showing the title of this application, the principal investigators' names, and the inclusive approval dates; 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, a USPHS-approved IRB must provide the assurance. If review is pending please note that and send the final assurance as soon as possible to CBCRP. 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, approvals from the boards of each will be required.

Instructions – VERTEBRATE ANIMALS (optional)

This form is required ONLY for applications involving vertebrate animals.

If your application involves vertebrate animals the 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. Although no specific page limitation applies to this section of the application, be succinct.

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 method 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 institution 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. Funds will not be released until all assurances are received by the CBCRP.

Instructions – APPENDIX COVER SHEET (required; contents optional)

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 may be included; the appendix is not to be used to circumvent page limitations of the application. No supplemental materials are allowed after the submission deadline unless requested by the

CBCRP. While there are no page limits for the appendix, we strongly recommend that the appendix be no more than 30 pages in length.

ALL APPENDIX MATERIALS will need to be "uploaded" to the proposalCENTRAL website (so therefore in PDF format). If the applicant plans to attach print materials (brochures, handbooks, etc.) they are advised to begin preparing those documents in uploadable formats well before the application deadline.

Copies of Assurances for Human Subjects and Vertebrate Animals. List organization names where the approval or exception was made.

Community Agency Resolution. Provide a copy of a resolution or the section of minutes from a meeting of the Community Applicant governing body (Board of Directors for a nonprofit organization or the individuals responsible for organizing an informal organization) indicating their review and agreement with the details outlined on the Collaborative Agreements form. The resolution or minutes should include the date of approval and should be signed by an officer of the organization.

Letters of Collaboration can be important in showing support for the research project from the community. The letters should be as specific as possible in describing the specific involvement of the individual or organization in designing the research project or the anticipated involvement in working with the collaboration in carrying out the research. General letters of support, without addressing the specific involvement of the individual or organization in the research project, are not as important as letters of collaboration, showing anticipated involvement in the project. **ALL LETTERS SHOULD BE COMBINED INTO ONE PDF DOCUMENT; DO NOT UPLOAD INDIVIDUAL LETTERS OF COLLABORATION.**

Supporting Documents. Supporting materials (such as questionnaires, consent forms, interview questions) that are directly relevant to the proposal may be included in the Appendix. 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 may be included: the appendix is not to be used to circumvent page limitations. Please itemize materials on the Appendix Cover Sheet.

Other CBCRP Application Policies and Guidelines

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 each cycle 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 SRI grants are not included in this limit. A PI may have more than one SRI 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 current 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.

Award Decisions

Applicants will be notified of their funding status by June 30, 2015. 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:

- 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.

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 can be obtained from the Program's office or viewed on our Web site: http://www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf