CALIFORNIA
Breast Cancer
Research Program

Request for Proposal
Occupational Chemical Exposures in California and Breast Cancer Risk

California Breast Cancer Research Program
California Breast Cancer Prevention Initiatives

Deadline to apply
October 22, 2014

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California Breast Cancer Research Program &
California Breast Cancer Preventions Initiatives

The **California Breast Cancer Research Program (CBCRP)** was established pursuant to passage by the California Legislature of the 1993 Breast Cancer Act (i.e., *AB 2055 (B. Friedman) [Chapter 661, Statutes of 1993]* and *AB 478 (B. Friedman) [AB 478, Statutes of 1993]*). The program is responsible for administering funding for breast cancer research in the State of California.

The mission of the CBCRP is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities.

- The CBCRP is the largest state-funded breast cancer research effort in the nation and is administered by the University of California, Office of the President
- The CBCRP is funded through the tobacco tax, voluntary tax check-off on personal income tax forms, and individual contributions
- The tax check-off, included on the personal income tax form since 1993, has drawn over $8.5 million for breast cancer research.
- Ninety-five percent of our revenue goes directly to funding research and education efforts
- The CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, the CBCRP has awarded over over $230 million in 939 grants to 107 institutions across the state. With continued investment, the CBCRP will work to find better ways to prevent, treat and cure breast cancer.

CBCPI Priority Areas

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

In March 2010, CBCRP's Council decided to build on the existing SRI by devoting 50 percent of CBCRP research funds between 2011 and 2015. This new effort is titled the California Breast Cancer Prevention Initiatives. Approximately $24 million will be dedicated to directed, coordinated, and collaborative research to pursue the most compelling and promising approaches to:

1. Identify and eliminate environmental causes of breast cancer.
2. Identify and eliminate disparities/inequities in the burden of breast cancer in California.
3. Population level interventions (including policy research) on known or suspected breast cancer risk factors and protective measures.
4. Targeted interventions for high-risk individuals, including new methods for identifying or assessing risk.

To focus these research efforts, the CBCRP issued a Request for Qualifications to fund a team to collaborate with the CBCRP to develop and implement the California Breast Cancer Prevention Initiatives planning process. In 2010, the grant was awarded to Tracey Woodruff, PhD, MPH, Professor and Director of the University of California, San Francisco, Program on Reproductive Health and the Environment (PRHE).

Occupational Chemical Exposures in California and Breast Cancer Risk

Available Funding

California Breast Cancer Research Program (CBCRP) is sponsoring an open Request for Proposals (RFP) for a pilot study to identify significant chemical exposures affecting large numbers of women in the California workplace. If the pilot is successful, further funding will be issued to expand the overall initiative, which aims to improve understanding of the scope of occupational chemical exposures and how they may increase breast cancer risk in California.

Up to $150,000 in direct costs is available for this RFP for up to 1.5 years. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for Non-UC Institutions and at 25% for University of California campuses.

Completed responses to this RFP are due by the deadline: noon, October 22, 2014. Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm **October 29, 2014**. The project start date is March 1, 2015.

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

Research Questions

Occupational exposures to chemicals can be a significant health risk for women. However, knowledge is lacking on what women are actually exposed to in the workplace. Improving our understanding of the scope of the problem in California is an important first step in understanding occupations that increase risk for breast cancer and other health problems. Proposed research for this initiative would answer the following key questions:

1. Where are women employed in California? What types of industries and what specific occupations?
2. What types of breast cancer-relevant chemical and physical exposures are women subjected to in these workplaces? What are the substantial exposures affecting large numbers of women?
3. What are the differences in exposures based on race, class, age, immigrant status and other demographic markers?
4. What are key industries in California that appear to pose the greatest breast cancer risk and should be investigated further?

5. What are the key data gaps in understanding occupational exposures to breast carcinogens in California?

The data collected will serve as the building blocks for a database and/or visual tool of California women's occupational exposures that may include but are not limited to:

- Known and suspected mammary gland carcinogens, such as the 216 chemicals identified as animal mammary carcinogens by Rudel et al (2007; 2014);
- Mammary gland toxicants, such as commercial chemicals or pharmaceuticals reported to induce morphological or functional change in the mammary gland (Rudel 2011), examples include high production/exposure chemicals such as chlorotriazine metabolites, perfluorinated compounds, parabens and BPA replacements);
- Endocrine disrupting chemicals, such as the summary list maintained by The Endocrine Disruption Exchange (TEDX); and/or,
- Other available chemical and physical occupational exposure data.

This research initiative will be divided into three phases. This RFP is for the first phase of this initiative, a pilot project to identify substantial chemical exposures affecting large numbers of women in the California workplace.

Phase 1

Aim 1: Identify substantial chemical exposures affecting large numbers of women in the California workplace.

- Using an established list of known or suspected breast carcinogens (See Appendix A), determine potential ways to identify and track which of these chemicals are used in high volumes or common occupational settings within California and which industries/occupations these chemicals are used in.

Phase 2

Aim 1: Identify where women are employed in California. Establish the following:

- What types of industries are women employed in?
- What specific occupations do women have?
- What is the breakdown of demographics for these occupations, including race, age (especially identifying women of child bearing age), socioeconomic levels, immigration status, etc?

Aim 2: Identify the overlap between where women are employed in California and what chemicals linked to increased risk for breast cancer they are exposed to.

- Using the data gathered in Phase 1 and Phase 2, Specific Aim 1 analysis will be done to present a clearer picture of what the key occupational exposures to mammary gland carcinogens are, how these exposures are distributed throughout different demographics, which industries present the areas of highest concern for occupational breast cancer risk.
- Data and analysis will be used to present findings in an accessible graphic form.

Aim 3: Identify key data gaps in occupational chemical exposures for women working in California.

