

SPECIAL RESEARCH INITIATIVES (SRI) STRATEGY DEVELOPMENT PLAN

CALIFORNIA BREAST CANCER RESEARCH PROGRAM

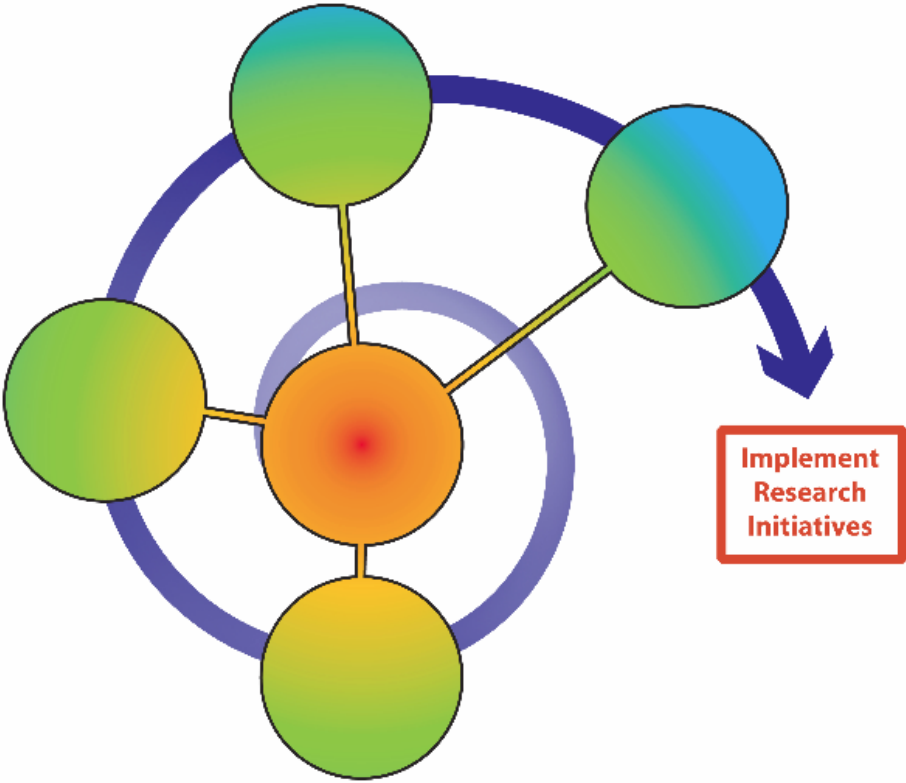


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I. Background

About the CBCRP. The California Breast Cancer Research Program is the nation's largest state-funded breast cancer research effort and the fourth largest breast cancer research funder in the world. The program's mission is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities. The CBCRP was founded in 1993, when breast cancer activists, scientists, clinicians, state legislators, and University of California officials collaborated to win passage in the state legislature of the California Breast Cancer Act. Funded primarily by a tax on tobacco products, since 1994, the CBCRP has awarded more than \$164 million for 672 research projects at 73 institutions throughout the state.

A New Direction. To prepare for its second decade of research funding, in 2001 the CBCRP initiated a comprehensive review of the program. The Director, staff, and the program's advisory Breast Cancer Research Council evaluated grants the CBCRP had made in relation to the program's mission and funding criteria. Scientists, clinicians, and advocates contributed to this review by preparing position papers, making presentations, and participating in council meetings. The review culminated in March 2004 with a decision to allocate 70 percent of the program funding over the next five years to the most successful types of awards we had previously made. The other 30 percent of funds—approximately \$18 million over five years—is being set aside. It will be used for coordinated, directive, and collaborative Special Research Initiatives on (1) the effects of the environment and lifestyle on the development of breast cancer and (2) the reasons why some groups of women are more likely to get breast cancer or to die from the disease. Our vision is to fund research that

not only increases knowledge about these questions, but also points to solutions that will reduce the suffering from breast cancer and move us closer to eliminating the disease.

Why a Two-Year Process? The CBCRP is following a carefully-crafted two-year strategy development process in order to select the best way to use a significant portion of our funds to push breast cancer research forward. We are taking a new approach because the current model of scientific research is not leading rapidly enough to prevention and cure. The questions we have selected to investigate hold great promise for progress against breast cancer, but they are also difficult to research. There's no scientific consensus on where to begin. Information about previous research into these questions is only available through widely scattered sources.

Our plan is designed to make sure that we don't duplicate previous research. It is also designed to allow us to base our efforts on the most up-to-date knowledge and on the opinions of experts nationwide. We have allowed time to make the best use of the state's resources by identifying and involving California institutions and organizations who can join forces to make progress against breast cancer. Another reason we are developing our strategy in this way is that we are a taxpayer-funded organization, committed to public accountability. Through each phase of the process, we have allowed time for California citizens to both monitor our activities and provide input.

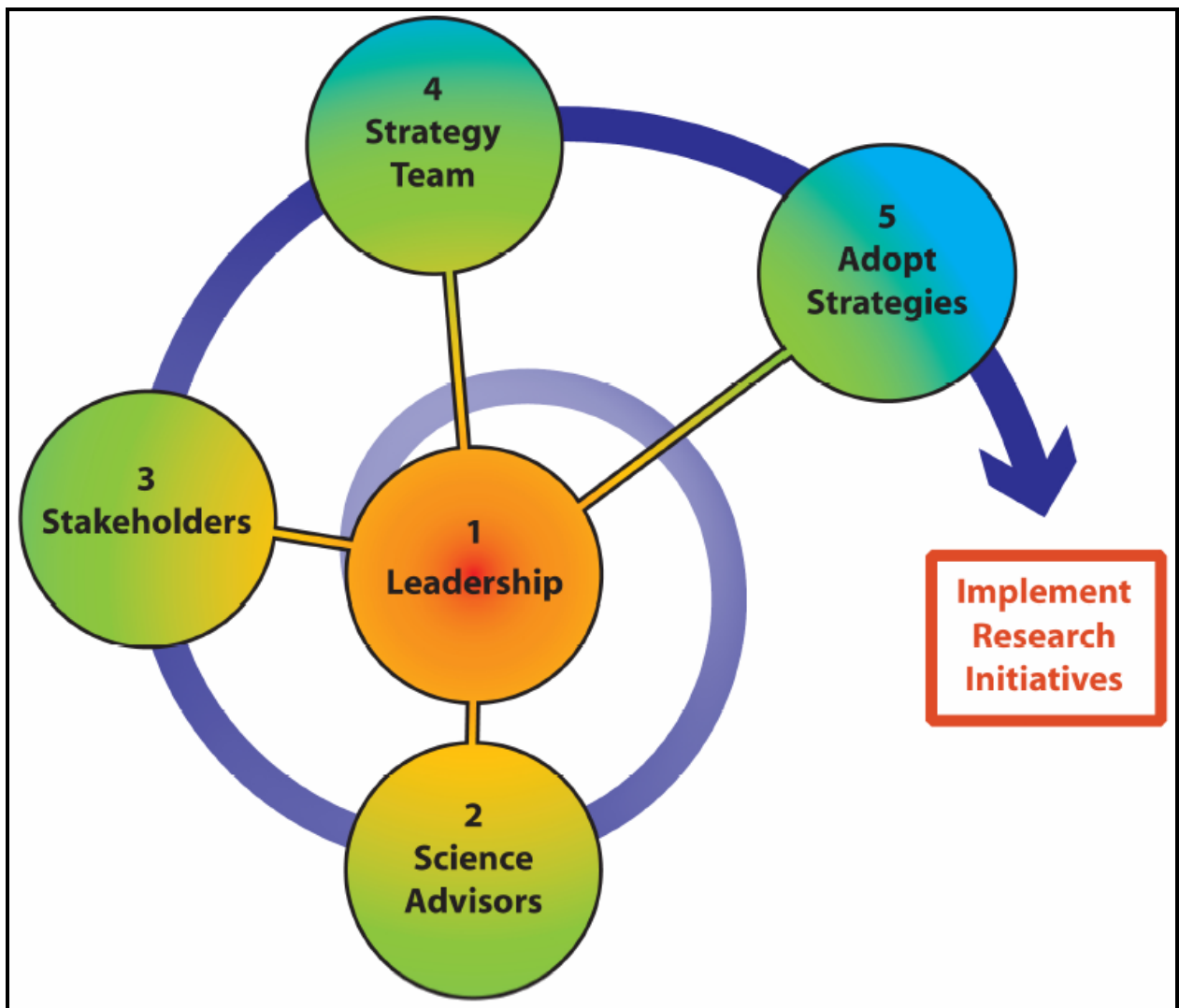
Creating an Effective Process. To create the most effective process to identify strategies for the Special Research Initiatives, we obtained advice from over sixty nationally prominent scientists, advocates, and research administrators. We have drawn from the most successful practices of other organizations that have developed comparable initiatives to

