



**California Breast Cancer Prevention Initiatives (CBCPI)
Submission Instructions
August 2014**

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

CBCPI Funding Announcements	Download RFP	Submission Deadline*
Chemical Safety Testing to Reduce Breast Cancer Risk	CBCPI Chemical Testing RFP 2014 [pdf]	October 22, 2014
Occupational Chemical Exposures in California and Breast Cancer Risk	CBCPI Occupational Exposure RFP 2014 [pdf]	October 22, 2014

*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 (<https://proposalcentral.altum.com/>) by September 2, 2014.

CBCPI Overview

The CBCRP announces funding opportunities through our Special Research Initiatives (SRI) outside of the annual funding cycle. Investigators will be supported to pursue research strategies that increase knowledge about and create solutions to both the environmental causes of breast cancer and the unequal burden of the disease. The next SRI funding round will consist of intermittent Calls for Applications beginning in late 2014 under the California Breast Cancer Prevention Initiatives (CBCPI). The first opportunities will pursue topics arising from the previous strategies and new research on address disparities and the environment. These will be followed by new efforts to research interventions for primary prevention at individual and population levels.

Initial CBCPI funding opportunities released August 2014 with applications due October 22, 2014 include the following:

- Request for Proposals: Chemical Safety Testing to Reduce Breast Cancer Risk
- Request for Proposals: Occupational Chemical Exposures in California and Breast Cancer Risk

The CBCRP: If you have not already reviewed our program's background, funding philosophy, or existing portfolio, then please consider doing so by visiting our website (www.cabreastcancer.org). The CBCRP's mission is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities. We are interested in funding novel topics and we are deeply committed to advocate involvement in all aspects of our portfolio and our program.

For both new and returning applicants it may be helpful to review general information on CBCRP's background, evaluation and funding process, advocacy involvement and other general information on our site. However, differences in the current CBCPI application process and requirements exist relative to the standard CBCRP single annual funding cycle, including no Letter of Intent (LOI) requirement from prospective applicants.

As with all CBCRP awards, 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.

The Special Research Initiatives and CBCPI: For information on previous SRI funded research please review information and the portfolio at <http://cbcrp/priorities/sri/>.

CBCPI Funding Announcement	Award Type	Project Duration & Direct Costs*	Submission Date
Chemical Safety Testing to Reduce Breast Cancer Risk Abbrev: CHEMTEST	Request for Proposals (RFPs)	Project Type 1: 3 Years & \$900,000 Project Type 2: 3 Years & \$150,000	October 22, 2014
Occupational Chemical Exposures in California and Breast Cancer Risk Abbrev: OCCEXP	Request for Proposals (RFPs)	1.5 Years & \$150,000	October 22, 2014

*Individual applicants may receive funding for all projects offered in these RFPs, but must submit separate applications for each project.

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 for Chemical Safety Testing to Reduce Breast Cancer Risk Project 1 and Occupational Chemical Exposures in California and Breast Cancer Risk is 10% FTE and 5% FTE for Chemical Safety Testing to Reduce Breast Cancer Risk Project 2. 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**.

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 <http://cbcrp/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 the following for the RFP *Chemical Safety Testing to Reduce Breast Cancer Risk*:

Project Type 1:	3 Years & \$900,000
Project Type 2:	3 Years & \$150,000

The maximum duration and direct costs may not exceed the following for the RFP *Occupational Chemical Exposures in California and Breast Cancer Risk*:

Pilot Project:	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 Chemical Safety Testing to Reduce Breast Cancer Risk Project 1 and Occupational Chemical Exposures in California and Breast Cancer Risk CBCPI PI is 1.2 months (= 10% FTE) and .6 months (= 5% FTE) for Chemical Safety Testing to Reduce Breast Cancer Risk Project 2.

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 Chemical Safety Testing to Reduce Breast Cancer Risk Project 1 and Occupational Chemical Exposures in California and Breast Cancer Risk CBCPI PI is 1.2 months (= 10% FTE) and .6 months (= 5% FTE) for Chemical Safety Testing to Reduce Breast Cancer Risk Project 2.

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 Chemical Safety Testing to Reduce Breast Cancer Risk - Project 1**
 5 pages Chemical Safety Testing to Reduce Breast Cancer Risk - Project 2
 10 pages Occupational Chemical Exposures in California and Breast Cancer Risk
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)¹ 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 MTDC 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.
- 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

¹ IDC is also commonly referred to as Overhead or Facilities and Administrative costs, or F&A.

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.