



CBCRP General Application Requirements and Conditions of Award (all award types)

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Eligibility- who may apply?

1. 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.

2. We encourage researchers new to breast cancer to apply. Applicants who have limited experience in breast cancer research should collaborate with established breast cancer researchers.

3. Previously CBCRP-funded PIs are welcome to apply, but the research aims must be distinct from their previously funded CBCRP grants.

4. Resubmissions. Individuals who submitted "not funded" applications in 2009 (Cycle 15), except for IDEA-competitive renewals, are eligible to submit revised applications in 2010 (Cycle 16). The CRC awards are open to re-submission from any previous grant cycle.

5. Multiple applications and grant limits for PIs. A PI may submit more than one application, but each must have unique specific aims. For Cycle 16 applicants are limited to a maximum of two (2) grants either as PI or co-PI, and these must be in different award types.

6. Overlap between mentor and postdoctoral fellowship/dissertation applications. It is strongly recommended that postdocs and dissertation PIs submit unique projects distinct from their mentor's other funding, because it shows a direction towards greater independence. In addition, all Cycle 16 submitted applications must be distinct projects with unique specific aims. If concurrent Cycle 16 applications are submitted from the same research group on a similar topic, then the differences must be clarified using the "Distinction from Other Funding" template. The peer review committee and Program will decide whether any overlap between applications is acceptable.

7. Mentor limits. Each mentor is limited to sponsoring a *total* of two applications (i.e., two postdoctoral fellowships, two dissertation awards, or one of each type).

8. Dissertation mentor eligibility. Dissertation award applications must include a mentor with research expertise in breast cancer [i.e., current breast cancer-focused funding (2010) or publications since 2008 as either first or senior author with breast cancer in the title or as a major topic].

9. Postdoctoral fellowship eligibility requirements. The total length of prior, current, and CBCRP-supported fellowship training cannot exceed five years. All fellowship applicants must have received a doctoral degree in 2008, 2009, or 2010 (expected). The applicant must be employed as a postdoctoral fellow to qualify for the award.

Note: Principal investigators with current CBCRP grant support will not be eligible to apply for additional funding unless the required scientific and fiscal reports are up-to-date. See below under "Policy on Applications from PIs with Delinquent CBCRP Grant Reports."

CBCRP research priority issues

The **four CBCRP priority issues** are broad breast cancer topics that define our critical research needs. To be responsive and eligible for funding, each applicant must explain the relevance of their proposed research to breast cancer using the priority issues listed as a guide. The descriptive text provides examples, which are not intended to be inclusive.

1. The Community Impact of Breast Cancer: the social context

Overview: What are factors that contribute to the unequal burden of breast cancer among diverse communities? Are there policy alternatives that would contribute to reducing disparities in access to prevention, detection, treatment, support, and/or survivorship services for California's underserved populations? What is the influence of poverty, race/ethnicity, and environmental factors on breast cancer? What are the sociocultural, behavioral, and psychological issues of those affected by breast cancer and what services are needed to reduce the suffering caused by the disease? We encourage health policy; health services; and sociocultural, behavioral, and psychological research that address disparities and the burden of breast cancer among California's diverse communities. Specific topics include:

► Health Policy

We encourage research examining the impact of public and private health policy on issues related to prevention, detection, and treatment of breast cancer as well as research into the formulation of policy alternatives that would reduce disparities related to prevention, detection, and treatment of breast cancer.

► Health Services

We encourage research examining the delivery of breast cancer-related services and how to most effectively deliver services, especially to the underserved.

► Sociocultural, Behavioral and Psychological Issues Relevant to Breast Cancer:

The Human Side

We encourage research into the sociocultural, behavioral, and psychological issues of those affected by breast cancer or at high risk for the disease. Research that examines patient and practitioner interactions, enhancing quality of life, long-term survival, and participation in clinical research is encouraged, especially research addressing the needs of high-risk and underserved populations.

► **Disparities:** Eliminating the Unequal Burden of Breast Cancer

We encourage research that aims to reduce disparities in breast cancer incidence, morbidity, and mortality, access to prevention, treatment, and/or survivorship services based on factors related to race/ethnicity, socioeconomic status, geographic location, sexual orientation, ability, age, occupation, and/or other factors. Intervention research that reduces disparities is encouraged.