create the following *Special Research Initiatives Strategy Development Plan*.

II. The Five Phases

The Strategy Development Plan for the CBCRP's Special Research Initiatives is divided into five phases [see Figure 1]. The five phases are designed to gather focused, innovative ideas, and ensure that all relevant resources are brought to bear on the problems tackled by the Special Research Initiatives.

Figure 1. Model of the CBCRP Special Research Initiatives Strategy Development Plan



Phase 1: Leadership, January-March 2006. The CBCRP will appoint a Special Research Initiatives Steering Committee of advocates and scientists to provide guidance.

Phase 2: State of the Science Review, May-December 2006. The Special Research Initiatives Steering Committee, CBCRP staff and Science Advisors will gather information and publish a State of the Science document. This document will contain comprehensive information on research to date into the questions to be investigated under our Special Research Initiatives. CBCRP staff will also gather information on and publish an analysis of current nationwide funding for research into these questions.

Phase 3: Involve Stakeholders, November 2006-April 2007. CBCRP staff will hold regional meetings across California to actively involve people who have a stake in our Special Research Initiatives. Stakeholders will include women affected by breast cancer, investigators who may conduct future research under the initiatives, clinicians, government officials, and interested members of the public.

Phase 4: Identify Strategies, May-October 2007. CBCRP staff will recruit at least one advisory board, the Special Research Initiatives Strategy Team. Taking into consideration the information gathered in Phases 2 and 3, the team or teams will brainstorm, prioritize and develop strategies that will be written up in a Strategy Report similar to an Institute of Medicine report.

Phase 5: Adopt Strategies, November 2007. The CBCRP advisory council will review recommendations made in the Strategy Report from Phase 4. The advisory council will then identify specific strategies that the CBCRP will begin implementing immediately.

III. Special Research Initiatives Planning Advisory Groups

The Special Research Initiatives Strategy Development will involve many people, as outlined below and illustrated in Figure 2.

CBCRP Advisory Council

The 16-member, advisory Breast Cancer Research Council is an ongoing CBCRP leadership body that provides vision, sets research priorities, and determines how the CBCRP invests its research funds. The council includes scientists, clinicians, representatives of industry and nonprofit health organizations, and breast cancer advocates. For the Special Research Initiatives, the council will provide input and help recruit members of the other advisory groups listed below. Council members will help plan and organize the regional meetings to be held in Phase 3. They will also develop ways to measure the success of the Special Research Initiatives. Finally, the council will consider recommendations made by the Strategy Team(s) and will adopt Special Research Initiatives strategies for the CBCRP to implement.

Steering Committee

During Phase 1, January–March 2006, the CBCRP will recruit the Special Research Initiatives Steering Committee. This committee will include the CBCRP Director, three scientists, and two advocates. To avoid conflicts of interest, most of the steering committee members will be from outside of California, potential conflicts of interest will be made public, and Steering Committee members will not be eligible for funding to conduct future research under the Special Research Initiatives. The members will possess outstanding leadership, expertise, and vision, and make a two-year commitment to this process. Working closely with senior CBCRP staff, the Steering Committee will guide the Strategy Development Plan. The

committee will help to identify and recruit Science Advisors, potential investigators, and Strategy Team members. Steering Committee members will serve as editors of the State of the Science document, help present the document to stakeholders around California, and provide leadership to the Strategy Team(s). The Steering Committee will also help prioritize strategy recommendations for final adoption by the CBCRP advisory council.

