

IDEA–COMPETITIVE RENEWAL TEMPLATE & FORM INSTRUCTIONS

Step #1: “Letter of Intent” (Required): the deadline is Thursday **January 14, 2010**. You must upload a “letter of intent” to proposalCENTRAL to notify the CBCRP of your plans to submit a full application. If the PI is eligible (i.e., having received a CBCRP IDEA award in the previous two years and not having previously applied for an IDEA–competitive renewal for the same project), then the LOI will be approved and access given to the remaining application forms.

Step #2: Application submission: the deadline for submission of the complete application is Thursday **February 11, 2010** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL’s Web site)

Step #3: Face Page submission with signatures:

- Print your application’s Face Page from proposalCENTRAL and obtain the necessary signatures (PI and institutional signing official are required).
- E-mail as a PDF attachment a scanned copy with signatures to: facepage@cabreastcancer.org before 5 pm (PST) by Thursday **February 18, 2010**.

Important Reminders

- When preparing your application be sure to use the “validate” function to assure that all required submission items are entered.
- You must select an institution with a tax ID (EIN) number in the Proposal Section called “Institution & Contacts.” In addition, the “signing official”, “contracts & grants official”, and “fiscal contact” must be selected from the pull down menu for that institution or have them register with proposalCENTRAL prior to submission. Work with your signing and contracts officials to both identify your institution (duplicates might be present in proposalCENTRAL).

Note: Portions of the application are prepared using pre-formatted Web pages in proposalCENTRAL. For other portions you must use CBCRP forms that are completed then uploaded as PDF attached files to your application (see below).

PROPOSAL SECTIONS (items pre-formatted on proposalCENTRAL Web pages)

Complete the Web formatted pages with special attention to required items marked with a *.

- **Title Page.** Enter the project title in 60 characters or less. Indicate whether the application is a resubmission of a previous application reviewed and not funded by the CBCRP.
- **Enable Other Users to Access this Proposal.** You should use this page to allow additional people to access your application.

- **Applicant/PI.** You must complete all the required information on this page. Enter the % effort on the project. IDEA-Competitive Renewal PIs have a minimum 5% FTE.
- **Institution & Contacts.** When you first register with proposalCENTRAL you should select an institution with a valid IRS tax ID number (EIN) from the pull-down menu. If done correctly, then you can directly add your institution's "Signing Official", "Contracts & Grants Official", and the "Fiscal Contact" who will handle budget and fiscal reports. If these individuals are not present on the pull down menu, then you need to contact them and have them register with proposalCENTRAL.
- **Abstracts.** Copy both Lay and Scientific abstracts for your project from the downloaded templates (refer to the detailed instructions below). Then, add the CSO Code (1 or 2 items) using the CSO Coding Instructions download. Next, add three (3) key words to describe your project. Finally, select the one CBCRP priority issue that best matches your project from the menu.
- **Budget Summary.** Follow these IDEA-Competitive Renewal Budget Guidelines:
 The **maximum duration is 2 years and the direct costs budget cap is \$200,000 or \$250,000** (projects using animal or human subjects). Use the following guidelines for placing your project into the appropriate IDEA award cap category:
 - Higher cap: \$250,000 (animal or human subjects) for studies where the use of human or vertebrate subjects is integral to the specific aims of the project. Specifically:
 - Human subjects studies, surveys, and data acquisition requiring institutional IRB-approval and an informed consent form.
 - Use of vertebrate subjects and experiments that require an institutional animal assurance approval. This would include animal tumor and metastasis models, 'knock-out mice', and studies where tumor growth/metastasis is inhibited by novel therapies.
 - Lower cap: \$200,000 for studies not using animal or human subjects and for those using animal and human subjects as follows:
 - Vertebrate subjects used in a minor portion of the project, such as generation of antibodies.
 - Using existing data sources, such as patient and cancer databases.
 - Use of archival breast cancer material, such as ATCC-type cell lines or stored tumor materials, generally under the 'exempt' categories of IRB approval.
- Equipment purchases up to \$10,000 are allowed. Only include individual items >\$5,000. Any items less than \$5,000 must be purchased under the "supplies" budget category.
- We will allow a maximum of \$400/year for travel to **CBCRP symposium** in year 1.
- **Scientific meeting travel** is capped at \$2,000/yr.
- Full indirect (F&A) costs are allowed for IDEA-Competitive Renewals only to non-UC institutions.
- **Organization Assurances.** Add the required information. You must have your Contracts & Grants official add your institutional Federal Wide Assurance (FWA) code or equivalent for Human Subjects and an Animal Welfare Assurance code for Vertebrate Animals.
- **Research Plan and Other Attachments.** The IDEA-Competitive Renewal specific and CBCRP General Application Requirements instructions are located here. All required items to complete and upload are listed. All uploads must be in PDF format.
- **Validate.** This function allows a check for any missing REQUIRED information or files. All missing required information will be listed on the screen. Please correct any missing information before proceeding to the Face Page and Submit sections.
- **Electronic submission:** the deadline for electronic submission of the complete application is **February 11, 2010** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL's Web site)
- **Face Page submission.** Print your application's Face Page from proposalCENTRAL and obtain the necessary signatures (PI and institutional signing official are required). E-mail as a PDF attachment a scanned copy with signatures to: facepage@cabreastcancer.org before 5 pm (PST) by Thursday **February 18, 2010**