Aim 4: Create a database and/or visual tool of women's occupational exposures to known and suspected mammary gland carcinogens, mammary gland toxicants, and/or endocrine disrupting chemicals in California.

Phase 3

Aim 1: Conduct a more in-depth pilot investigation into key industries in California that appear to pose the greatest breast cancer risk to women, based on the findings of Phase 2.

Background/Justification

Breast cancer is a complex disease. Despite decades of intensive research, its causes and basic biology remain unclear. All known risk factors for breast cancer taken together can only account for some percentage of the disease. The percentage is in dispute, with estimates ranging from 50-70 percent. This means that 30-50 percent of all cases of breast cancer lack an identified risk factor which may have contributed to causing the disease (CBCRP 2007). This gap in knowledge magnifies the need to understand possible environmental risk factors for breast cancer, which are largely unexplored.

This attention is urgently needed as more than 310,000 Californians are living with breast cancer, and over 24,000 more will be diagnosed this year. Every two hours, on average, a California woman dies of breast cancer; more than 4,200 California women die of breast cancer each year (American Cancer Society 2014). With women often spending a significant amount of time at the workplace, it is a critical area to better understand what workplace exposures may be contributing to increased breast cancer risk.

An important step in understanding occupational breast cancer risk is to begin to map out what women's employment looks like in California and what the significant chemical exposures are in the jobs where significant numbers of women work.

A limited body of research on occupational breast cancer risks does exist. For example, preliminary research indicates potentially elevated risk for flight attendants (Reynolds 2002), women working in the canning (Ji 2008) and food and beverage processing industry (Brand 2000, Brophy 2012), as well as plastics and rubber industries (Petralia 1998, Brophy 2012). Exposure to solvents (Brody and Rudel 2003) and pesticides may also increase risk for breast cancer (Brody and Rudel 2003, Rudel 2007, Rudel et al 2014). Other industries, such as nail salon workers, do not have established links to breast cancer risk, but focus groups have found that women working in these salons are concerned about the long-term breast cancer risk from exposure to solvents and endocrine disrupting chemicals (Quatch 2008).

But understanding the root of these findings can be complex: workers are often exposed to multiple chemicals simultaneously, and these combinations can magnify the risk of exposure to individual chemicals. For example, one occupational study found that women exposed to both benzene and PAHs had higher breast cancer risk than if exposed to these chemicals individually (Brody and Rudel 2003). Additionally, the timing of exposure is important, with impacts especially magnified at critical windows of development, such as puberty or pregnancy.

Yet creating a coherent picture of women's occupational risks for breast cancer is a complex task. California has one of the largest, most diverse economies in the country, currently

employing nearly 17 million people (EDD 2013), approximately 42% of whom are women (Bureau of Labor Statistics 2013). Where women are employed in California differs significantly from men. For example, women make up more than 72% of California educational and health services employees, yet less than 6% of mining workers are women (Bernick 2013). Office/ administrative jobs are the most prevalent jobs for women (20% of the women employed in California) and sales ranking second (12%) (CRB 2013). Each occupation has its own unique profile of environmental health risks.

From 1981 to 1983 the National Institute for Occupational Safety and Health conducted the National Occupational Exposure Survey, surveying 4,490 establishments in more than 500 different industries. They found nearly 13,000 different potential exposure agents (NIOSH 1983). No study of this magnitude has been conducted in the United States since.

Unfortunately, the State of California lacks any systematic tracking system to identify which chemicals are used in different occupational settings. In the early 2000's the Hazard Evaluation System and Information Service (HESIS) in the California Department of Public Health Occupational Health Branch worked with the Center for Occupational & Environmental Health, University of California, Berkeley to determine whether various state and national hazardous materials databases could locate workplaces where seven select test chemicals are used. Due to various deficiencies, none of the databases provided usable information. Attempts to get manufacturers to provide the information voluntarily also failed (HESIS).

Canada has one of the most advanced initiatives to track occupational exposures. Their CAREX (CARcinogen EXposure) database tracks what carcinogens people are exposed to, where they are exposed, how many people were exposed and, if possible, how much of a carcinogen people were exposed to occupationally (CAREX). Additionally, the European Chemical Agency is tracking chemical use in the European Union, which requires manufactures and importers to submit dossiers for chemicals that include extensive use information (ECHA). Currently more than 10,000 chemicals have been reported.

Currently there is no comprehensive database or tool that provides an overview of women's occupational breast cancer risk in the California workplace. Important information, such as at what age they are being exposed, what the demographic distribution of women's occupational exposures is, how long women stay in each job and other key data sources, are also not tracked in a way that demonstrates women's occupational breast cancer risk.

In order to develop successful California policy interventions that address occupational breast cancer risk, a clearer understanding of the scope of the problem the most affected populations is needed. This proposal seeks to fill that void by supporting the development of a data-rich online tool that answers some of these key questions.

Approaches (Methods)

Phase 1 (Pilot study):

Aim 1: Identify substantial chemical exposures affecting large numbers of women in the California workplace.

The first phase of research will be a pilot study to determine the feasibility of creating a tool or database to describe women's occupational risk for breast cancer in California. The most critical first step is to determine if it is possible to find strong enough data on chemical exposures in the California workplace that may increase a woman's risk for breast cancer. Currently the government has no organized tracking system. However, it may be possible to assess a broad range of data sources to determine what data exists and if it is possible to combine data from various sources in a meaningful way. Sources of data may include:

- literature reviews,
- government publications,
- surveys of occupational exposures,
- hazardous materials inventories (managed by Certified Unified Program Agencies),[1]
- freedom of information requests, and,
- other sources.

Areas of primary focus will ideally include:

- industries that employ significant numbers of women; and/or,
- industries that use High Production Volume chemicals.

Develop a system for capturing this data for as many years as possible since 2000.

