



Request for Proposals (RFP)
MAKING CHEMICALS TESTING RELEVANT TO BREAST CANCER
University of California
California Breast Cancer Research Program
Special Research Initiatives

DEADLINE: March 22, 2011

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About the CBCRP and the Special Research 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 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 million for breast cancer research and funded 56 grants
- 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 \$213 million in 894 grants to 101 institutions across the state with continued investment, the CBCRP will work to find better ways to prevent, treat and cure breast cancer.

In 2004, the CBCRP launched its **Special Research Initiatives (SRI)**. This effort has identified and is pursuing 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 SRI is leveraging California's unique and diverse geographic, population, and research resources to support critical studies that significantly move these fields forward.

SRI Priority Areas

The following are the priority areas for the SRI:

- **Environment:** Developing recommendations for state chemicals policy that specifically consider breast cancer; creating new protocols and methods for chemical screenings; and investigating transgenerational, environmental causes of breast cancer.

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- Disparities: Pooling existing data to explore racial and ethnic differences in breast cancer survival; identifying demographic measures that will enhance our understanding of disparities in breast cancer; and studying the characteristics of immigration that affect breast cancer risk.
- Both Environment and Disparities: Creating statistical and other complex models that could provide a new approach to understanding and studying the multiple, interacting factors that impact breast cancer; and investigating disparities and environmental exposures and breast cancer among a large, diverse cohort of women.

In March 2010, the council decided to build on the existing SRI by devoting 50 percent of CBCRP research funds over the next five years to directed, coordinated, and collaborative research into: Identification and elimination of environmental causes of breast cancer; Identification and elimination of disparities/inequities in the burden of breast cancer in California; Population-level interventions (including policy research) on known and suspected risk factors and protective measures; and Targeted interventions for high-risk individuals including new methods for identifying or assessing risk.

Making Chemicals Testing Relevant to Breast Cancer

Available Funding

California Breast Cancer Research Program (CBCRP) is sponsoring an open Request for Proposals (RFP) to select studies that would build a toxicity testing strategy for breast cancer by identifying biological mechanisms that play a role in breast cancer, developing tests to screen chemicals for activity in these mechanisms, and demonstrating the relevance of these tests for breast cancer using experimental cell based and animal models. *This project aims to shape chemicals policy in California by supporting the development of updated, functionally relevant assays that take into account all of the known or suspected mechanisms by which chemicals can contribute to breast cancer.*

Up to **\$5,000,000** total costs is available for this RFP. Individual proposals focused on developing new methods for screening chemicals are capped at **\$900,000** in direct costs for up to three years duration; however, smaller projects are also encouraged. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses.

Completed responses to this RFP are due by the deadline: noon, March 22, 2011.
The project start date is **June 1, 2011.**

For more information and technical assistance, please contact:

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Direct Line (510) 987-9876

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CBCRP Toll free: (888) 313-2277

Research Question (Specific Aim)

The grants under this initiative will advance the science of chemicals policy by expanding and improving the repertoire of assays specific to mechanisms known or suspected of contributing to breast cancer. Successful applicants will develop and validate new methods and/or model systems for identifying and testing chemicals for their potential to contribute to breast cancer.

Background/Justification

There is growing recognition of the potential role of environmental chemicals and cancer risk, as evidenced by the recent findings of the President's Cancer Panel http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08-09_508.pdf. It is also becoming clear that the long-standing systems for evaluating chemicals introduced into public use have been inadequate, but progress was made on this front with the European Union's adoption of the paradigm-shifting REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) and California's adoption of the Green Chemistry Initiative.

One of the most formidable challenges to understanding the role chemical toxicants may play in breast cancer is the dearth of publicly available basic hazard data for the tens of thousands of chemicals now in common use. Federal and state regulations do not systematically require manufacturers to generate and disclose information on chemicals to the public, government, or downstream businesses (Wilson and Schwarzman, 2009). Indeed 95% of all chemicals have not yet undergone basic toxicity testing. Therefore, there exists a data gap on the properties of common chemicals in commerce. This lack of basic information impacts consumers, and the private and public sectors: businesses wanting to adopt greener practices are hampered by lack of toxicity data on the chemicals that they purchase; consumers cannot choose safer products because they have an inadequate basis for comparing them; and regulatory agencies do not have the information they need to control and prevent risks to human health and the environment. This lack of data also interferes with our ability to learn about the contribution of chemical exposure to the incidence, progression and mortality of breast cancer.