RESEARCH PLAN AND OTHER ATTACHMENTS SECTION– CBCRP templates (application forms) to be downloaded, completed, converted to PDF files, and uploaded

List of templates (those marked * are required uploads):

- Lay Abstract*
- Scientific Abstract*
- Critical Path & Additional Criteria*
- Distinction from Other Funding*
- PI Biographical Sketch & Other Support*
- Budget Summary* (note: separate .xls & PDF uploads are required)
- Budget Justification & Facilities*
- Key Personnel*
- Other Key Personnel Biosketches & Other Support
- Renewal Report*
- Human Subjects
- Vertebrate Animals
- Appendix List
- Research Plan from previous IDEA application*
- Milestones from previous IDEA application*

Instructions – LAY ABSTRACT (required)

This item is evaluated mainly in the programmatic review. **The text is also entered in the appropriate box in the “abstracts” page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the box in the “abstracts” page.

The **Lay Abstract** must include the following sections:

- A **non-technical introduction** to the research topics
- The **question(s) or central hypotheses** of the research in lay terms
- The **general methodology** in lay terms
- **Innovative elements** of the project in lay terms
- **Advocacy involvement and human issues.** Briefly describe the role of advocates in planning and carrying out the research. Describe how the project addresses the human issues associated with breast cancer. We suggest that applicants request assistance from their institution’s public affairs office.

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, such as might appear in *Time* or *Newsweek*. Avoid the use of technical terms and jargon not a part of general usage. Place much less emphasis on the technical aspects of the background, approach, and methodology. Ask a family member or friend who is not a scientist to read the abstract and tell you what they don’t understand.

Examples advocacy concerns/human issues can be sourced through web sites, such as:

- <http://www.networkofstrength.org/> Breast Cancer Network of Strength
- <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

Instructions - SCIENTIFIC ABSTRACT (required)

This item is evaluated mainly in the peer review. **The text is also entered in the appropriate box in the “abstracts” page of the Proposal Sections.** Do not use symbols or other special text, as these will not transfer to the box in the “abstracts” page.

The Scientific Abstract should include:

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

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

Instructions – CRITICAL PATH & ADDITIONAL CRITERIA (required)

This item is evaluated in the programmatic and peer reviews.

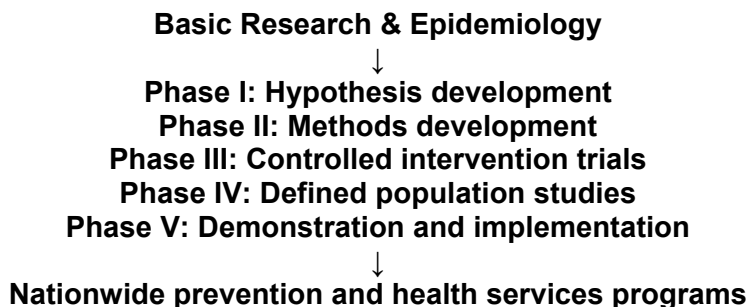
Limit the text to two pages.

A. Critical Path

Purpose: The point of asking for the “critical path” is to have the PI place the project on a research continuum (i.e., temporal trajectory) that begins with an idea or hypothesis and continues through development leading to a defined result of practical value (e.g., in the clinic or community). First, ask yourself the question: How will my project and its research goals/milestones lead to a measurable impact on the prevention, detection, diagnosis and treatment, reduction in community and social burden, or improved patient quality of life for breast cancer?