Identify chemicals to be surveyed for occupational use and women's exposures in California. With thousands of chemicals in use, determining which chemicals are a priority for this investigation will have a significant impact on how meaningfully the results can be translated to policy interventions. Proposals should assume that the chemicals included in this investigation are used in large volume (such as High Production Volume or HPV chemicals), or are used in ways that expose a large number of women to a chemical of high concern.

The following categories of chemicals to be investigated should include but are not limited to:

- **Mammary Carcinogen Review Database, Silent Spring Institute, High-exposure Chemicals (Rudel 2007):** The Science Review database includes information on 216 chemicals that increased mammary gland tumors in animal studies. This list can be narrowed to include only High Production Volume chemicals added to food, found in air pollution or consumer products or causing greater than 5,000 women annually to be exposed occupationally.

- **Mammary gland developmental toxicants**: *Environmental Health Perspectives* article "Environmental Exposures and Mammary Gland Development: State of

[1] See http://www.dtsc.ca.gov/HazardousWaste/CertifiedUnifiedProgramagencies.cfm. Though it is unlikely this will be a comprehensive source of data, there may be data available for some of the larger counties that could prove illuminating.

the Science, Public Health Implications, and Research Recommendations" lists these chemicals in the supplemental materials attachment (Rudel 2011).

- **Flame retardants:** Environmental Science & Technology article **"**After the PBDE Phase-Out: A Broad Suite of Flame Retardants in Repeat House Dust Samples from California" lists these chemicals in Table SI4 (Dodson 2012).

- **Endocrine disruptors:** A list is available from The Endocrine Disruption Exchange TEDX) at http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/chemicalsearch .

Proposals for Phase 1 must be from researchers who have a working knowledge of occupational exposure issues in California and potential sources of data. Applicants should demonstrate capacity to investigate and assess existing data from a myriad of government sources that often do not present data in parallel, compatible formats. Additionally, applicants must possess a basic understanding of government institutions at the state and federal level, as well as their available resources.

Phase 2

If the results of Phase 1 are strong enough, then a second phase of the research will be pursued to cross reference occupational exposure data with occupational and demographic data in California.

Aim 1: Identify where women are employed in California.

Research all relevant sources of data that can help map in what types of industries women in California are working. Identify which sources include data from 2000 to the present to establish which years are possible for full analysis and identify whether other years where there may be less available data are appropriate for analysis.

For all data sets, collect demographic data, including race, age (especially identifying women of child bearing age), immigrant status, socioeconomic levels, immigration status, etc.) where available. A transparent, standardized system for combining data sets should be developed with a defined geographic unit(s) to aid further research aims.

Examples of available data include:

- **Occupational Employment Statistics' Employment and Wages by Occupation:** [Source:http://www.labormarketinfo.edd.ca.gov/LMID/OES_Employment_and_Wages.html] Although, this employment data does not break data down by gender, it does list nearly 900 occupations (in the recent listing) in California and the mean hourly and mean annual income for each occupation (and by county). Data available online from 2001 to 2013.

- **Data for Affirmative Action/EEO Plans:** [Source:http://www.calmis.ca.gov/htmlfile/subject/demoaa.htm] This data was derived from 2000 Census population, labor force data, and summary occupational information for use in developing affirmative action programs, also

known as Equal Employment Opportunity (EEO)**,** as required for federal and state contract compliance. Data is broken down by gender and race; however, the occupational categories are much more broadly defined than what is available in the Occupational Employment Statistics Employment and Wages by Occupation data listed above. Data available at the state and county level, though only for 2000.

- **The Report on the Status of Women and Girls in California 2013.** [Source:http://www.msmc.la.edu/PDFFiles/status-of-women/2013/RSWG-2013-FINAL.pdf] This report contains some disaggregated data on women's employment in California.

In addition, researchers are encouraged to investigate the availability and utilization of the on-site confidential data access at the U.S. Bureau of Labor Statistics to derive California sex-specific industry/occupation categorized (by NAICS code) data for the Quarterly Census of Employment and Wages (QCEW) and other databases. Information on the confidential research program can be found at Researcher Access to Confidential Data Files at the BLS http://www.bls.gov/bls/blsresda.htm.

Aim 2: Identify the overlap between where women are employed in California and what chemicals linked to increased risk for breast cancer they are exposed to.

Using the data gathered in Phase I and Phase 2: Specific Aim 1, conduct analysis for all years available, starting with 2000. Develop a system for merging datasets gathered in Phase I and Phase 2: Specific Aim 1. Identify areas of highest concern for occupational breast cancer risk.

Aim 3: Identify key data gaps in occupational chemical exposures for women working in California.

This is the first time information like this will be gathered and analyzed. The research process will likely reveal significant gaps in data. Identifying these gaps will be key a finding of this effort and can serve as a critical piece of information for future policy efforts.

Aim 4: Create an online database and/or visual tool, such as an interactive map, of women's occupational exposures to known and suspected mammary gland carcinogens (Rudel 2007), mammary gland toxicants (Rudel 2011), and/or endocrine disrupting chemicals (TEDX) in California.

Work with programmers, developers and data visualization specialists to present a tool that can be accessed by the general public to educate decision makers, advocates and others on industries in California that pose the highest concern for occupational breast cancer risk.

Upon completion of Phase 2, Aims 1-4 the team will hold a one-day meeting to present findings to date, especially highlighting the industries of highest concern in California.

The meeting will be open to people interested in applying to lead Phase 3 (the team leading Aim 1-4 is eligible to apply to lead Phase 3, though not assumed to be the team to lead Phase 3).

Phase 3

If the results of Phase 1 of the research are not strong enough to pursue Phase 2 of the research, Phase 3 may still be funded. Applicants will need to develop a strong case for why the industry they are interested in researching is of high priority to California's workforce.

