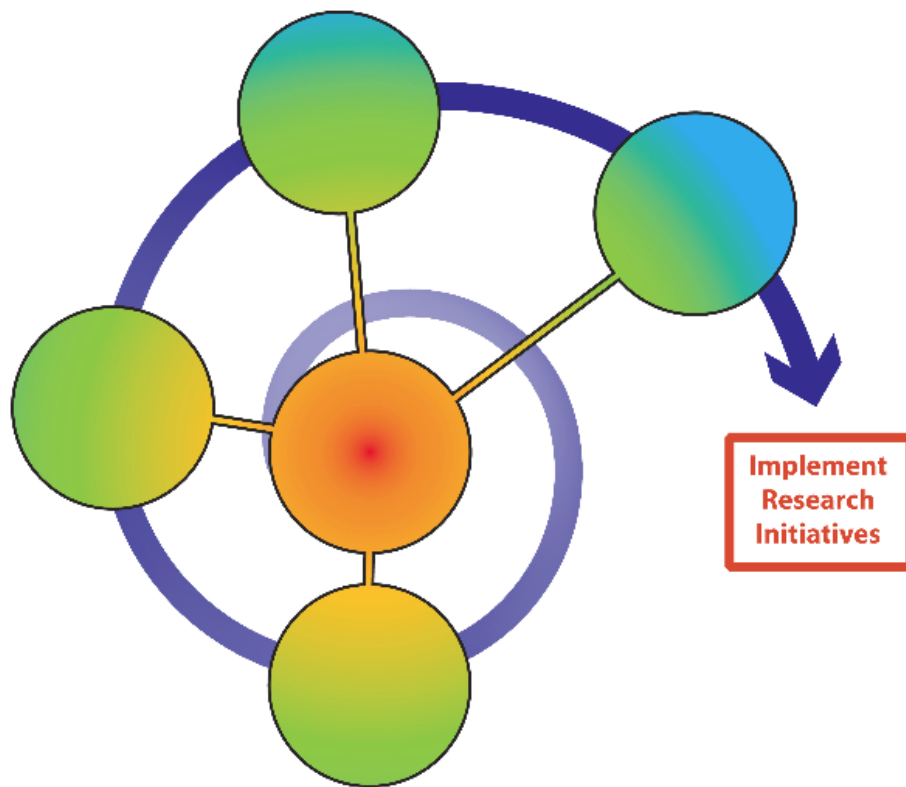


SPECIAL RESEARCH INITIATIVES STRATEGY DEVELOPMENT PLAN

CALIFORNIA BREAST CANCER RESEARCH PROGRAM



REVISED AUGUST 2007

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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 \$181 million for 761 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 (Advisory 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 Advisory 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 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 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 for 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. Throughout 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 addressed 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 staff will appoint a Special Research Initiatives Steering Committee of advocates and scientists to provide guidance on the development and implementation of a strategy plan. (See appendix A for a list of Steering Committee members).

Phase 2: Identify the Gaps in Research, March 2006-August 2007. The Special Research Initiatives Steering Committee, CBCRP staff and Science Advisors will gather information and produce a review of the gaps in research. (See appendix B for a list of Science Advisors). This document will contain information on research to date into the questions to be investigated under our Special Research Initiatives.

Phase 3: Involve Stakeholders, February 2007-September 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 those affected by breast cancer, investigators who may conduct future research under the initiatives, clinicians, government officials, and interested members of the public. Stakeholders will also have the opportunity to brainstorm research ideas on-line and also give feedback to key SRI decision makers at the CBCRP's Research Symposium.

Phase 4: Identify Strategies, May 2007-February 2008. CBCRP staff will convene an advisory board, the Special Research Initiatives Strategy Team. (See appendix C for a list of Strategy Team members). Taking into consideration the information gathered in Phases 2 and 3, the team 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, March 2008. The CBCRP Advisory Council will review recommendations made in the Strategy Report from Phase 4. (For an updated list of the Advisory Council members, go to www.cabreastcancer.org/about/council/). The Advisory Council will then identify specific strategies that the CBCRP will begin implementing.