The Toxic Substances Control Act (TSCA), which became law in 1976, is the linchpin of U.S. chemicals policy. TSCA requires little or no human health testing for the 62,000 chemicals that came onto the market before 1979 or the 20,000 chemicals introduced into commerce since then. The grandfathered chemicals still constitute the vast majority of chemicals in circulation. For example, 92 percent of the high-volume chemicals on the market today entered the marketplace prior to 1979 and thus are exempted from testing (Wilson and Schwarzman, 2009). A voluntary federal program to provide minimal hazard data for only the highest volume chemicals has foundered (Dennison, 2007).

While any available toxicology data on new chemicals must be reviewed by the EPA, chemical companies are not required to generate any toxicology data when they begin marketing new chemicals and in practice, they provide very little such information. Nor does the EPA conduct such testing itself. Rather, the EPA has relied on modeling to predict potential toxicity. The U.S. General Accounting Agency has found EPA's protocols under TSCA insufficient to predict public health consequences (US GAO, 2005). Accordingly, most new chemicals reach the market with no actual toxicity data made available to government or the public. TSCA compels manufacturers to provide toxicity and exposure data only once EPA shows that a risk exists, yet the EPA cannot demonstrate risk without toxicity and exposure data; U.S. chemicals policy is held in the grip of logical paralysis (Wilson and Schwartzman 2009). A 2010 legislative proposal to strengthen TSCA did not come to a vote.

Meanwhile, with the adoption of REACH, Europe http://ec.europa.eu/enterprise/reach/index_en.htm embraced a new approach to chemicals policy that requires health and environmental data on all chemicals sold over certain volume thresholds. Based on the principle of "no data, no market," REACH, which came into force in June 2007, demands production of toxicity data on all chemicals, including older chemicals grandfathered by prior EU law just as by TSCA in the US. Registration means that chemicals in commerce provide mandated data to enter or remain on the market. The higher the production volume, the greater the data required. The data requirements of REACH are set forth on their website: guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_b_en.

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[pdf?vers=20_10_08](#). Much of the data will be publicly available. Other provisions of REACH require that chemicals deemed "very high concern," must be evaluated by government officials, and that industry must demonstrate that the benefits of such chemicals outweigh their risks. More data may be requested if emerging evidence suggests that a substance poses a threat. Based on the results of these evaluations, high concern chemicals can be authorized but only for particular uses.

One criticism of REACH is that the specific data requirements were often derived from existing European regulatory programs. Some scientists believe that the data requirements are outdated, failing to take into account more recent scientific knowledge and not reflecting our understanding of mechanisms of action that may contribute to cancer, including breast cancer. There is a sense among these scientists that a more informative, more useful, cheaper and more efficient set of data requirements could be developed that would lead to better chemicals decision-making.

This sense is reflected in the recent report by the National Research Council, *Toxicity Testing in the 21st Century: A Vision and a Strategy* (National Academies Press, 2007), which called for development of chemical screening tools that rely on new genomic and high-throughput technologies. The US EPA and National Toxicology Program have announced a joint initiative to develop new, more cost-effective screening methodologies and have begun developing and testing a variety of short term *in vitro* assays of various types of biological activities via ToxCast (see www.epa.gov/ncct/toxcast/index.html) and other High Throughput Testing Programs (e.g. see ntp.niehs.nih.gov/?objectid=05F80E15-F1F6-975E-77DDEDBDF3B941CD). In these initiatives, they have specifically asked for collaborators to contribute information that will improve relevance of the testing to specific target organs, for example the mammary gland. Thus, this new testing initiative provides an important opportunity to improve the relevance of chemicals testing programs to breast cancer. However, this opportunity will only be realized if new research fosters the development and validation of tests relevant to chemical effects on breast cancer.