Aim 1: Conduct more in-depth pilot investigation(s) into key industries in California that appear to pose the greatest breast cancer risk to women, based on the findings of Phase 1/2.

A third call for proposals will be released for Phase 3. Applicants are encouraged to describe a methodology that could answer these questions. Industries for consideration may include clean rooms, semiconductor work, health care, canning, plastics, agriculture or other industries that either have intensive exposure to breast carcinogens and/or lower-level exposures of breast carcinogens but that result in significant numbers of women being exposed or women being exposed at exceptional levels. This stage of research is an opportunity to explore more detailed exposure assessments, including investigation/measurement of the concentrations/levels chemical workers are actually being exposed to.

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Budget

It is anticipated that up to $150,000 in direct costs is available for **Phase 1 of this initiative**. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses, which receive 25% F&A.

Future funding opportunities under Phase 2 and Phase 3 of this initiative are dependent on the Phase 1 research outcomes.

How We Evaluate RFPs

CBCRP uses a two-tier evaluation process: peer review and programmatic review. It is a combination of, (i) the peer review rating, (ii) the programmatic rating, and (iii) available funding that determines a decision to recommend funding.

Peer Review
All applications are evaluated by a peer-review committee of individuals from outside of California. The committee is comprised of scientists from relevant disciplines and breast cancer advocates and other community representatives.

- **Innovation** Extent to which the project explores new and potentially useful information. Are the concepts and hypotheses speculative and exploratory? Are methods novel and original? Has(ve) the investigator(s) thought creatively about identifying the breadth of chemicals in occupational settings that affect health?

- **Impact:** Potential for the project, if successful, to provide a new tool or database for assessing chemical exposures. Will the research provide a prioritization of the chemicals that should be targeted for research that will translate into policy interventions?

- **Approach:** The quality, organization, and presentation of the research plan, including methods and analysis plan. Will the research planned answer the research questions? Are the design, methods and analyses well-developed, integrated and appropriate to the aims and stated milestones of the project? Does the application demonstrate an understanding of the research question and aims?

- **Feasibility:** The extent to which the aims are realistic for the scope and duration of the project; adequacy of investigator's expertise and experience, and institutional resources; and availability of additional expertise and integration of multiple disciplines. Does the investigator (and do co-investigators) have demonstrated expertise and experience working in the topic area? Can the project be completed as proposed given the available funding, time frame and the staff knowledge, skills, experience, and institutional resources?

Programmatic Review
This review is conducted by the Breast Cancer Research Council and involves reviewing and scoring applications with sufficient scores from the peer review process based on the criteria listed below. The individuals on the Council performing this review include advocates, clinicians, and scientists from a variety of disciplines. In performing the Programmatic Review the advisory Council evaluates **only a portion of the application materials** (exact forms are underlined). Pay careful attention to the instructions for each form. The Programmatic criteria include:

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

template and the content of the Lay and Scientific abstracts to the CBCPI topic area. (A score of "0" for Responsiveness is an automatic disqualification.)

- **Dissemination and translation potential.** The degree to which the applicant's statements on the Additional Criteria template provides a convincing argument that the proposed research has the potential to inform the development and/or implementation of California chemicals policy.

- **Quality of the lay abstract.** Does the Lay Abstract clearly explain in non-technical terms the research background, questions, hypotheses, and goals of the project? Is the relevance to the research initiative understandable?

- **Advocacy Involvement.** Are the named advocate(s) and advocacy organization appropriate for the proposed research project? Were they engaged in the application development process? Are meetings and other communications sufficient for substantive engagement? Are the roles and responsibilities of the PI and the advocate(s) clearly outlined and is the agreement for advocate compensation and reimbursement clear?

Application Process and Instructions

Submission Deadline: Applications must be submitted through proposalCENTRAL (https://proposalcentral.altum.com/) by **Wednesday October 22, 2014** at 12 noon Pacific Standard Time.

Signed face pages of submitted applications must be emailed to RGPOgrants@ucop.edu by 5pm **October 29, 2014**.

The application materials will be available on proposalCENTRAL by September 2, 2014.

proposalCENTRAL Online Submission Instructions

Formatting Instructions

All submissions must be in **English**.

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

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

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

Online Application (Proposal) Management

The CBCRP requires applications be submitted via an online system: proposalCentral. Following are instructions on how to register and how to submit your response to the RFP. The submission deadline is 12 noon Pacific Time **Wednesday October 22, 2014.** *Note*: the proposalCENTRAL site shows East Coast times. Do NOT wait until the deadline to submit your application; if you miss the deadline, the system will not allow you to submit.

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

Online Registration

The PI as well as the institution's signing official, contracts & grants manager and fiscal contact must be registered in proposalCENTRAL: https://proposalcentral.altum.com/. Start with "Click here to register". Fill out all the necessary fields on the registration page: First Name, Last Name,

Email Address, User ID (can be your name), Password (case-sensitive), Challenge Question, and Answer.

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

Online Forms and Fields

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

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

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

❒ Title Page

On the "Title Page" enter the Project Title in the space provided (do not exceed 60 characters). Enter the total budget amount requested for the project, including indirect costs, if eligible. The projected start date for this project is March 1, 2014. Enter the end date of the project (up to 3 years).

❒ Download Templates & Instructions

This section includes these instructions as well as the relevant application forms. You will need these forms in order to respond to this RFP.

❒ Enable Other Users to Access this Proposal

Note: A person must be registered in proposalCentral before s/he can be given access.
Read the instructions on this page thoroughly to understand the different levels of access. At the bottom of that page, in "Proposal Access User Selection," type in the email address of other individuals who will be working on the RFP, then click "Find User." Select the desired level of access and Click "Accept Changes" to save.