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 Advisory Council includes scientists, clinicians, representatives of industry and nonprofit health organizations, and breast cancer advocates. For the Special Research Initiatives, the Advisory Council will provide input and help recruit members of the other advisory groups listed below. Advisory 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. At the end of the process, the Advisory Council will consider recommendations made by the Strategy Team 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. 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 gaps in research document, help present the document to stakeholders around California, and provide leadership to the Strategy Team. The Steering Committee will also help prioritize strategy recommendations for final adoption by the CBCRP Advisory Council.

Science Advisors

During Phase 2 (March 2006–August 2007), with the guidance of the Steering Committee, CBCRP staff will recruit experts in the fields related to the research topics of the Special Research Initiatives to act as Science Advisors. These experts will review the draft literature review in their field to be included in the Gaps document. The role of the Science Advisors is to evaluate whether the draft accurately reflects the current science, to provide any additional critical evidence and references, and to edit the document to ensure it is balanced. The Science Advisors will also be asked to provide their recommendations for promising areas of future research.

Stakeholders

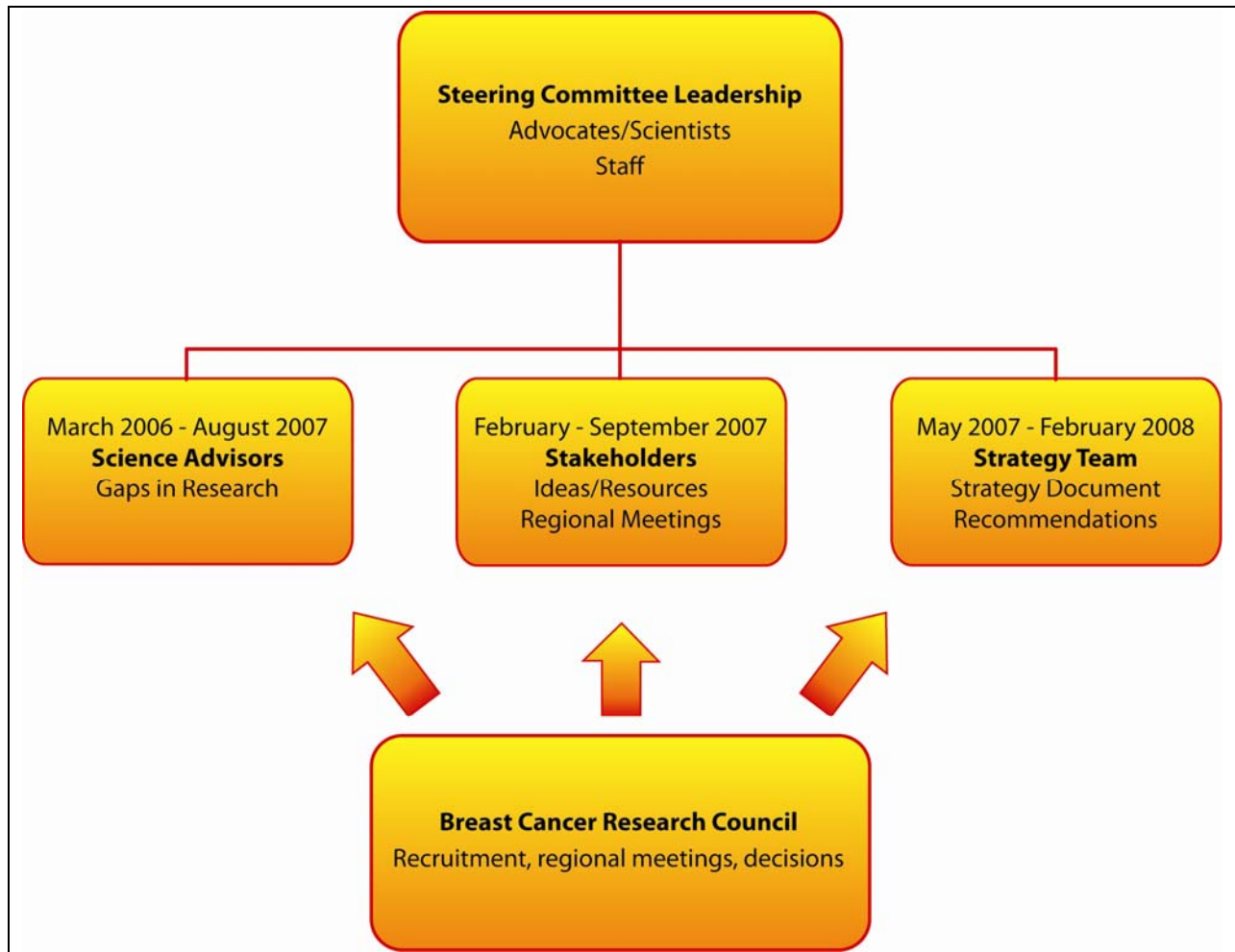
During Phase 3, (February –September 2007), the CBCRP staff will hold regional meetings. These meetings will inform and involve stakeholders in our Special Research Initiatives. Stakeholders include representatives of breast cancer advocacy organizations and of community-based organizations serving women with breast cancer; scientists; clinicians; government officials, and interested members of the public. We will share information on the Special Research Initiatives gaps in research with stakeholders. We will also invite stakeholders to brainstorm and share ideas for Special Research Initiatives strategies.