2. Etiology and Prevention: finding the underlying causes

Overview: What environmental and biological factors interact to increase the risk of developing breast cancer? What approaches can be used to reduce or eliminate breast cancer risk? We especially encourage new California-based studies that seek an understanding of the environmental and lifestyle causes of breast cancer, and how these increase risk and impact different communities in California. Specific topics include:

► **Etiology:** The Role of Environment and Lifestyle

We encourage studies on breast cancer initiation that may be due to environmental exposures that subject women to agents that they, as individuals, cannot control. Other key topics of interest include breast cancer causes related to lifestyle (e.g., diet, exercise) and the underlying metabolic, hormonal, and environmental interactions. Studies on causative gene-environment interactions specific to breast cancer, especially those having the potential to lead to prevention strategies, are encouraged.

► **Prevention and Risk Reduction:** Ending the Danger of Breast Cancer

Research exploring methods to prevent breast cancer or reduce risk, including elimination of external causative factors and the identification of surrogate markers for use in prevention trials are encouraged. Examples include nutritional factors, xenoestrogens, exercise, studies of genetic variation, and methods to modify known breast cancer genes and risk factors.

Note: Basic science research (e.g., using molecular, cell, and animal models) on the genetic, “mechanistic” causes of breast cancer (e.g., p53 and BRCA genes) should be submitted under the **Biology of the Breast Cell** topic.

3. Biology of the Breast Cell: the basic science of the disease

Overview: Although basic science research in cancer is well-supported by other agencies, there remains a critical need to understand the pre-neoplastic, causative events of breast cancer at the tissue level, including the stroma. The genetic changes in disease progression and the tumor heterogeneity need clarification at the basic science level. Breast cancer stem cell research is especially encouraged. Specific topics include:

► **Biology of the Normal Breast:** The Starting Point

Research should explore aspects of normal breast biology (e.g., aging) that are linked to the earliest stages of breast cancer, and which could provide insights into new approaches to prevent, detect, or treat the disease.

► **Pathogenesis:** Understanding the Disease

Research must specifically focus on breast cancer tumor and stromal biology, including: (1) studies of relevant proteins and genes with an emphasis on their relationship to the actual disease, and (2) elucidating key cell signaling, growth control, cell cycle, and apoptosis pathways. We especially encourage new research on the process of metastasis and the development of tools and models to better understand the key metastatic events that impact patient survival.

Note: We encourage basic science hypothesis-building projects. We welcome researchers from other cancer types and fields of biology to apply, but obtaining breast cancer data and establishing breast cancer relevance must be the primary aims of the project. The CBCRP is less interested in basic science research that involves (1) the incremental advance of an established basic science hypothesis, or (2) a lateral study from another cancer type. We discourage applications with an entirely “reductionist” rationale (i.e., the concept that the entire subject of breast cancer can be understood solely by analysis at the molecular level).

4. Detection, Prognosis and Treatment: delivering clinical solutions

Overview: Clinical advances for breast cancer will utilize novel imaging technologies, new biomarkers, and genomic/proteomic approaches for more accurate diagnosis and prognosis. We encourage projects whose aims are on the critical path for translation. We support research into less toxic and more individualized therapies, mechanisms of drug resistance, and studies to evaluate alternative medicines and natural products. Specific topics include:

► **Imaging, Biomarkers, and Molecular Pathology:** Improving Detection and Diagnosis

We encourage research into new, cost-effective technological and biological approaches for molecular imaging and new approaches for tumor analysis at the individual patient level. This includes advanced types of molecular classification, new biomarker development, and improved technologies for patient diagnosis and prognosis, especially using techniques to replace the current practice of screening mammography and biopsy.

► **Innovative Treatment Modalities:** Search for a Cure

Promising leads from biology-based studies are encouraged to begin the critical path to clinical translation. Examples include immunotherapy, delivery technologies, gene therapy, new drug development/testing, and new approaches to clinical decision-making. Testing investigational anti-breast cancer agents for mechanism of action and identifying target patient populations are encouraged.

Submission requirements and revised applications

It is the responsibility of the PI(s) to submit the required items through proposalCENTRAL, meet the submission deadline for the award type, and follow the detailed instructions for preparing the forms. In addition, applicants must submit by e-mail to CBCRP (facepage@cabreastcancer.org) a signed copy of the Face Page within one week of the electronic submission deadline.