Science Advisors

During Phase 2, April–December 2006, the CBCRP will recruit Science Advisors, experts in various fields who are based inside and outside California. The Science Advisors will review the draft of the State of the Science document, review in detail sections or chapters, and review the final document.

Stakeholders

During Phase 3, October 2006–June 2007, the CBCRP will hold regional meetings. These meetings will inform and involve stakeholders in our Special Research Initiatives.

Stakeholders include representatives of breast cancer advocacy organizations and of community-based organizations serving women with breast cancer, scientists, clinicians, government officials, and interested members of the public. We will share the Special Research Initiatives State of the Science document with stakeholders, and register interested investigators. We will also invite stakeholders to brainstorm and share ideas for Special Research Initiatives strategies.

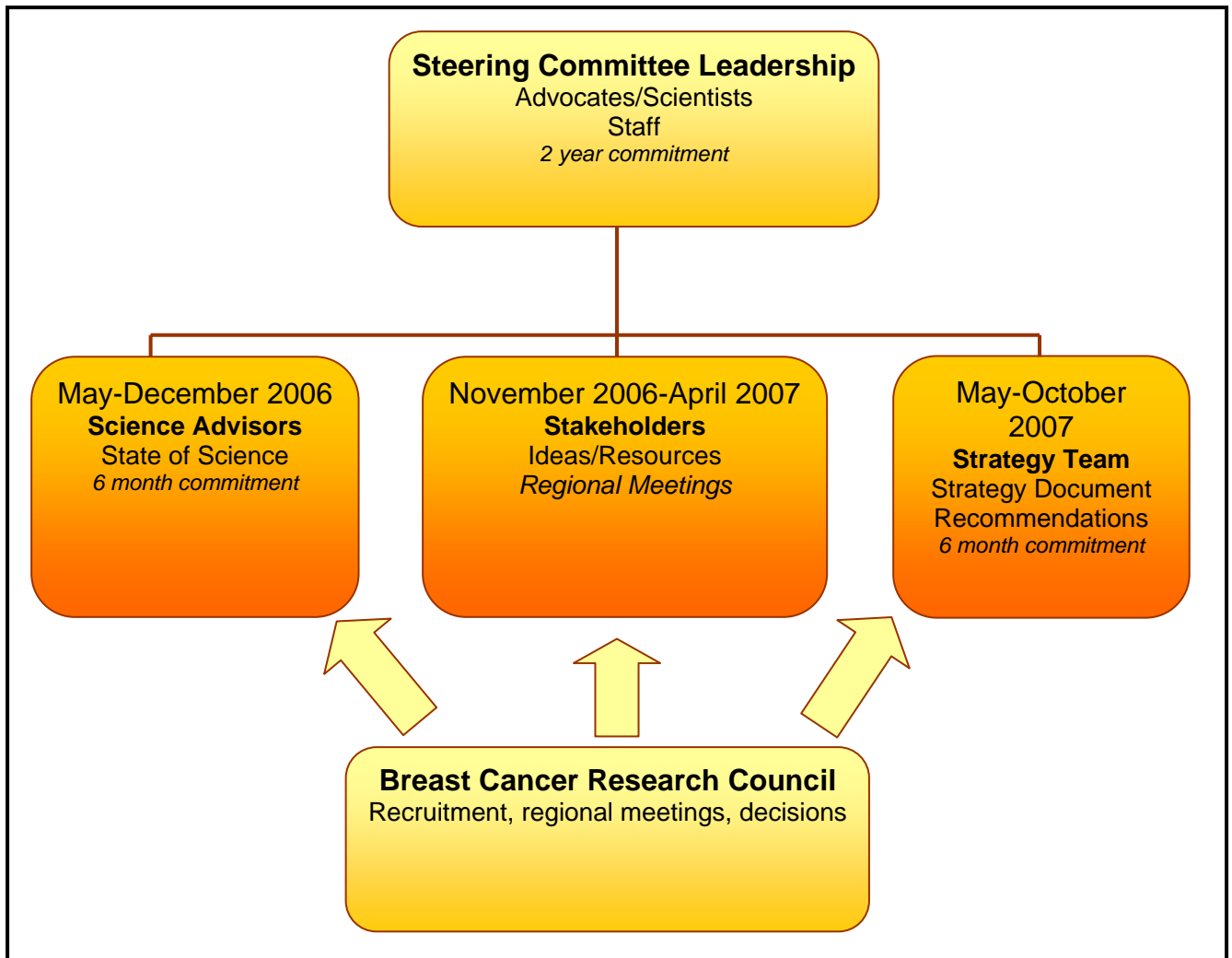
Strategy Team(s)