The state of California is stepping into the U.S.-E.U. chemicals breach. In 2007, California launched its Green Chemistry Initiative to examine how the state can reform its management of chemicals. Its initial report included a call to create a "chemical roadmap" through the creation of a state-based chemical inventory (Cal EPA, 2008). In December 2008, California's Department of Toxic Substances Control (DTSC) made recommendations for overhauling how chemicals are managed in California, including steps to close the data gap in chemical information and make it easier for the state to regulate hazards (www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GREEN_Chem.pdf). There are obvious advantages in modeling the California program after some aspects of REACH, but DTSC also recognized that the state may be able to do better and design a program tailored to the state's needs. California has a unique historical opportunity to shape a new chemicals policy in ways that prioritize the identification and testing of chemicals that damage human health and the environment, including those that contribute to breast cancer. The primary goal of such a policy is the early identification of hazards so that they can be avoided by the commercial market from the beginning.

The CBCRP sought to inform and provide tools for the Green Chemistry Initiative by funding the Breast Cancer and Chemicals Policy Project in which a multidisciplinary panel of experts formulated an approach for identifying chemicals that contribute to the development and promotion of breast cancer. They also made recommendations for improving the array of tests available to determine the effect of chemicals on breast cancer risk. The full description of their work is published in *Pathways to Breast Cancer: A Case Study for Innovation in Chemical Safety Evaluation*, (Schwarzman, Janssen, et al., 2010) at <http://coeh.berkeley.edu/greenchemistry/cbcrp.htm>.

The panel identified three categories of biological processes associated with breast cancer: cellular and molecular mechanisms; tissue changes; and susceptibility factors. They then developed a testing scheme for identifying substances that could increase breast cancer risk called the Hazard Identification Approach.

Table: Hazard Identification Approach

Rapid (<i>in vitro</i>) screening	
<p>Genotoxicity Mutagenicity (e.g., Ames or equivalent) Chromosome aberrations (e.g., OECD TG 473) Micronuclei formation (e.g., OECD TG 487) DNA strand breaks (e.g., COMET assay)</p> <p>Cell cycle Changes Cell division (e.g., ³H thymidine proliferation assay) Altered apoptosis (e.g. TUNNEL assay)</p>	<p>Endocrine Disruption Activation or inhibition of: Estrogen-mediated transcription (e.g., E-screen) Androgen-mediated transcription (e.g., A-screen) Enzymes specific to synthesis or metabolism of estrogen, androgen or progesterone (e.g., aromatase activity assay)</p>
Animal Studies (<i>in vivo</i>): development and maturation	
<p>Genotoxicity in breast epithelial cells Mutagenicity Chromosome aberrations Micronuclei formation DNA strand breaks</p> <p>Precursor changes, biomarkers and induction of mammary gland tumors Modification of existing long-term cancer bioassays* redesigned to evaluate mammary gland endpoints, and: Include whole mounts of mammary tissue Include in utero exposures Assess effects over the whole lifespan Use an animal strain appropriate to the exposure and endpoint</p>	<p>Cell cycle changes in breast epithelial cells Cell proliferation Decreased apoptosis</p> <p>Endocrine disruption Estrogenic activity (e.g., uterotrophic assay) Androgenic activity (e.g., Hershberger assay) Developmental changes in female and male mammary gland tissue (e.g. TEB formation, ductal branching, ER and AR levels) Reproductive changes in male and females (e.g., AGD, nipple retention, altered cyclicity, pubertal timing) Altered circulating hormone levels (e.g., steroid or peptide hormones)</p>
<p>*Assessed in OECD extended one generation bioassay or the NTP enhanced reproductive assessment by Continuous Breeding Protocol</p>	

This model is the basis for prioritizing assays based on the currently available assays, but a truly comprehensive and efficient analysis will require the development of new toxicity

testing methods, particularly the creation of *in vitro* chemical screening techniques and cost effective methods.