Criteria for Application Rejection

1. Submission is after the stated deadline or the “face page” with required signatures is not submitted by e-mail before the deadline.
2. Formatting requirements (i.e., page limits, font size, character/line spacing) are violated
3. The PI is delinquent for submission of existing CBCRP grant reports (see below).

Policy on Applications from PIs with Delinquent CBCRP Grant Reports

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 a Cycle 16 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.

General items

All applications must be in **English**.

Follow these format requirements for submitted written text, which are consistent with the NIH's 398 form instructions:

- The height of the letters must not be smaller than 11 point. Times New Roman or Arial are the suggested fonts.
- Type density, including characters and spaces, must be no more than 15 characters per inch (cpi)
- Line spacing must no more than 6 lines of type within a vertical inch.
- Page margins, in all directions, must be at least ½ inch.

Deviations from the page format, font size, specifications and page limitations, especially the page limit for the Research Plan, will be grounds for the CBCRP to reject and return the entire application without peer review.

Appendix Guidelines

The Research Plan should be self-contained and understandable without referring to the appendix. The supporting materials could also include supplemental tables or figures related to the project background and preliminary data, and publications and pre-prints to support the investigator's background and capability to conduct the research. **The appendix size is limited to 30 pages, except CRCs (no size limit).**

Revised Application Guidelines

Individuals who submitted "not funded" applications in 2009 (Cycle 15), except for IDEA-competitive renewals, are eligible to submit revised applications in 2010 (Cycle 16). The CRC awards are open to re-submission from any previous grant cycle. **A revised application must have the same principal investigator as the original application.** When possible it should have the **same title as the original application.** However, if the specific aims of the project have changed sufficiently, then a modified title may be chosen. **A revision submission for all eligible award types (except CRCs) must include a section of not more than 2 pages** uploaded as a part of the Research Plan. This section is **a summary of the substantial additions, deletions, and changes** that have been made. It must also include responses to criticisms in the previous Review Committee evaluation. This material does not count towards the normal page limit for the Research Plan. We also recommend emphasizing in the Research Plan any relevant work done since the previous application. CRC applicants should follow the directions in the CRC application materials regarding resubmissions.

Submission of Additional Materials

No supplemental application materials (e.g., manuscripts or publications) will be accepted after the deadline, unless explicitly requested and approved in advance by the CBCRP.

Application evaluation (peer and programmatic reviews)

Applicants should carefully consider how their projects will be evaluated and the criteria involved. The Program takes pride in the detail of the review process, the accuracy of review scoring, and the communication of scores and application evaluations to the PIs. The **CBCRP uses a two-tiered funding process**. First, the peer review committees rate applications for scientific merit. Second, the Program's advisory Breast Cancer Research Council evaluates those applications with "sufficient merit" for several criteria of programmatic relevance. The Council consists of 16 members from the advocacy, clinical, research, health care, and industry communities.

Peer Review Committees

Review Committees (i.e., study sections) are assembled around specific award types and/or priority issues. Scientific and breast cancer advocate reviewers are chosen from outside California to minimize possible conflicts of interest. The reviewers have demonstrated expertise in breast cancer and/or the specific research topics in the applications. Scientist reviewers are a mixture of senior and more junior researchers, and they are selected from academic, nonprofit institutions, biotech/industry, and clinical research settings. Advocates often have training and/or prior experience in application review. The Committee Chair is usually a more senior researcher with significant review committee experience. The Chair may assist in recruiting reviewers and assigning applications. The Program conducts the Review Committees consistent with NIH practice.

IDEA, IDEA-competitive renewal, postdoctoral fellowship, dissertation, and CRC-Pilot applications are evaluated by two scientific reviewers (primary and secondary) and an advocate reviewer. Translational awards and CRC-Full Research Awards will be assigned an additional tertiary scientific reviewer. Each reviewer prepares written comments that concentrate on the strengths and weaknesses of the proposed research with respect to the scientific merit scoring criteria specific for each award type. In addition, the application is read by the committee Chair. Approximately 40-45% of the applications in each committee will be "triaged" due to low average scientific merit score (see below), and these applications will not receive a final score and committee discussion. The remaining applications will be discussed at a meeting of the entire review committee and final scientific merit scores are voted by the committee members. All applicants will receive a detailed written evaluation. The Committee ballots and final score calculations are verified by the University of California Auditor.