❒ Applicant/PI

Click on "Applicant/PI" and make sure that all required fields (identified with a red asterisk) are complete. (Click "Edit Professional Profile" to enter any missing data.)

Click "Return to Proposal" after entering missing data. Enter the % effort that the PI will devote to this project. The minimum effort is 10% FTE . Click "Save."

❒ Institution & Contacts

On the "Institution & Contacts" page, make sure that all required fields (identified with a red asterisk) are complete, including the Signing Official, Contracts and Grants Official, and Fiscal (Accounting) Contact for the applicant institution. To complete these fields select the name or enter the email address of the individual in each of those roles and click "Add."

If you add someone, the "Contact Screen - Applicant Institution" screen will open. Make sure that all required fields (identified with a red asterisk) are completed.
Click "Save", then click "Close Window".
Then click "Save" on the Institution & Contacts page.

❒ Abstracts

Copy each the Lay Abstract and the Scientific Abstract from the CBCRP templates into the appropriate boxes on the proposalCENTRAL page. ***Note***: symbols or other special text will not copy.

On this page you should also select and add CSO codes. At www.cancerportfolio.org/cso.jsp you will find the seven major CSO categories, each with 4-9 sub-categories. Choose a major heading for your research and read the subcategory description. Choose the one that most closely fits. If your project fits under more than one CSO category, add a second code. The second code should represent a different, but integral, part of the research and about half of the total effort.

❒ Budget

Provide the total costs for the entire funding request for each grant year on this page. Make sure the budget numbers are exactly the same as those in the provided Excel Budget Summary form that you upload.

❒ Organization Assurances

Provide any required information for Human Subjects. If assurances will be required and have not yet been received, mark "pending" and enter the (proposed) date of submission in the "Approved or Pending Date".

❒ Upload RESEARCH PLAN and Other Attachments

This page contains a duplicate list of the forms and instructions that are in Download Templates and Instructions (above and Proposal Section 2). This is where you will upload the CBCRP forms and any other attachments to your proposal; the required items are listed.

To upload attachments, fill in the fields at the top of the page:

- **Describe Attachment:** Provide a meaningful description, such as Jones CV.
- **Select Attachment Type:** From the drop down menu, select the type of form that is being attached.
- **Allowable File Type:** Only Adobe PDF document may be uploaded. Do not Password Protect your documents. Help on converting files to PDF can be found on the proposalCentral site at https://proposalcentral.altum.com/FAQ/FrequentlyAskedQuestions.asp.
- **Select File From Your Computer to attach:** The Browse button allows you to search for the PDF on your computer; click Open to select the file.

Note: Explicit instructions on the content of the documents to be uploaded follow in the "Instructions for CBCRP Forms" section.

❒ **Validate**

This function allows you to check whether all required items have been completed and attached. Don't wait until the last minute to check! Validate often during the course of completing your application so you have time to address missing items. Clicking the "Validate" button will either result in a link to missing items so you can easily go to the page and complete them, or a message at the top of the page "Has been validated and is ready to submit."

❒ **Print Face Page When Application Complete**

Applicants must print application's Face Page and obtain the necessary PI and institutional signing official signatures within a week of the electronic submission (see below).

❒ **Submit**

Submission is only possible when all required items have been completed and all required forms have been attached. Once an applicant hits "Submit," the application cannot be recalled.

❒ **Email Face Page Submission**

The PI, institution's signing official, Contract and Grants official and Fiscal (or Accounting) official all must sign the printed Face Page. Scan the signed form as a PDF and email to RGPOGrants@ucop.edu before 5 pm (Pacific Time) by **Wednesday, October 29, 2014.**

CBCRP Uploaded Form Instructions

Lay Abstract (REQUIRED)

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

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

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

Scientific Abstract (REQUIRED)

This item is evaluated mainly in the peer review. The Scientific Abstract is limited to one page and should include:

- A short introductory paragraph indicating the background and overall topic(s) addressed by the research project
- The central hypothesis or questions to be addressed in the project.
- A listing of the objectives or specific aims in the research plan
- The major research methods and approaches used to address the specific aims
- A brief statement of the impact that the project will have on breast cancer.

Provide the critical information that will integrate the research topic, its relevance to breast cancer, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum level of information. Make the abstract understandable without a need to reference the detailed research plan.

Other Review Criteria (REQUIRED)

This item is evaluated in the programmatic review. Limit the text to two pages. The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan. The information on this template allows the CBCRP Research Council to rate the application for adherence to the objectives of the CBCPI research area as outlined in the specific RFP and by the CBCRP Council/SRI Steering Committee (see www.cabreastcancer.org/funding-opportunities/sri).

CBCPI Focus: Provide a clear, brief summary for the CBCRP Council (1 or 2 paragraphs) of how your proposed research addresses the specific RFP topic area, by increasing or building on specific scientific knowledge; by pointing to additional solutions to identify and eliminate environmental causes, and or disparities in, breast cancer; and/or, by helping indentify or translate into potential prevention strategies.

Advocacy-sensitivity and Inclusion: Discuss what involvement, if any, advocates had in the development of this proposal and will have in the project, if funded. Explain how this proposal shows awareness and inclusion of breast cancer advocacy concerns involved in the proposed research.

Dissemination and Translation Potential: Describe how research findings will be shared with various stakeholder audiences (i.e., policymakers, community members, breast cancer advocates, other researchers/agencies, health care providers, funders etc.). Describe the potential for how the research findings will be translated into policy and/or other practice.

Advocacy Involvement (REQUIRED)

Follow the instructions on the form, and address the requested three items (Advocacy Organization/Advocate(s) Selection and Engagement to Date, Advocate(s) Role in Proposed Research and Meeting and Payment Plans). Limit the text to one page.

Letter(s) of Commitment (REQUIRED)

Please use the template as a basis for commitment letters from the advocate, scientific and/or subcontracting individuals/institutions. Limit the text to two pages.