References:

1. Wilson MP and Schwarzman MR. "Toward a New U.S. Chemicals Policy: Rebuilding the Foundation to Advance New Science, Green Chemistry and Environmental Health." *Environ Health Perspect.* 2009. 17(8):1202-9.
2. Denison RA. "High Hopes, Low Marks: a Final Report Card on the High Production Volume Chemical Challenge", Environmental Defense Fund, July 2007.
3. U.S. Government Accounting Office Report. "Chemical Regulation - Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program" GAO-05-458, 2005 <http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=f:d05458.pdf>
4. National Research Council. "Toxicity Testing in the 21st Century: A Vision and a Strategy" National Academies Press, 2007.
5. California Environmental Protection Agency and Department of Toxic Substances Control. "California Green Chemistry Report", 2008 http://www.dtsc.ca.gov/PollutionPrevention/GreenChemistryInitiative/upload/GR EEN_Chem.pdf
6. Schwarzman, Janssen, et al. "Pathways to Breast Cancer: A Case Study for Innovation in Chemical Safety Evaluation", 2010 <http://coeh.berkeley.edu/greenchemistry/cbcrrp.htm>.
7. Schwarzman, Janssen, et al. "Toxicity Testing Matrix: A Working Document for the Breast Cancer and Chemicals Policy Panel", 2010 <http://coeh.berkeley.edu/greenchemistry/cbcrrpdocs/matrix.pdf>

Approaches (Methods)

Successful applicants should adhere to the following approaches/methods in developing their response to this RFP:

1) Applicants should construct their research plans to:

Develop and validate new testing methods and model systems for identifying chemicals for their potential to contribute to breast cancer. Examples for projects include, but are not limited to:

- Adapt existing methods to be more relevant to breast cancer. For example the current aromatase activity assay uses an isoform of aromatase found in the adrenal gland; this could be adapted for the isoform(s) found in normal breast tissue and in breast tumors.
- Determine the gene expression or proteomic profiles of suspected or known mammary gland carcinogens and correlate them to relevant biological mechanisms.
- Explore new paradigms for mechanistic pathways relevant to the role of chemicals in breast cancer. Examples of currently available mechanistic assays can be found in "Toxicity Testing Matrix", a working document prepared by

the Breast Cancer and Chemicals Policy Panel.

<http://coeh.berkeley.edu/greenchemistry/cbcrpdocs/matrix.pdf>

- Develop and evaluate three-dimensional cell culture models and normal tissue engineering models as platforms for evaluating chemical effects on mammary gland development and carcinogenesis.
 - Explore how chemicals that are known to affect mammary gland development following *in utero* exposure affect tumor rates following chronic exposure or in response to a carcinogen challenge.
 - Develop a conceptual approach and computational methods for dose-response assessment and risk assessment for chemicals acting as promoters, enablers, developmental disruptors, etc. For example, develop an approach for dose-response assessment of estrogens in relation to breast cancer risk.
 - Develop approaches to evaluate effects of environmentally plausible chemical mixtures in assays relevant to breast cancer mechanisms.
 - Explore opportunities to reduce or eliminate animal testing through models such as organ and cell culture.
 - Identify *in vitro* screens relevant to mammary carcinogenesis that could be added to ongoing, high throughput predictive toxicology programs such as ToxCast and NTP's HTPS, but must recapitulate an appropriate microenvironment for tumor development.
 - Develop and validate new methods for detecting biological events that are likely to alter breast cancer risk, where current tests are inadequate. This could include tests for progesterone receptor binding and transcriptional activation; activity of protein hormones such as growth factors or prolactin; DNA enzyme repair mechanisms; and mechanisms associated with carcinogenesis in general, such as immune modulation, oxidative stress, and cell cycle changes that lead to increased cell proliferation or decreased apoptosis.
- 2) The most competitive proposals will involve researchers from multiple disciplines with demonstrated expertise in mammary gland biology, toxicology, cancer biology and chemical regulations. In order to ensure study designs that will be useful in regulatory chemicals testing, proposals should include collaborations with regulatory toxicologists such as scientists at California Environmental Protection Agency's Department of Toxic Substances Control and/or Office of Environmental Health Hazard Assessment, or at federal agencies such as Environmental Protection Agency, Centers for Disease Control and Prevention, and/or National Toxicology Program.
- 3) Applicants should be prepared to work with the Breast Cancer and Chemicals Policy panel members and other investigators funded under this initiative. At a minimum, this will include presenting ideas, approaches and findings at an annual meeting, and offering feedback to other researchers on their work. Investigators from other CBCRP-funded projects and outside experts may also participate in these meetings.