Background: Breast cancer research funding has been successful in the creation of new knowledge. However, the useful application of this knowledge to prevent and detect the disease, and increase survival and quality of life for breast cancer patients could be improved. If funding agencies and researchers are to be accountable to stakeholders, more emphasis needs to be placed on the “critical path” from research-to-practice. In 2003 Best et al. ([Cancer Epidemiology Biomarkers & Prevention,12:705-712](#)) distinguished two pathways to practical application of research, “..... it is important to view “translational research” to encompass not only the pervasive view of transfer of basic science discoveries into clinical applications (“bench to bedside”), but also its transfer into effective interventions at the population level with active community participation in the process (“bench to trench”). Collaboration between research producers and research consumers in this translational approach is critical to reduce the cancer burden at the population level, the ultimate measure of benefit to all people.”

An early conceptualization and model for a “critical path” between research and action, developed in the context of smoking/tobacco, was advanced in 1985 by Peter Greenwald and Joseph Cullen (*J. Natl. Cancer Inst.*, 74:543-551) who distinguished phases of cancer control research:



In addition, Phases I-V incorporate “feedback loops”, so new hypotheses and methods can be generated in concert with novel intervention efforts. The “take home message” from this model is that the CBCRP expects researchers to actively consider where and how their results might find practical applications at the end of the “critical path.” Thus, your research decision making and innovative approach should incorporate these elements when planning projects: (i) an awareness of the social (i.e., human and community) needs and environmental determinants of health and disease, (ii) limitations of current prevention, detection, prognosis, and treatment strategies, (iii) the state of the existing science for the topic being addressed, (iv) an understanding of the limitations and barriers that block translation to a higher level, and (v) a framework for visualizing the desired research outcome and potential benefit (practical uses).

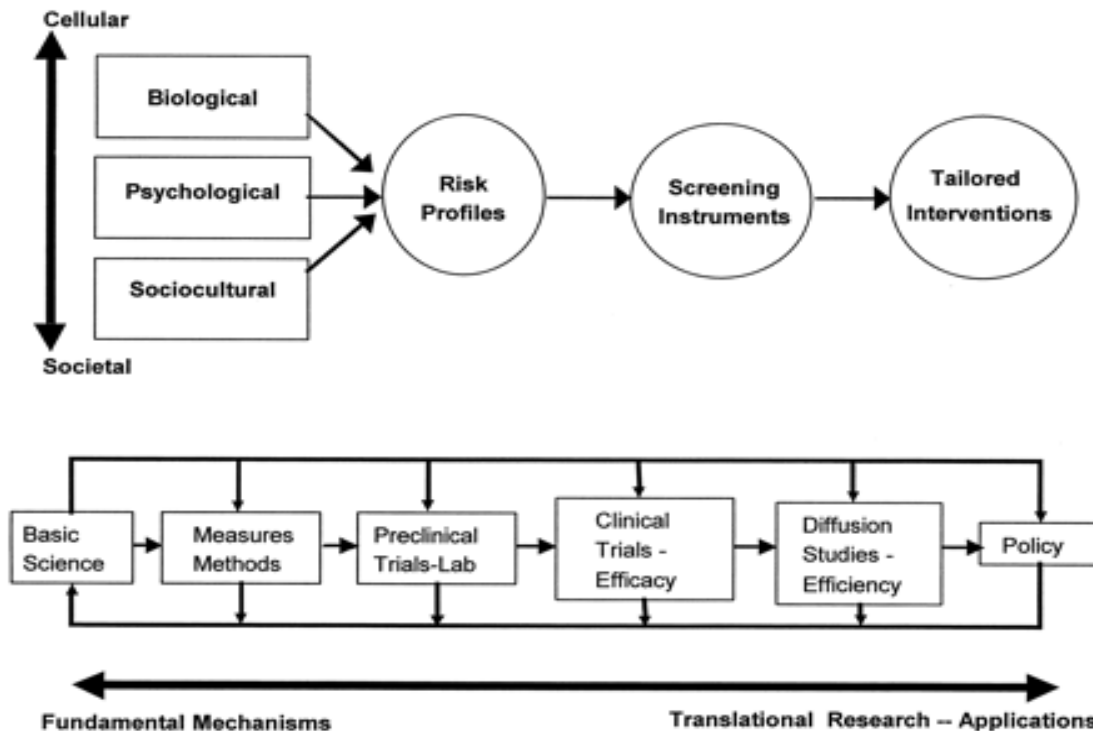
Overview and conceptual framework: The CBCRP believes that each grant should be capable of advancing the topic under investigation along the “critical path.” To provide an outline to get you started, we have developed the following chart, which derived and greatly expanded from Table 1 in the FDA’s “Challenge and Opportunity on the Critical Path to New Medical Products” (<http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>). For the “critical path” dimensions/levels we have added definitions and provided examples of activities relevant to both the “basic science/clinical” and the “public health/community/population/social science” disciplines.