Note: PIs that have been previously funded by the CBCRP should inspect our Web site www.cbcrp.org/research/ to read through the posted abstracts for their grant(s). Reviewers are instructed to look through previous CBCRP funding to evaluate whether applications are novel and worthwhile additions to previously funded research. We advise PIs to address the distinction of their new applications from previously-funded CBCRP grants using the template—"Distinction from Other Funding."

Review Merit Criteria

CBCRP does not evaluate and score application in review committees by a single merit score like the NIH. Rather, we use independent components (e.g., innovation, impact, feasibility) of scientific merit and they are scored separately by our peer reviewers to reflect the requirements specific to each award type. The use of merit score components allows the Program and the Breast Cancer Research Council to better judge the strengths and weaknesses of each application. When preparing the application, please consider how your application has addressed the specific merit score components for the award type you have chosen.

After an application has been peer reviewed, the Program will calculate an **average scientific merit score** that weights all the merit components equally. Depending on application volume and available funds to award new grants, the CBCRP advisory Council may exclude additional applications from considerations for funding based on low scientific merit scores.

The following will be evaluated by the scientific peer review committee and Program staff, but they are not included in the merit score:

► **Budget/Duration and Overlap:** The appropriateness of the requested direct cost budget and duration of the project will be reviewed by the Program staff and the review committee. The Program can require changes in duration and award amount to any grant, and awards are contingent upon acceptance by the investigator(s) of a revised budget. Note the specific allowed budgetary items and caps for each award type. **Equipment** is defined as: (1) non-expendable, tangible, personal property, (2) having an acquisition value of \$5,000 or more, (3) free standing, and (4) with a normal life expectancy of 2 years or more. PIs need to state the distinction between the application and other research funding on item Distinction from Other Funding. The review committee and Council will examine these items and make comments on research overlap.

► **Human subjects and Vertebrate animal use:** If a project proposes activities that pose unacceptable potential for human and animal subject risks, then a recommendation either not to fund or to delay funding until the issue is resolved may result. IRB approval, human subject “exemption” approval, or animal assurance documentation must be provided prior to funding, but is not needed for application review. Clinical trials may be required to provide a data and safety monitoring board (DSMB) as described in the NCI policy release, <http://deainfo.nci.nih.gov/grantspolicies/datasafety.htm>. The DSMB is in addition to institutional IRB approval, and provides a multi-disciplinary approach to ensure patient safety, confidentiality, and study monitoring.

Programmatic Review

The programmatic review is conducted by the advisory Breast Cancer Research Council. The specific criteria used for the Programmatic Review are listed in the award type (e.g., IDEA, Translational Research Award, Dissertation, Postdoctoral Fellowship, and CRC) instructions.

Note: Applicants sometimes fail to get funded because they pay too little attention in addressing the criteria for the programmatic review. This is especially true for non-CRC applicants in your statements on advocacy involvement and sensitivity to the concerns of breast cancer advocates. It is not enough to mention breast cancer incidence and death rates as a rationale for more research. Develop your

thinking on the underlying scientific and community barriers that limit our current abilities to understand, prevent, detect, and treat the disease. Consider the additional burden that breast cancer places on certain communities. Find the connections between your research topic and ways it might be translated and impact the lives of women with breast cancer and those at risk. Think about how to involve advocates directly in your research program. The instructions for the “Lay Abstract” and “Critical Path/Additional Criteria” forms will have more detailed information regarding advocacy sensitivity and involvement.

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 first evaluates **only a portion of the application items**. These should be prepared using a style and language comprehensible to the general public. Pay careful attention to the instructions for each form used in the programmatic review.

Award decisions and pre-funding requirements

The final approval for funding is made by the Director, California Breast Cancer Research Program, Dr. Marion Kavanaugh-Lynch. **Applicants will be notified by mail by early June 2010 of their funding status.** The written application critique from the review committee, the merit score average, component scores, percentile ranking, and programmatic evaluation are provided at a later time. Some applications could be placed on a ‘waiting list’ for possible later funding.