Strategy Team

During Phase 4, (May 2007 –February 2008), the CBCRP will convene a Strategy Team to brainstorm, prioritize, and develop research strategies. The team will include advocates, clinicians, policy makers, and scientists from within and outside California. Using the

information gathered in Phases 2 and 3, the Strategy Team will identify and prioritize strategies that utilize innovative approaches, break through the limitations of traditional scientific 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.

Tasks:

- The CBCRP staff 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.
- 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 -breast cancer connection and the reasons why some groups of women bear more of the burden of breast cancer.

PHASE 2: IDENTIFY GAPS IN RESEARCH

May 2006–August 2007

Charge: Review and synthesize the current literature on the environmental links to breast cancer and the unequal burden of the disease to identify the gaps in research and the most promising areas for research.

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. The goal is to produce a targeted review that will help to generate ideas for future research rather than producing a comprehensive review of all the literature in the field.

Tasks:

- Steering Committee and CBCRP staff recruit leading experts in the fields being investigated through our Special Research Initiatives to act as Science Advisors.

- Science Advisors review the draft gaps in research document, identify additional literature, if needed, and refine the synthesis to ensure that it is technically accurate and balanced.
- Steering Committee acts as editors of the gaps document and approves final document.
- Steering Committee determines how to disseminate the gaps document and to make it available to other funding agencies, researchers, advocates, and other interested parties.

Expected Outcomes:

- Engaged Science Advisors
- Finalized State of the Science document

PHASE 3: INVOLVE STAKEHOLDERS

February 2007- September 2007

Charge: Inform California stakeholders and engage them in developing strategies for the Special Research Initiatives; recruit and sign-up 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. 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.

Tasks:

- Advisory Council and staff begin planning stakeholder meetings.
- The CBCRP staff hold regional stakeholder meetings across California. CBCRP staff members present the gaps in research document and information about the Special Research Initiatives.
- CBCRP staff produces a summary of the statewide regional meetings.
- CBCRP staff produces a SRI resource database.

Expected Outcomes:

- Stakeholder meetings held and attended by a range of stakeholders.
- Information about gaps in research widely distributed to California stakeholders.
- Potential investigators signed up on SRI resource database.
- Summary of meetings document written and distributed.
- Strategy Team members identified and recruited.

PHASE 4: IDENTIFY THE STRATEGIES

May 2007-February 2008

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 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/or undertake critical studies that significantly move breast cancer research forward. Furthermore, these strategies will not use funding approaches traditionally employed by the CBCRP, such as soliciting yearly requests for applications covering the questions to be investigated.