Budget Summary (REQUIRED)

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

The maximum duration and direct costs may not exceed 1.5 Years & $150,000

Note: The amount of the subcontracted partner's F&A costs can be added to the direct costs cap. Thus, the direct costs portion of the grant to the recipient institution may exceed the award cap by the amount of the F&A costs to the subcontracted partner's institution.

Personnel. List the PI for the application and "individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested." (NIH definition). Include those at the level of postdoctoral fellow and higher. Upload a NIH "Biographical Sketch and Other Support" form for each individual listed. The minimum "Months Devoted to Project" required for each CBCPI PI is 1.2 months (= 10% FTE).

Other Project Expenses. Enter the costs associated with each category presented on the template (description to be provided in Budget Justification).

Advocate(s) Expenses. Include any travel, meeting, and consultation costs/fees associated with advocate engagement.

Equipment. Purchases up to $10,000 are allowed. Only include individual items >$5,000. Any items less than $5,000 must be purchased under the "supplies" budget category above.

Travel Expenses. Requested travel costs must be broken down and justified as Project-related, Annual meeting (third year only) or Scientific meeting (PI only capped at $2,000 per year).

Subcontracts. In the case of University of California applicants, subcontracts need to be categorized and broken out as one of two types, University of California-to-University of California (UC to UC) sub agreements or transfers; or, Other. Both categories require additional description (Budget Justification) and documentation (Appendix).

Service Agreements and Consultants. Both categories require additional description (Budget Justification) and documentation (Appendix).

Indirect (F&A) costs. Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 25% MTDC*

**Allowable expenditures in the MTDC base calculation include salaries, fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from the modified total direct cost base calculation.*

Please see the RFP under **Allowable Indirect (F&A) Costs** for more information.

Budget Justification & Facilities (REQUIRED)

This item is evaluated in the peer review. Limit the text to two pages. Follow the instructions on the template. The minimum "Months Devoted to Project" required for each CBCPI PI is 1.2 months (= 10% FTE).

Key Personnel (REQUIRED)

This item is evaluated in the peer review. Limit the text to one page. Follow the instructions on the template.

Biographical Sketch & Other Support (REQUIRED)

This item is evaluated in the peer review. Use the NIH form. Limit the length of each biosketch to *no more than* four (4) pages.

Research Plan (REQUIRED)

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

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

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

The Research Plan and all continuation pages must conform to the following four format requirements:

1. The height of the letters must not be smaller than 11 point; Times New Roman or Arial are the suggested fonts.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi).
3. No more than 6 lines of type within a vertical inch;

4. Page margins, in all directions, must be at least ½ inch.

Use the appendix to supplement information in the Research Plan, not as a way to circumvent the page limit.

Applicants should be clear in describing how their proposed research project adheres to, and/or builds on, approaches/methods described in the RFP including the expectations at the end of each Project Type 1 area of interest (A through D). A proposed research project may include to one or more of these interest areas.

Suggested content:

Introduction and Hypotheses: Provide a brief introduction to the topic of the research and the hypotheses/questions to be addressed by the specific aims and research plan. The relationship of the project to the specific CBCPI Project Type and expectations outlined within the RFP should be clear.

Specific Aims: List the specific aims, which are the steps or increments deemed necessary to address the central hypothesis of the research. The subsequent research plan will detail and provide the approach to achieving each of these aims.

Background and Significance: Make a case for your project in the context of the current body of relevant knowledge and the potential contribution of the research.

Preliminary Results: Describe the recent work relevant to the proposed project. Emphasize work by the PI and data specific to breast cancer.

Research Design and Methods: Provide an overview of the experimental design, the methods to be used, and how data is to be collected and analyzed. Describe the exact tasks related to the Specific Aims above. Provide a description of the work to be conducted during the award period, exactly how it will be done, and by whom. Include a letter of commitment if the applicant PI will be using a data set that they do not control/own. Recognition of potential pitfalls and possible alternative approaches is recommended. How will technical problems be overcome or mitigated? Cover all the specific aims of the project in sufficient detail. Identify the portions of the project to be performed by any collaborators. Match the amount of work to be performed with the budget/duration requested. A timeline at the end will demonstrate how the aims are interrelated, prioritized, and feasible. Explain the use of human subjects and vertebrate animals and show their relationship to the specific aims.

Resources and Facilities: Describe the resources and facilities to be used (e.g., laboratory space, core facilities, major equipment, access to populations, statistical resources, animal care, and clinical resources) and indicate their capacities, relative proximity and extent of availability. Include an explanation of any consortium/ contractual arrangements with other organizations regarding use of these resources or facilities. Describe resources supplied by subcontractors and those that are external to the institution. Make sure all of the research needs described in the research plan are addressed in this section.

Human Subjects (OPTIONAL)

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

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

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

1. Provide a detailed description of the proposed involvement of human subjects in the project.
2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and the CBCRP that research involving human subjects must include members of underserved groups in study populations. Applicants must describe how minorities will be included and define the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated.
3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records or data.
4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained, who will seek it; the nature of the information to be provided to the prospective subjects; and the method of documenting consent.
5. Describe any potential risks —physical, psychological, social, legal, or other. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
6. Describe the procedures for protecting against, or minimizing, any potential risks (including risks to confidentiality), and assess their likely effectiveness. Where

appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also, where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.

7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects, and in relation to the importance of knowledge that may be reasonably expected to result.

Documentation of Assurances for Human Subjects

In the appendix, if available at the time of submission, include official documentation of the approval by the IRB, showing the title of this application, the principal investigator's name, and the approval date. Do not include supporting protocols. Approvals obtained under a different title, investigator or organization are *not* acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, an USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible, but **no later than January 1, 2015**. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

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

Vertebrate Animals (OPTIONAL)

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

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

1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Plan. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
2. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the veterinary care of the animals involved.
4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic and tranquilizing drugs, and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.
5. Describe any methods of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If it is not, present a justification for not following the recommendations.