Proposed Budget

It is anticipated that up to **\$5,000,000** total costs is available for this RFP. Individual proposals focused on developing new methods for screening chemicals are capped at **\$900,000** in direct costs for up to three years duration; however, smaller projects are also encouraged. Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses.

We anticipate that a successful applicant will have the following items in their budget proposal:

- Principal Investigator(s)
- Co-investigators and support staff salaries
- Supplies
- Equipment, with sufficient justification
- Travel and housing for two California-based one day meetings with other funded investigators (one Northern and one Southern)

Applicants should consider the following elements when constructing their budgets:

- a) **Expertise:** Proposals must involve researchers with proficiency in breast cancer biology, toxicology and include a translational/policy expert
- b) **Capacity:** Applicants should demonstrate possession of or access to appropriate tools and technologies (e.g. laboratory facilities and equipment, animal facilities, etc.)

Milestones

The deadline for completion of this initiative is 3 years from the contract start date. Applicants must describe expected milestones in their response to this RFP.

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 tests for biologically relevant effects of chemicals on breast tissues and development. Are the concepts and hypotheses speculative and exploratory? Are methods novel and original? Has(ve) the investigator(s) thought creatively about possible mechanisms, pathways and/or addressing multiple factors relevant to breast cancer?

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- **Impact:** Potential for the project, if successful, to refine or generate biologically relevant assay(s) that will improve current testing modalities for setting chemicals policy. Does the research address relevant mechanisms, methods and/or models for testing chemicals? Are there plans to validate the new assay in a biological system. Will the data yielded by the assays be to sufficient to inform policy? Can the assays be designed to be financially realistic?
- **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 SRI 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-sensitivity and inclusion.** Does the PI express sensitivity to and awareness of the human issues involved in the research and the concerns of breast cancer advocates? Has the PI committed his/herself to be proactive in disseminating the research to the lay audience? Does the research include advocates? [The Advisory Council will examine the PI's statements on the Lay and Scientific Abstracts and Additional Criteria forms.]

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 Tuesday, **March 22, 2011**. *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://v2.ramscompany.com/Login.asp>. 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 June 1, 2011. 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 5%. 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.”

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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. Likely codes for this RFP are: 2.4, 7.1 or 7.2. 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 your application's Face Page and obtain the necessary 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 Facepage@cabreastcancer.org before 5 pm (Pacific Time) by **Tuesday, March 29, 2011**.

Instructions for CBCRP Forms

The Templates for the CBCRP forms may be downloaded from Proposal Section 2 or Proposal Section 9. After completing the forms on your computer, upload each one as a PDF to attach it to your application in Proposal Section 9. Please pay close attention to the following instructions.

Lay Abstract

This item is evaluated mainly in the programmatic review. The text is pasted into a box on the proposalCENTRAL Abstracts page. **Note:** symbols or other special text will not copy.

The Lay Abstract must include:

- A project title
- 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
- Community involvement and sensitivity to advocacy concerns.

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The abstract should be written using a style and language comprehensible to the general public. The scientific level should be comparable to either a local newspaper or magazine article (e.g. *Time* or *Newsweek*). Avoid technical terms and jargon. Place much less emphasis on the technical aspects of the background, approach, and methodology. Ask a family member or friend who is not a scientist to read the abstract and tell you what they don't understand.

Examples of advocacy concerns can be found through web sites, such as:

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

Scientific Abstract

This item is evaluated mainly in the peer review. The text is pasted into a box on the proposalCENTRAL Abstracts page. **Note:** symbols or other special text will not copy.

The Scientific Abstract must include:

- A project title
- A short introductory paragraph indicating the background and overall topic(s) addressed by the research project
- The central hypothesis or questions to be addressed in the project.
- A listing of the 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.
- Community involvement and sensitivity to advocacy concerns

Provide the critical information that will integrate the research topic, the specific aims, the methodology, and the direction of the research in a manner that will allow a scientist to extract the maximum amount of information. Make the abstract understandable without a need to refer to the research plan.