During Phase 4, April–October 2007, the CBCRP will recruit one or more Strategy Teams to brainstorm, prioritize, and develop research strategies. The team or teams will

include advocates, clinicians, policy makers, and scientists from within and outside California. The Special Research Initiatives Steering Committee and the initial Strategy Team will decide how many teams are necessary. Using the information gathered in Phases 2 and 3, the Strategy Team(s) will

identify and prioritize strategies that utilize innovative approaches, break through the limitations of traditional biomedical research, and hold promise to make the most impact.

Figure 2. Special Research Initiatives Planning Advisory Groups



IV. Special Research Initiatives Strategy Development Plan

The following section provides details and outlines the charges, tasks, and expected outcomes for each of the five phases of the Strategy Development Plan.

PHASE 1: LEADERSHIP

January–March 2006

Charge: Recruit and form Special Research Initiatives Steering Committee to provide guidance throughout the strategy development process.

Steering Committee members will be national leaders in the research areas of our Special Research Initiatives. To minimize conflicts of interest, most of the steering committees members will be from outside California, potential conflicts of interest will be made public, and Steering Committee members will not be eligible for future funding for research to be conducted under the initiatives.

Tasks:

- The CBCRP recruits and forms the Special Research Initiatives Steering Committee.
- Steering Committee familiarizes itself with the goals and vision of the Special Research Initiatives.
- Steering Committee finalizes the Special Research Initiatives Strategy Development Plan.
- CBCRP staff prepares a draft State of the Science document with guidance from Steering Committee.
- Steering Committee provides guidance to begin identifying Science Advisors for Phase 2.

Expected Outcomes:

- Formed and functioning Special Research Initiatives Steering Committee.
- Draft State of the Science document covering previous research into the environment-lifestyle-breast cancer connection and the reasons why some groups of women bear more of the burden of breast cancer.
- Draft analysis of current nationwide funding for research into the questions to be covered by the Special Research Initiatives.

PHASE 2: STATE OF THE SCIENCE REVIEW

May–December 2006

Charge: Review and synthesize the current literature on why some groups of women are more likely to get breast cancer or to die from the disease, and on the environment-lifestyle-breast cancer connection. Review and synthesize an analysis of nationwide funding for research in both these areas.

Activities during this phase are designed to make sure the Special Research Initiatives do not duplicate previous research and to make sure our efforts are based on the most up-to-date knowledge and on the opinions of experts nationwide.

Tasks:

- Steering Committee and CBCRP staff recruit and engage leading experts in the fields being investigated through our Special Research Initiatives. The experts will act as Science Advisors.
- Science Advisors review the draft State of the Science document, identify additional literature, if needed, and refine the synthesis.
- Special Research Initiatives Steering Committee acts as editors of the State of the Science document and approves final document.
- CBCRP staff prepares an analysis identifying funding for current research into questions to be investigated through our Special Research Initiatives. The funding analysis includes CBCRP grant funding, along with grants provided by other major breast cancer funders, such as the National Cancer Institute (NCI), American Cancer Society (ACS), the Komen Foundation and the Department of Defense Breast Cancer Research Program.
- Advisory council and staff begin planning stakeholder meetings to be held across California during Phase 3.