Documentation of Assurances for Vertebrate Animals

Grants will not be awarded for research involving vertebrate animals unless the program for animal care and welfare meets the standards of the AAALAC or the institution has a U.S. Public Health Service assurance. In the appendix, if available at the time of submission, include official documentation of institutional review committee approval showing the title of this application, the principal investigator's name, and the inclusive approval dates. Do not include supporting protocols. Approvals obtained under a different title, investigator or institutions are not acceptable unless they cross-reference the proposed project. If review is pending, final assurances should be forwarded to the CBCRP as soon as possible, but **no later than January 1, 2015**. Funds will not be released until all assurances are received by the CBCRP.

Appendix List (OPTIONAL)

Follow the instructions and items list on the template. **The appendix may not be more than 30 pages in length.**

Note that the *research plan must be self-contained* and understandable without having to refer to the appendix. Only those materials necessary to facilitate the evaluation of the research plan or renewal report may be included.

General Funding Policies

Who May Apply

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.

Note: 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 an CBCPI 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.

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.

Conditions of Awards

Details concerning the requirements for funding recipients are available in a separate Program publication, the University of California, Office of the President, "***Grant Administration Manual 2011-2012***." It is sent to every funding recipient principal investigator, contracts and grants official, and the accounting contact. The Manual can be obtained from the Program's office or viewed on our Web site: www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf.

Awardees are expected to account for the expenditure of funds and for the performance of work as agreed upon in a timely manner, so that the CBCRP may file reports and answer inquiries from the legislature and the public. They are also expected to adhere to the stated goals of the legislation, which include the systematic dissemination of research results to the public and to the healthcare community and the facilitation of translation of research results into commercial, alternate technological and other applications. The Institutional Official's and Principal Investigator's **signatures on the Face Page of the application signify that the individuals are aware of the conditions for receiving funding** from the Program.

To ensure the proper management of these public funds, a prospective funding recipient must satisfy the **following standard requirements** before an award will be made:

- Have adequate organizational and fiscal management, and accounting systems to administer the award and assure compliance with award terms and conditions.
- Have adequate liability insurance and bonding, including indemnification of the UC Regents.

- Ensure nondiscrimination in employment, and assurances regarding the treatment of animal or human subjects and research safety and ethics.
- Have adequate financial resources, equipment, facilities, and technical skills to perform the proposed work, or the ability to obtain them.
- Be able to perform the proposed work within the approved time frame, taking into consideration all existing commitments.
- Have a satisfactory record of integrity and business ethics.
- Maintain mechanisms to assure integrity and honesty in the conduct of research, safe conduct of research, and fair practice for all employees and research subjects.
- Certify that none of the key personnel on the initiative are barred by the U.S. Public Health Services Office on Research Integrity from performing comparable roles on federally funded grants.

Individuals who are to be awarded funds may meet these requirements directly or by making arrangements with a research organization that does. A funding recipient may satisfy modified requirements, if this is determined to be appropriate upon review by the University of California's Office of Research Administration, Office of Risk Management and General Counsel.

Though the research must be conducted primarily in California by California investigators, part of the work may be done outside California if the need to do so is well justified (i.e., it is integral to the achievement of a specific aim and cannot reasonably be performed in California) and the results of such work may be applied to furthering the achievement of the Program's goals.

Grant awardees must agree to:

- Use award funds only as approved by the CBCRP. The Program must approve changes in the specific aims of an initiative.
- Maintain accounts, records and other evidence pertaining to work performed and costs incurred.
- A final scientific report and any interim reports as specified in this announcement.
- File annual fiscal reports and a final fiscal report.
- Participate in CBCRP sponsored activities to disseminate research results as able and as requested.
- Ensure the timely translation of research results into commercial applications, public policy, and public communications as appropriate and/or required by this announcement.
- Attend CBCRP research symposiums, if scheduled during the award period, or forfeit budget amounts assigned to this item.

Award Period and Indirect (F&A) Costs

If a multiple year award, continuation funding for additional years is released upon receipt of an Annual Progress Report showing research effort/progress, no overlap with other support, maintenance of sufficient FTE percentage by the PI, continuing approval of Human and Animal subjects use, submission of publication copies, and reporting any changes in Key Personnel. If funding is delayed, or if all funds are not expended in the normal award period, then the

investigator(s) may request a no-cost time extension for a maximum of one year in order to complete the work.

The CBCRP encumbers the funds for all approved years of an award from the appropriation in the year the funds are awarded; thus full funding of a multi-year initiative is assured, dependent only on timely submission of the required reports. Funds will be disbursed annually, contingent on receipt of required progress and fiscal reports.

For one-year initiatives, and for the final budget year of multiyear initiatives, 20% of the approved budget is withheld (except for UC institutions) and paid in arrears upon receipt and acceptance by the Program of all required final reports.

Direct Costs
CBCRP award funds may be used only for expenditures necessary to carry out the approved initiative, as specified in the approved budget. Significant changes in proposed expenditures must be approved in advance by a CBCRP Research Administrator. Please follow the policies in the "SRP Grant Administration Manual" regarding allowable changes in expenditures and the guidelines for submitting a formal request form to change initiative budgets.

Allowable direct cost expenditures may include administrative costs only if the following two conditions are satisfied: (a) the services, functions, or activities are directly necessary for the conduct of the initiative; and, (b) these administrative costs have not been included in the calculation of the recipient institution's indirect cost rate agreement approved by the Federal government. In other words, the Program policy does not prohibit administrative costs, but it is careful to ensure that costs meet both conditions (a) and (b).