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.
- Non-UC only: Supply up-to-date documentation for approved indirect rate (F&A costs) agreements and any derived calculations.

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, and award amount in a “Compendium of Awards” for each funding cycle, (ii) the costs (both direct and indirect) in the CBCRP’s “Advances” annual report, (iii) the project abstract and progress report abstracts on the CBCRP Web site. If the Program receives a request for additional information on a funded grant, 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 grant 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.

Conditions of awards

Details concerning the requirements for grant recipients are available in a separate Program publication, the University of California, Office of the President, "**Special Research Programs Grant Administration Manual 2007-2008.**" This manual will continue in effect until June 2010. It is sent to every grant 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.cbcrp.org/reports/grantManual.php

General Conditions of Award

The Program encumbers all funds for a grant in the year it is awarded; thus full funding of a multi-year project is assured.

Enabling legislation (AB 2055 and AB 478 of 1993, as amended by AB 3391 of 1994) authorizes the appropriation of public monies to the University of California for the CBCRP. Awardees are expected to account for the expenditure of grant 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 a grant** from the Program.

Grants to conduct research or research career development activities in California may be awarded to qualifying (see below) California individuals or organizations, which may be public or private, for-profit or not-for-profit. Eligible organizational awardees include, but are not limited to: community organizations, publicly or privately owned corporations and other businesses, volunteer health organizations, health maintenance organizations, hospitals, laboratories, research institutions, colleges, and universities. Applicants who have limited experience in scientific research or in scientific grant writing are encouraged to collaborate with established researchers in the design of studies and the preparation of applications in order to present the most well designed application possible

To ensure the proper management of these public funds (as described above), a prospective grant recipient must satisfy the **following standard requirements** before an award will be made:

- Have adequate organizational, management, and accounting systems to administer the award and assure compliance with award terms and conditions.
- 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 grant are barred by the U.S. Public Health Services Office on Research Integrity from performing comparable roles on federally funded grants.

A grant 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. Individuals who are to be awarded grants may meet these requirements directly or by making arrangements with a research organization that does. These requirements include satisfactory fiscal management, accounting practices, liability insurance, bonding, indemnification of the UC Regents, nondiscrimination in employment, and assurances regarding the treatment of animal or human subjects and research safety and ethics.

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 and Priority Issues.

Grant awardees must agree to:

- Use award funds only as approved by the CBCRP. The Program must approve changes in the specific aims of a grant.
- Maintain accounts, records and other evidence pertaining to work performed and costs incurred.
- File annual progress reports and a final scientific report.
- File annual fiscal reports and a final fiscal report.
- Participate in CBCRP sponsored activities to disseminate research results as able and as requested.
- Make good faith efforts to ensure the timely translation of research results into commercial applications and report these efforts to the Program.
- Make good faith efforts to communicate with the public about the funded work.
- Attend CBCRP research symposiums, if scheduled, or forfeit budget amounts assigned to this item.

Award Period and Indirect (F&A) Costs

The start date for the CBCRP Cycle 16 awards will be July 1, 2010. Continuation funding for additional project years is released upon receipt of an Annual Progress Report showing research effort/progress, no overlap with other grant support, maintenance of sufficient PI effort, continuing institutional approval of human and animal subjects use, submission of publications 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 project.

Postdoctoral fellows can delay the start of their project for up to 6 months to finish another project or to complete their doctoral training. They must notify the program in writing to

activate a delayed start. However, the fiscal year will remain July 1-June 30, and a no-cost extension will be needed to finish a full 2-year project.

The CBCRP encumbers the funds for all approved years of an award from the appropriation in the year the grant is awarded; thus full funding of a multi-year project 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 projects, and for the final budget year of multiyear projects, 20% of the approved budget is withheld (non-UC institutions only) 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 project, 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 submitted a formal request form to change grant 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 grant research and (b) these administrative costs have not been included in the calculation of the recipient institutions 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 as grant recipients or subcontractors.

Non-UC Institutions:

For organizations other than University of California Campuses the CBCRP will pay indirect (F&A) costs (overhead) based on the approved direct cost budget. Full F&A costs on Translational Research Awards, IDEAs and CRCs 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. Community groups as part of CRC budget without a federally-approved F&A rate will be allowed a nominal 25% rate for indirect costs.