<u>Dimension/Level</u>	<u>Definitions</u>	<u>Examples of activities</u>
Concept & hypothesis development	<p>Discovery and exploration</p> <p>The links between the hypothesis and a research problem in breast cancer</p> <p>Considering problems from novel perspectives</p> <p>Initial tests in basic systems</p> <p>Establishing the basis for scientist-community interactions</p>	<p><u>Basic science/clinical track:</u></p> <ul style="list-style-type: none"> ○ Assessing background information in breast cancer, other cancer types, and cell/biological models. ○ Developing new information on breast cancer through data collection. ○ Establishing relationships to breast cancer. ○ “Mining” basic science for new treatment, detection, and prognosis concepts. ○ Pilot testing of new compounds and detection/prognosis strategies. <p><u>Community/population/intervention track:</u></p> <ul style="list-style-type: none"> ○ Considering social needs, disparities, and community issues from new perspectives. ○ “Mining” basic science for new

<u>Dimension/Level</u>	<u>Definitions</u>	<u>Examples of activities</u>
		<p>epidemiological, behavioral, psychological, sociocultural or policy concepts.</p> <ul style="list-style-type: none"> ○ Conceptualizing possible interventions. ○ Planning culturally appropriate, acceptable, and feasible delivery approaches for new community-based interventions and prevention strategies. ○ Identifying target populations and establishing new collaborations. ○ Demonstrating or gaining trust and acceptance by the community. ○ Pilot data collection and field methodology developed. <p>(Cancer control phase I --Cullen & Greenwald model)</p>
<p>Methods development and establishing “proof-of-principle”</p>	<p>Obtaining significant data to substantially support the hypothesis and point the direction for future work</p> <p>Establishing direct relevance to breast cancer in the basic science, clinical, or community settings</p> <p>Active scientist-community “partnering” in the research</p> <p>“Multi-disciplinary” collaborations (researchers in different disciplines work <u>independently</u> or sequentially on a common problem)</p> <p>Testing in small populations & initial data gathering</p>	<p><u>Basic science/clinical track:</u></p> <ul style="list-style-type: none"> ○ Studies in model systems. ○ Integration into and challenging existing information on breast cancer. Publication. ○ Early pre-clinical phases (e.g., rational drug design, validate lead compounds). ○ Showing the potential to challenge and improve upon existing therapies and detection/prognosis standards. <p><u>Community/population/intervention track:</u></p> <ul style="list-style-type: none"> ○ Refine prevention strategies and collaborative networks. ○ Preliminary field tests of epidemiological hypotheses, policies or intervention methods and delivery systems. ○ Determination of outcome and process variables. ○ Development of measurement tools and data collection procedures. <p>[Cancer Control Phases II and III (small trials) —Cullen & Greenwald model]</p>
<p>Developmental and testing phase</p>	<p>Formulating a strategy for practical application</p> <p>Stimulate interest in other researchers and “interdisciplinary” collaborations (researchers working <u>jointly</u> to address a common problem)</p> <p>Generation of derivative concepts (feedback loop)</p> <p>Demonstrating efficacy or</p>	<p><u>Basic science/clinical track:</u></p> <ul style="list-style-type: none"> ○ Significant findings showing a clear connection to the disease. ○ Formulation and testing in animal models. ○ Publication and dissemination. ○ Late pre-clinical studies and early (Phase I & II) clinical trials. ○ Analysis of target groups and cost effectiveness. ○ Definitive links to target populations for detection, prognosis, treatment strategy. <p><u>Community/population/intervention track:</u></p>