Research Plan

Limit to 10 single-spaced pages following the formatting instructions above. Page limits are exclusive of bibliographical references, which should follow the research plan. Suggested section titles and required information are described below:

I. Statement of Goals, Research Questions, and Specific Aims

In a short paragraph, describe your specific goals, research questions, and aims of your proposed project.

II. Preliminary Work:

Describe the PI's qualifications in the area(s) of expertise listed; capacity related to areas of expertise, including access to relevant data, record of conducting similar work, and past performance of the investigator, specific staff and sub-awardees that demonstrate

capability to successfully complete similar initiatives. Describe the recent work relevant to the proposed project. Emphasize work by the PI and preliminary work specific to breast cancer. If the investigator is new to breast cancer, then this section should illustrate that there is sufficient expertise in place on the research team to develop significant new information in breast cancer.

III. Research Methodology: Research Design and Data Analysis

Describe in detail the exact tasks related to the Statement of Goals, Research Questions, and Specific Aims above. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. Describe the chemicals that will be assessed and the rationale for selecting them. Describe the steps that will be taken to validate your assay. Include a letter of commitment if the applicant PI will be using a data set that they do not control/own. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline of milestones related to this project.

IV. 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.

V. Community Involvement And Benefit

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. (See examples of advocacy concerns in Lay Abstract section above.)

VI. Dissemination And Translation

Describe the plan for the results of this initiative to be more broadly distributed and applicable to other scientists, communities, policy makers, and the general California population.

Budget Summary

Enter the specific costs by category on the Excel Budget Summary form. Detailed instructions are included in the second tab.

Note that the maximum duration is **3 years** and the direct costs budget is capped at **\$900,000**.

Proposed Start Date: 6/1/2011

Proposed End Date: For a 2-year study, enter 5/31/2013; for a 3-year study enter 5/31/2014.

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses.

□ Budget Justification

A budget justification form must be completed for each applicant and subcontract. Limit to 2 single-spaced pages following the formatting instructions above.

Peer reviewers examine the budget and budget justification carefully. Please put considerable thought into this section. Relate each item explicitly to the research plan. Items not well justified are likely to be deleted or reduced. Provide special justification for any unusual expenses.

Personnel

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

For each position, include:

- The percent FTE (full time equivalent) appointment at the applicant institution
- The percent time devoted to this project
- The percent salary requested (which cannot exceed the percent time devoted to this project)

When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income.

Graduate students may be paid as personnel and may also receive tuition remission from awards. Tuition remission in this circumstance, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition) allowable will be \$35,568 per year per FTE. There are no constraints on how this amount is divided between salary and tuition.

Subcontracts and Consultants

For each subcontract and consultant:

- Enter the name(s), role(s), and total annual costs
- Provide total costs, itemizing direct and Indirect/Facilities & Administration (F&A)

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

Though the research must be conducted primarily in California by California investigators, subcontracts or consultant arrangements may be made with out-of-state

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collaborators. An out-of-state collaboration must be well justified (i.e., it is integral to the achievement of a specific aim and cannot reasonably be performed in California).

Supplies and Expenses

Itemize supplies and expenses in categories, such as glassware, radioisotopes, publication costs, computer charges, meeting space rental, etc.

Equipment

These are items that exceed \$5,000 and must be listed individually. Justify each item of equipment on the Budget Justification form.

Travel

- If this is a 3-year project, funds should be designated for the Fall 2013 CBCRP Symposium. Estimate travel based on a Southern California site and estimate hotel costs at \$185 per room/night. All estimates for air or auto travel, meals, etc. should be based on rules of your institution (per diem or actual costs).
- Travel and housing for one California-based project meeting in the first year of funding should be included. Other initiative related travel must be separately justified and will be paid at the level approved by the review committee.
- Travel to general scientific meetings is limited to \$2,000 per year.

Indirect/Facilities & Administration (F&A) Costs

Indicate the F&A rate chosen, whether the rate is a DHHS negotiated rate, a rate established by some other means or authority, or the default rate of 25% for nonprofit organizations. For more information about allowable F&A costs please consult the CBCRP General Proposal Requirements and Conditions of Awards.