Tasks:

- The CBCRP convenes a Strategy Team composed of leading advocates, clinicians, policy makers, and scientists.
- The Strategy Team, 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 will outline several strategies to push forward research in the areas covered by the Special Research Initiatives. The report will also incorporate an overview of the gaps in research and resources in California.

Expected Outcomes:

- Strategy Team 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 gaps in the research, California resources that could potentially play a role in addressing the Special Resources Initiatives, and prioritized research strategies.

PHASE 5: ADOPT STRATEGIES

March 2008

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

Tasks:

- Advisory Council carefully reviews the Strategy Report, 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 on the development of breast cancer and (2) the reasons why some groups of women bear more of the burden of breast cancer.

Appendix A: List of Special Research Initiatives Steering Committee Members

Julia G. Brody, PhD

Executive Director
Silent Spring Institute

Marion (Mhel) H.E. Kavanaugh-Lynch, MD, MPH

Director
California Breast Cancer Research Program

Olufunmilayo I (Funmi) Olopade, MD

Walter L. Palmer Distinguished Service Professor of Medicine
University of Chicago Medical Center

Susan Matsuko Shinagawa

Breast Cancer and Chronic Pain Survivor/Advocate, Intercultural Cancer Council;
Asian and Pacific Islander National Cancer Survivors Network

Sandra Steingraber, PhD

Author and Distinguished Visiting Scholar
Ithaca College

David R. Williams, PhD

Department of Society, Human Development and Health
Harvard School of Public Health

Appendix B: List of Special Research Initiatives Science Advisors

Deborah Bowen, PhD, Professor, Social Behavioral Sciences, Boston University

Judy Bradford, PhD, Director, Community Health Research, Virginia Commonwealth University

Linda Burhansstipanov, MSPH, DrPH, Grants Director, Native American Cancer Research

Christina A. Clark, PhD, Research Scientist, Northern California Cancer Center

Lisa Clarke, MS, Research Associate, Northern California Cancer Center

Richard W. Clapp, DSc, MPH, Professor, School of Public Health, Boston University

Melissa B. Davis, PhD, Postdoctoral Fellow/Scholar, Center for Interdisciplinary Health Disparities Research, University of Chicago

Suzanne E. Fenton, PhD, Research Biologist, Reproductive Toxicology Division, U.S. Environmental Protection Agency

Maria Feychting, PhD, Professor, Institute of Environmental Medicine, Karolinska Institute

Scarlett Lin Gomez, PhD, Research Scientist, Northern California Cancer Center

Robert B. Gunier, MPH, Research Associate, Northern California Cancer Center

Dawn Hershman, MD, Assistant Professor of Medicine, Columbia University

Chanita Hughes Halbert, PhD, Associate Professor, University of Pennsylvania

Susan E. Hurley, MPH, Research Associate, Northern California Cancer Center

Esther M. John, PhD, Research Scientist, Northern California Cancer Center

Lovell Jones, PhD, Director, M. D. Anderson's Center for Research on Minority Health

Sue Joslyn, PhD, Professor of Epidemiology, Associate Dean of Graduate Academic Affairs, University of Northern Iowa

Marjorie Kagawa-Singer, PhD, RN, MN, MA, Professor, School of Public Health and School of Asian American Studies, University of California, Los Angeles

Judith Salmon Kaur, MD, Medical Director, Professor of Oncology, Native American Programs, Mayo Comprehensive Cancer Center

Steve Kaye, PhD, Associate Professor, University of California, San Francisco

Charles Land, PhD, Senior Investigator, National Cancer Institute

Robert Millikan, PhD, Professor, University of North Carolina, Chapel Hill

Rachel Morello-Frosch, MPH, PhD, Associate Professor, Center for Environmental Studies, Department of Community Health, School of Medicine, Brown University

Kirsten Moysich, PhD, Associate Professor, Roswell Park Cancer Institute

Margaret Nosek, PhD, Professor, Baylor College of Medicine

Sharon Perry, PhD, Senior Research Scientist, School of Medicine, Stanford University