Expected Outcomes:

- Engaged Science Advisors
- Finalized State of the Science document
- Draft analysis of current funding for research into the questions to be addressed in the Special Research Initiatives
- Stakeholder meetings planned

PHASE 3: INVOLVE STAKEHOLDERS

November 2006–April 2007

Charge: Inform California stakeholders and engage them in developing strategy for the Special Research Initiatives; recruit and register interested investigators.

The primary goals of Phase 3 are to gather input from across the state, engage potential investigators who may conduct research to be funded under the Special Research Initiatives, and inform the public about this effort.

Tasks:

- The CBCRP holds regional stakeholder meetings across California. CBCRP staff members present the State of the Science document and information about the Special Research Initiatives. Stakeholders—including representatives of breast cancer advocacy organizations and community-based organizations serving women with breast cancer, scientists, clinicians, government officials, and interested members of the public—are invited to generate ideas

for strategies for the Special Research Initiatives. Staff also recruits and registers interested potential investigators. The stakeholder meetings provide an opportunity for the CBCRP to reach out to both existing CBCRP funded investigators as well as other investigators who have not previously had the opportunity to work with the CBCRP.

- Special Research Initiatives Steering Committee, CBCRP staff, and advisory council identify and recruit members for the Strategy Team(s) who will work together to identify strategies during Phase 4.
- CBCRP staff produces a summary of the statewide regional meetings.
- CBCRP staff produces a report of resources in California that could play a role in implementing the Special Research Initiatives.

Expected Outcomes:

- Stakeholder meetings held and attended by a range of stakeholders.
- State of the Science document widely distributed to California stakeholders.
- Potential investigators registered with CBCRP.
- California resources document written and distributed.
- Summary of meetings document written and distributed.
- Strategy Team members identified and recruited.

PHASE 4: IDENTIFY THE STRATEGIES

May-October 2007

Charge: Brainstorm, prioritize, and develop strategies that will coordinate and leverage California resources to conduct research that will make the most impact.

The primary goals of Phase 4 are to involve experts from within and outside California to generate new, creative strategies for investigating (1) the effects of the environment and lifestyle on the development of breast cancer and (2) the reasons why some groups of women are more likely to get breast cancer or die of the disease. These strategies will include recommendations that can be implemented not only by the CBCRP but also by others interested in making an impact in the areas of the Special Research Initiatives. We anticipate that these strategies will support a coordinated statewide effort to explore innovative ideas and new theories; leverage California's unique and diverse geographic, population, and research resources; and undertake critical studies that significantly move breast cancer research forward. Furthermore, these strategies will not include implementing funding approaches previously employed by the CBCRP, such as soliciting yearly requests for applications covering the questions to be investigated.

Tasks:

- The CBCRP convenes one or more Strategy Teams composed of leading advocates, clinicians, policy makers, and scientists.
- Strategy Teams, under the leadership of the Steering Committee, identify, develop, and prioritize research strategies that will make the most impact in the two areas of the Special Research Initiatives.

- The CBCRC produces a Strategy Report, similar to an Institute of Medicine report, that outlines several strategies to push forward research in the areas covered by the Special Research Initiatives. The report also incorporates the previous State of the Science document produced during Phase 2 and the summary of California resources produced during Phase 3.

Expected Outcomes:

- Strategy Team(s) formed and convened at least three times.
- Research strategies identified, developed, and prioritized that will coordinate and leverage California resources to make the most impact in the areas of the Special Research Initiatives.
- Strategy Report created that incorporates the State of the Science document, California resources that could potentially play a role in addressing the Special Resources Initiatives, innovative funding models, and prioritized research strategies.

PHASE 5: ADOPT STRATEGIES

November 2007

Charge: Advisory council reviews the Strategy Report and selects recommendations for the CBCRP to invest in.

Tasks:

- Advisory council carefully reviews the State of the Science, the California resources, research on innovative funding models, and the recommendations identified by the Special Research Initiatives Steering Committee. The Steering Committee provides expertise and background.
- Advisory council selects recommendations for the CBCRP to implement and invest in.

Expected Outcomes:

- Recommendations the CBCRP can immediately implement to investigate (1) the effects of the environment and lifestyle on the development of breast cancer and (2) the reasons why some groups of women bear more of the burden of breast cancer.