Key Personnel

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

Biographical Sketch & Other Support

Complete a biographical sketch for each person listed in Key Personnel; Limit each to four pages. Do not send reprints or manuscripts as part of this form. Corresponding NIH (PHS 398) forms are acceptable.

A. Personal statement: Briefly describe why your experience and qualifications make you particularly well-suited for your role (e.g., PI, programmer, coordinator) in the proposed project.

B. Education: Begin with baccalaureate and end with the most recent, including postdoctoral training.

C. Research and/or Professional Experience: List positions in chronological order.

D. Publications: CBCRP encourages applicants to limit the list of selected peer-reviewed publications or manuscripts in press to no more than 15 items. Do not include manuscripts submitted or in preparation. The individual may choose to include selected publications based on recent contributions, importance to the field, and/or relevance to the proposed research.

E. Other grant support: List all active and pending grants. Include: (1) grant title, (2) active or pending & period of support, (3) funding agency/grant number, (4) role in grant & percent effort, (5) one sentence that describes the aims of the grant, and (6) description of the overlap issues and possible resolution with the present proposal.

Examples:

Increasing Adherence to Follow-up of Breast Abnormalities in Low-income Chinese American Women: A Randomized Controlled Trial.

Active 6/1/03-11/30-06

Department of Defense, DAMD17-05-1-0876 (PI, B. Smith)

Co-investigator, 5%

We will design a culturally tailored intervention and evaluate it in a randomized design in Chinese American women who have a potential breast abnormality and have missed their first follow-up appointment.

No overlap.

Psychological Well-being in Long-Term Adult Cancer Survivors

Active, 8/99-7/04

Cancer Institute-CA 21972 (PI, S. Klein)

Co-investigator, 5%

This two-phase study will identify the unique aspects of psychological well-being associated with LTS and to document the long-term impact of cancer and its treatment over the adult lifespan.

No overlap.

Additional Criteria

This form is included in the Peer review and Programmatic review. **Limit text to two pages.**

The CBCRP Council (who conducts the programmatic review) will NOT see your Research Plan. You may choose to copy parts of your Research Plan's Community Involvement and Benefit section. For additional guidance, see "How We Evaluate RFPs" on p. 10.

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, health care providers, funders etc.). Describe the potential for how the research findings will be translated into policy and/or other practice.

Advocacy-sensitivity and inclusion: Explain how this proposal shows awareness and inclusion of breast cancer advocacy concerns involved in the proposed research. Describe the interest, support, potential benefits to, and involvement of the breast cancer advocates in the project. Include information about how this proposal addresses the concerns of breast cancer advocates. (See examples of advocacy concerns in Lay Abstract above).

Vertebrate Animals

This form is included in peer review and only required for applications that use Vertebrate Animals.

If you have answered “**YES**” to the Vertebrate Animals item on the Organizations Assurances page of your application, 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 August 1, 2011**. Funds will not be released until all assurances are received by the CBCRP.

Human Subjects

This form is included in the Peer review and only required if the proposed study will involve human subjects and does not have a final approved Human Subjects Assurance.

If a Human Subjects Assurance has been approved, do not fill out this form. Include a copy of the approval in the Appendix. (See Documentation of Assurances for Human Subjects below.)

If your proposal will involve human subjects, and you have not received approval or an exemption, you must address the seven points below. In addition, when research involving human subjects will take place at collaborating site(s) or other performance site(s) provide this information before discussing the seven points. If the study has been designated Exempt, respond to item 1 below and address the issues of racial/ethnic composition of the subject population, as instructed in item 2. Although no specific page limitation applies to this section, be succinct.

1. Provide a detailed description of the proposed involvement of human subjects in the work outlined in the research plan.
2. Describe the characteristics of the subject population, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and the CBCRP that research involving human subjects must include males, females, and members of minority groups in study populations. Applicants must describe how minorities will be included as research participants and identify the criteria for inclusion or exclusion of any sub-population. If this requirement is not satisfied, the rationale must be clearly explained and justified. For example, adequate inclusion of minorities as subjects in research studies may be impossible or inappropriate with respect to the purpose of the research, due to the health of the subjects, or for other legitimate scientific reasons. Also explain the rationale for the involvement of special classes of subjects, if any, such as fetuses, pregnant women, children, prisoners, other institutionalized individuals, or others who are likely to be vulnerable. Applications without such documentation are ineligible for funding and will not be evaluated. It is not necessary in this application to document inclusion of women.
3. Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
4. Describe the plans for recruiting subjects and the consent procedures to be followed, including: the circumstances under which consent will be sought and obtained and who will seek it, the nature of the information to be provided to the prospective subjects, and the method of documenting consent. State if the IRB has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent.
5. Describe any potential risks (physical, psychological, social, legal, or other) and assess their likelihood and seriousness. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.