Blase N. Polite, MD, MPP, Instructor of Medicine, University of Chicago

Anh-Thu Quach, MPH, Research Associate, Northern California Cancer Center

Peggy Reynolds, PhD, Senior Research Scientist, Northern California Cancer Center

Stephanie Robert, PhD, Associate Professor, School of Social Work, University of Wisconsin-Madison

Ruthann Rudel, MS, Senior Scientist, Toxicologist, Silent Spring Institute

Theresa M. Saunders, BA, Research Program Manager, Northern California Cancer Center

Ted Schettler, MD, MPH, Science Director, Science & Environmental Health Network

Richard Stevens, PhD, Cancer Epidemiologist, Department of Community Medicine and Health Care, University of Connecticut

Joseph Thornton, PhD, Associate Professor, Center for Ecology & Evolutionary Biology, University of Oregon

Julie Von Behren, MPH, Research Associate, Northern California Cancer Center

David Wallinga, MD, MPA, Director of the Food and Health Program, Institute for Agriculture and Trade Policy

Barbour Warren, PhD, Research Associate, Program on Breast Cancer & Environmental Risk Factors, Cornell University

Tom Webster, DSc, Associate Professor, Environmental Health, School of Public Health, Boston University

Mary Wolff, PhD, Professor, Mount Sinai Medical Center

Appendix C: List of Special Research Initiatives Strategy Team Members

Nancy Adler, PhD, University of California San Francisco, Health Psychology Program

Martha Arguello, Physicians for Social Responsibility - Los Angeles

Janice Barlow, BSN, NP, Zero Breast Cancer

Leslie Bernstein, PhD, University of Southern California, Norris Comprehensive Cancer Center

Vernal Branch, The Virginia Breast Cancer Foundation

Barbara Brenner, JD, Breast Cancer Action

Linda Burhansstipanov, MSPH, DrPH, Native American Cancer Research, Corp.

José Escarce, MD, PhD, Rand Corporation

Harold Freeman, MD, Ralph Lauren Cancer Center, North General Hospital

Sarah Gehlert, PhD, University of Chicago, School of Social Service Administration

Joseph Guth, JD, PhD, Science and Environmental Health Network

Robert Hiatt, MD, PhD, University of California, San Francisco, Comprehensive Cancer Center

Marjorie Kagawa-Singer, PhD, RN, MN, MA, University of California, Los Angeles, School of Public Health; Community Health Sciences

Jean Latimer, PhD, University of Pittsburgh Cancer Institute, Center for Environmental Oncology

Michael Lerner, Commonwealth Cancer Help Program

Michael Lipsett, MD, JD, California Department of Public Health, Environmental Health Investigations Branch

Bob Millikan, DVM, PhD, University of North Carolina School of Public Health

Rachel Morello-Frosch, PhD, MPH, University of California Berkeley, Department of Environmental Science, Policy and Management

Kirsten Moysich, PhD, Cancer Prevention and Population Sciences, Roswell Park Cancer Institute

Lisa Newman, MD, MPH, FACS, University of Michigan, Breast Care Center

Debra Oto-Kent, MPH, Health Education Council

Blase Polite, MD, MPP, University of Chicago, Department of Medicine

Deborah Prothrow-Stith, MD, Harvard School of Public Health, Health Policy and Management

Cathie Ragovin, MD, Massachusetts Breast Cancer Coalition

Peggy Reynolds, PhD, Northern California Cancer Center

Jeanne Rizzo, RN, Breast Cancer Fund

Charmaine Royal, PhD, Duke University, Center for Genome Ethics, Law & Policy

Ted Schettler, MD, MPH, Science and Environmental Health Network

Gina Solomon, MD, MPH, Natural Resources Defense Council

Ana Soto, MD, Tufts University School of Medicine, Department of Anatomy & Cellular Biology

Charles Thomas, MD, Oregon Health & Science University, Department of Radiation Oncology

JoAnn Tsark, MPH, Papa Ola Lökah

Michelle Van Ryn, PhD, MPH, University of Minnesota, School of Public Health