<u>Dimension/Level</u>	<u>Definitions</u>	<u>Examples of activities</u>
	<p>utility in a human detection, prognosis, or therapeutic setting.</p> <p>Researchers and community groups “partner” and reach common goals</p>	<ul style="list-style-type: none"> ○ Larger scale testing of epidemiological hypotheses, policies, or interventions in a well-defined populations enabling generalization to ultimate target populations (efficacy trial). ○ Systematic testing of epidemiological hypotheses, policy proposals, or community-based intervention in a larger population under “real-world” conditions (effectiveness trial). ○ Publication and dissemination. <p>[Cancer Control Phases III (larger trials) & IV—Cullen & Greenwald model]</p>
Implementation & translation	<p>Wide acceptance of concept</p> <p>Improvements for detection, diagnosis, prognosis, and treatment</p> <p>Tangible social benefit</p> <p>New public health policies evolve from community-driven needs and researcher-driven outcomes to decrease disparities in detection, treatment, and disease burden</p> <p>Prevention and lowering risk for breast cancer</p>	<p><u>Basic science/clinical track:</u></p> <ul style="list-style-type: none"> ○ Final basic research studies to validate a new clinical approach. ○ Feedback loop to stimulate new concepts to be tested (level #1) ○ Phase III & IV clinical trials. ○ Application of new therapies and chemoprevention approaches. ○ Advancing the standard of care. <p><u>Community/population/intervention track:</u></p> <ul style="list-style-type: none"> ○ Demonstration and implementation on a large scale. ○ Diffusion studies to other populations and communities. ○ Integration into cancer control health policy. ○ Interventions to lower disease incidence and mortality. <p>(Cancer Control Phase V—Cullen & Greenwald model)</p>

Finally, a major “critical path” limitation is the absence of cross-talk between disciplines. “Basic/clinical” and “public health/social/population/community” researchers often work apart. Thus, the CBCRP is asking researchers to consider and explore avenues of research communication and common interest that allow the different disciplines to become integrated and lead to practical applications directed at breast cancer. This approach was recently presented by Best et al. ([Cancer Epidemiology Biomarkers & Prevention,12:705-712](#)), who proposed the term “transdisciplinary research.” “*Transdisciplinarity* is a process by which researchers work jointly using a shared conceptual framework that draws together discipline-specific theories into a new synthesis of concepts, methods, measures, and approaches to address a common problem.”



Final thoughts: Provide a brief, thoughtful discussion of how your research project would advance along a “critical path” to take your topic from one level to the next and provide practical applications. How might your innovative research “make a significant difference” and provide “transdisciplinary links” between the basic science, clinical, and public health/social/population/community research landscapes?

B. Additional Criteria
Limit to 1 page

Part #1. Address the project’s (i) focus on underserved populations, and (ii) advocacy involvement in the research and sensitivity to advocacy concerns. Do not address these issues with “n/a.” Take the time to study the human issues of breast cancer and the extra burden the disease places on different communities, and consider how your project might address the needs of the underserved (including those that are underserved due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive limitations, age, occupation and/or other factors) in prevention, detection, prognosis, and treatment.

Part #2. Indicate your intentions to interact with advocates and advocacy organizations and involve them in planning and carrying out the research project. Here are some suggestions:

- Contact an advocate/activist group in your area to discuss your research project with them and receive feedback and suggestions.
- Use advocates/activists as a resource to find the “human link” between your project and their experience as breast cancer survivors to better appreciate the social/community issues related to breast cancer.
- Visit advocate/activist displays and posters at cancer meetings (e.g., San Antonio Breast Cancer Symposium) to discuss your research interests. Many advocates welcome interactions with researchers.
- Examine the literature and Web sites of advocate/activist organizations to get a sense of their social/research concerns and needs.
- Obtain a “letter of collaboration” from an advocate/activist organization describing their role in your project.

Instructions – DISTINCTION FROM OTHER FUNDING (required)

This item is evaluated mainly in the programmatic review.

Limit the text to one page.

Overview: Applicants should highlight the unique aspects of the proposed research compared to their other current and previously funded projects. The peer review committee considers this information when evaluating “innovation”, “impact.”, and “translational potential.”

Detailed instructions: Discuss the unique properties of the current application from, (i) other current and past grant support to the PI, (ii) the current CBCRP portfolio as shown on our Web site (<http://www.cabreastcancer.org/>) under the link “Research Portfolio”, and (iii) general research in the topic under investigation on display on the International Cancer Research Portfolio (ICRP) Web site: <http://www.cancerportfolio.org/> If you are not fully independent and applying as an IDEA–junior investigator, then discuss the distinction between the proposed project and ongoing work and grant funding in your supervisor’s research environment. If appropriate, name the supervisor in the Appendix cover page and provide this person’s other grant support.