No indirect costs will be allowed for the Postdoctoral Fellowship, Dissertation, and Joining Forces Conference Awards.

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 #1 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 projects 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 as grant recipients or as subcontractors. Research institutes and foundations that are affiliated with the University of California, but which 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 grant 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.

Policy Regarding Scientific Misconduct

The University of California manages the CBCRP within its Office of Research and Graduate Studies (<http://www.ucop.edu/research/about/welcome.html>) 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 grants from CBCRP must promptly inform the Program or University Auditor (<http://www.ucop.edu/audit/about/mgmtplan.html>) 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 grant applications, research, and

publications, that agreement would apply to that investigator's grant applications to, or awards from, the SRP.

Grant applicants or recipients may request that HHS administrative actions be waived or modified with respect to a grant 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/

For-Profit Reimbursement of Awards

It is the goal of the CBCRP to discover new information, which can lead to the prevention, control and eradication of breast cancer. Hence, it is anticipated that some CBCRP grant recipients will conduct clinical trials and ultimately develop profitable products or services from work funded in part or in whole by the CBCRP. The Program strongly encourages, but does not require that, such individuals or institutions/companies consider:

- **Donating to the CBCRP** to further advances in breast cancer research
- **Making experimental therapies available on a compassionate access** protocol during clinical trials
- Providing **assistance to low-income women** in gaining access to therapy

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.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 Manager, Core Funding to obtain full information on the appeals process.

Final decisions on application funding appeals will be made by the Vice President of UCOP's Office of Research and Graduate Studies, Dr. Steven Beckwith.

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.

Special California data sources for breast cancer research

CBCRP encourages research that explores new hypotheses using existing data sources (from previously funded studies, tissue banks, or from databases such as the California Cancer Registry) especially that take advantage of the ethnic diversity of the state to explore differences between ethnic populations. Two opportunities are:

1. California Health Interview Survey

The California Health Interview Survey (CHIS) is the nation's largest state health survey. Every two years, CHIS surveys up to 56,000 households in California on a range of health

issues. The results of that survey provide policy makers, health advocates, community organizations, media, healthcare providers, foundations, researchers, and many others with critical health information.

Survey structure: CHIS is a random digit dial (RDD) survey incorporating a geographically stratified sample so that estimates are possible for individual counties or groups of small counties. Beginning in 2007, CHIS also includes a significant sample of households with cell phones. Additionally, CHIS has the capacity to oversample select counties, cities and service areas, such as Los Angeles and San Diego counties.

Diversity: Since 2001, CHIS has been conducting interviews of interviews with adults, adolescents and children, as well as with ethnic and racial groups underrepresented in almost all other health surveys. CHIS includes large samples of Latinos and several Latino ethnic groups, African Americans, American Indian/Alaska Natives (urban and rural sub-samples) and Asians (including large sub-samples for Chinese, Filipinos, Japanese, Korean, Vietnamese, and South Asians). CHIS is conducted in English, Spanish, Chinese (Cantonese and Mandarin), Korean, and Vietnamese.

Cancer: The National Cancer Institute (NCI) and the Centers for Disease Control (CDC) have sponsored a range of cancer-related content, including cancer screening, breast cancer history, mammography screening, and the Gail risk model variables. NCI sponsored a substantial cancer screening module in CHIS 2003. In 2005, NCI sponsored more than 400 variables related to family cancer history.

Access: Quick health statistics are available through AskCHIS, a free, easy-to-use online tool: www.AskCHIS.com. Public-use files are available free on the CHIS Web site. More detailed and more confidential information is accessible by application through special data access centers located at the UCLA Center for Health Policy Research in Los Angeles (fees may apply) and at the Department of Health Services in Sacramento for state researchers. CHIS is conducted by the UCLA Center for Health Policy Research in collaboration with the California Department of Public Health, the Department of Health Care Services, and the Public Health Institute. For more information, visit: www.chis.ucla.edu.

2. California Cancer Registry.

If a proposed project requires access to data from the California Cancer Registry (www.ccrca.org/), then the application must include a letter of collaboration from a Registry official. If you have questions, please contact Ann Brunson (916) 779-2673, California Department of Public Health, Chronic Disease Research and Surveillance Branch, Cancer Surveillance Section