Cost Base for Determining Indirect Cost Allocations for UCOP RGPO Awards
The "cost base" for determining the indirect cost (IDC)[2] recovery for RGPO awards will consist of: salaries and wages, fringe benefits, materials and supplies, services, travel, and sub grants and subcontracts to an outside institution up to the first $25,000 of the initial sub-award budget (excluding renewals or extensions). This base is called the Modified Total Direct Cost, or MDTC base. Equipment or other capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, as well as the portion of each sub grant and subcontract *in excess* of the first $25,000, and the total cost of any subcontract from one UC to another UC campus, are **excluded** from this MTDC base. Any questions about interpretation of the MTDC base can be directed to the CBCRP Program Officer, and/or the RGPO Contracts and Grants Analyst assigned to an awarded grant.

Allowable Indirect (F&A) Costs
For primary grantees the following conditions apply regarding recovery of indirect costs:

- For awards to UC Campuses, a cap of no more than 25% MTDC is allowable on grant awards. See below for additional discussion on indirect on subcontracts.

[2] IDC is also commonly referred to as Overhead or Facilities and Administrative costs, or F&A.

- For awards to Non-UC institutions, the CBCRP awards allow F&A cost recovery utilizing the MTDC base, at the applicable federally approved F&A rate for the Non-UC Institution. (The rate approved by a federal cognizant agency must be used if available). In the absence of a federally negotiated rate agreement, an equivalently documented F&A rate for the institution may be used (upon approval of UCOP RGPO).

For indirect costs for award subcontracts the following conditions apply:

- For subcontracts to UC Campuses, a cap of no more than 25% MTDC is allowable on subcontracts related to CBCRP awards.
- For awards to Non-UC institutions, the subcontractor F&A costs recovery utilizing the MTDC base is allowed at the appropriate federally approved F&A rate for the Non-UC Institution. (An approved Department of Health and Human Services (DHHS) rate must be used if available). In the absence of a federally negotiated rate agreement, an equivalently documented F&A rate for the institution may be used (upon approval of UCOP RGPO).
- For subcontracts awards to UC-managed National Labs (LBNL, LANL, LLNL) please contact the CBCRP Program Officer.

Individuals without an institutional affiliation will not be eligible for indirect costs.

Provisional or pending increases in indirect rates will be included in awards only if they are documented prior to execution of the award agreement and disbursement of year one funding. The maximum indirect costs which CBCRP pays is the lesser of: (a) the federally approved rate current for the budget year, or (b) the rate provided for in the final approved budget.

Under no circumstances will funded initiatives be supplemented to reflect an unanticipated increase in the F&A rate; nor can funds originally awarded as direct costs be shifted to cover increases in the F&A rate. If the F&A rate decreases below that provided for in the approved budget, the CBCRP will pay overhead at the new lower rate starting on the date of change, and will decrease the award to the institution by the difference between the originally approved amount and the amount to be accrued at the new rate.

Both to initiate funding and for continuation funding of existing awards, the Program requires a copy of the institution's current indirect cost agreement annually.

University of California Campuses

In accord with University of California policy, investigators who are University employees and who receive any part of their salary through the University must submit applications and proposals through their campus contracts and grants office ("Policy on the Requirement to Submit Proposals and to Receive Awards for Grants and Contracts through the University," Office of the President, December 15, 1994). Exceptions must be approved by the UC campus where the investigator is employed.

Fraud and Scientific Misconduct

Policy Regarding Scientific Misconduct

The University of California manages the California CBCRP, Tobacco-Related Disease Research Program (TRDRP), and the California HIV/AIDS Research Program (CHRP) within its Special Research Programs in general accord with the policies and procedures employed by the National Institutes of Health (NIH), including those that apply to scientific misconduct. The Department of Health and Human Services' (HHS) Office of Research Integrity is responsible for implementing HHS regulations regarding scientific misconduct in research conducted with NIH and other support from the US Public Health Service.

The administrative actions imposed by HHS include the following: correction of the scientific literature; special plan of supervision to ensure integrity of the scientific research; certification of the accuracy of the scientific data; certification of the accuracy of sources and contributions for scientific ideas and writings; prohibition against service on PHS advisory committees or as a consultant; and, debarment from receipt of Federal funds. These actions are for a specified duration, depending on the nature and seriousness of the misconduct.

Applicants for or recipients of funding from the Special Research Programs (SRP) must promptly inform the University of an administrative action for scientific misconduct that is imposed by HHS by providing a copy of the final notice of the administrative action (i.e., after the disposition of any appeal), either at the time of application or within 30 days of the imposition of the administrative action. In general, the University will apply the same administrative action. For example, if HHS has debarred an investigator from applying for or receiving NIH awards for a specified period of time, that investigator would also be excluded from applying for or receiving awards from any of the SRP programs. To take another example, if an investigator has entered into a voluntary agreement with HHS for special oversight and supervision of the investigator's applications, research, and publications, that agreement would apply to that investigator's applications to, or awards from, the SRP.

Applicants or recipients may request that HHS administrative actions be waived or modified with respect to an application or award from the SRP. In such case, the applicant must present a justification for the request.

Fraud or Misuse of CBCRP Funds

Report fraud or misuse of CBCRP funds to either the CBCRP Director, Dr. Marion Kavanaugh-Lynch, at (510) 987-9878, or to the Office of Audit Services, at (510) 987-0478 or www.ucop.edu/audit/.

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.

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, the costs (both direct and indirect), the initiative abstracts, and progress report abstracts. CBCRP uses a variety of media to communicate this information including (i) the "Compendium of research" for each funding cycle, (ii) CBCRP's "Advances" annual report, (iii) CBCRP's e-news, web site, and social media, and (iv) other special communication tools such as press releases. If the Program receives a request for additional information on a funded initiative, 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 application 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.