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6. Describe the procedures for protecting against, or minimizing, any potential risks (including risks to confidentiality), and assess their likely effectiveness. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects on the subjects. Also where appropriate, describe the provision for monitoring the data collected to ensure the safety of subjects.
7. Discuss why the risks are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of knowledge that may be reasonably expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the IND has been obtained.

Documentation of Assurances for Human Subjects

If your project has received Human Subjects Assurance, include official documentation of the approval from IRB(s) in the Appendix to your application. This should include the title of this application, the principal investigator's name(s), and the inclusive approval dates; do not include supporting protocols.

Approvals obtained under a different title, investigator, or organization are not acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, a USPHS-approved IRB must provide the assurance. If review is pending please note that and send the final assurance as soon as possible to CBCRP. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, approvals from the boards of each will be required.

☐ Appendix Materials

To be included, appendix materials must be uploaded as a PDF. This form (Cover Sheet) and the materials that follow are included in the Peer review only. The research plan must be self-contained and understandable without having to refer to the appendix. We strongly recommend that the appendix be no more than 30 pages.

APPENDIX COVER SHEET

The Appendix Cover Sheet provides a list of appendix items, followed by those materials in the following order:

1. **Copies of Human Subjects Approvals or Exemptions and Approved Assurances for Vertebrate Animals.** This is required only if applicant plans to use Vertebrate Animals or Human Subjects. List organization names where the approval or exception was made and attach a copy of the assurance if it has been approved. Approved assurances must include the principal investigator's name, refer to the CBCRP grant by project title and provide an approval date and period.
2. **Letters of Support.** These can be important in showing support for the study from both the scientific and lay communities. Include letters of support, letters of collaboration, letters of commitment to provide research resources, subcontract agreements, letter of acknowledgment for UC employees named in non-UC grant applications, etc.

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3. **Contractual Budget(s):** Include a “Budget Summary” template for each sub-contract and a brief justification for each item. The budget summary must include the name of the contracted person/institution
4. **Other Supporting Documents** (itemized on Appendix Cover Sheet). Materials that will help in evaluating the proposed research and that are directly relevant to the proposal, such as questionnaires, consent forms, interview questions, may be included.

General Funding Policies

Who May Apply (Eligibility)

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 SRI 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.

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, “*Special Research Programs Grant Administration Manual 2007-2008*.” The Manual can be obtained from the Program’s office or viewed on our Web site:

www.cabreastcancer.org/reports/grantManual.php

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 Officials’ 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.

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- 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 US 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 symposia, 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).

Indirect (F&A) Costs

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

For organizations other than University of California Campuses the CBCRP will pay indirect or facilities and administration (F&A) costs (overhead) based on the approved direct cost budget. Full F&A costs are computed on a “direct cost basis” at the recipient organization’s appropriate federally approved indirect cost recovery rate. If the institution has an approved rate from the Department of Health and Human Services, it must be used. In the absence of a federally approved rate, an alternative documented indirect rate for the institution may be used. In the absence of any documented indirect rate, one will be negotiated by the University and the recipient organization.

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

Campuses of the University of California will not be paid indirect costs. Research institutions and foundations that are affiliated with the University of California, but are legally separate entities (e.g., National Laboratories), may be paid indirect costs.

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.

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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 the University Auditor, at (510) 987-0478 or www.ucop.edu/audit/

Appeals of Funding Decisions

An appeal regarding the funding decision of an 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 Director, or by contacting us through the CBCRP Web site: www.cbcrp.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 Director or Special Research Initiatives Manager to obtain full information on the appeals process.

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 and web site, 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.