Instructions – BUDGET SUMMARY (required)

Budget Summary. Follow these IDEA-Competitive Renewal Budget Guidelines:

- The **maximum duration is 2 years and the direct costs budget cap is \$200,000 or \$250,000** (projects using animal or human subjects). Use the following guidelines for placing your project into the appropriate IDEA award cap category:
 - Higher cap:** \$250,000 (animal or human subjects) for studies where the use of human or vertebrate subjects is integral to the specific aims of the project. Specifically:
 - Human subjects studies, surveys, and data acquisition requiring institutional IRB-approval and an informed consent form.
 - Use of vertebrate subjects and experiments that require an institutional animal assurance approval. This would include animal tumor and metastasis models, ‘knock-out mice’, and studies where tumor growth/metastasis is inhibited by novel therapies.
 - Lower cap:** \$200,000 for studies not using animal or human subjects and for those using animal and human subjects as follows:
 - Vertebrate subjects used in a minor portion of the project, such as generation of antibodies.
 - Using existing data sources, such as patient and cancer databases.
 - Use of archival breast cancer material, such as ATCC-type cell lines or stored tumor materials, generally under the ‘exempt’ categories of IRB approval.
- **Equipment purchases up to \$10,000 are allowed.** Only include individual items >\$5,000. Any items less than \$5,000 must be purchased under the “supplies” budget category.
- We will allow a maximum of \$500/year for travel to **CBCRP symposium** in year 1.
- **Scientific meeting travel** is capped at \$2,000/yr.
- Full indirect (F&A) costs are allowed for IDEA-Competitive Renewals only to non-UC institutions.

Instructions – BUDGET JUSTIFICATION & FACILITIES (required)

This item is evaluated in the peer review.

Limit the text to two pages

Follow the instructions on the template.

Instructions – KEY PERSONNEL (required)

This item is evaluated in the peer review.

Limit the text to one page

Follow the instructions on the template.

Instructions–BIOGRAPHICAL SKETCH & OTHER SUPPORT (required)

This item is evaluated in the peer review.

Limit the length of each biosketch to *no more than four (4) pages*.

The information provided is evaluated to assess the expertise, training, and background relative to the methods employed in the project. For career development, the biosketch is evaluated to determine the additional training or benefit the research will contribute to the PI's capabilities in breast cancer research.

Use the Form provided or substitute the current [NIH Form 398](#) for biosketch and include the requested information:

- Name
- Role in Project
- Education. Include steps from baccalaureate through postdoctoral training.
- Research and professional experience. List positions in chronological order.
- Publications. List the relevant publications for this application first, then list others as space permits. Do not include items 'submitted' or 'in preparation.'
- Other grant support. List all items of current and pending grant support with the grant title, agency, role in project, percent FTE devoted to grant, a brief summary of aims, and overlap/resolution with the present application.

Instructions – RENEWAL REPORT (required)

The **limit is seven (7) pages**.

An additional 3 pages are allowed for references.

This section is the **most important** for the peer review. Keep in mind that the peer review committee will be provided the research plan and peer review evaluation summary from the funded IDEA application. Thus, avoid recapitulating elements of the research that were described previously.

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

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

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

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

We recommend including the following sections:

Introduction and hypotheses: Provide a brief introduction to the topic of the research and the hypotheses/questions addressed by the original research plan.

Progress towards specific aims: List the specific aims of the funded IDEA and detail the work accomplished for each one. Indicate any aims that were not addressed and provide the reason.

Milestones: Indicate the significant findings for the project to date, and how the expected results of the original award were achieved. Present any unexpected results or findings not anticipated in the prior award. Address how the “high risk” elements of the project have been mitigated. To what extent has the work to date shown “proof of principle” for the topic under investigation? Discuss comparable research elsewhere, especially published studies that either confirm or contradict your findings.

Future plans: State any new or revised aims for the project. Outline the continued and new experimental approaches to be employed in the renewal project period. Indicate the developmental path to make the research endeavor suitable for publication or competitive for full-scale research funding from another agency. How will continuation of the project enable “high-reward” outcomes? How will the proposed work lead to translation and impact on breast cancer?

Instructions – HUMAN SUBJECTS (only if needed)

This item is evaluated in the peer review.

This form is required only for applications that use Human Subjects, including those in the "Exempt" category.
Use additional pages, if necessary.

For applications requesting “Exemption” from regular IRB review and approval. Provide sufficient information in response to item #1 below to confirm there has been a determination that the designated exemptions are appropriate. The final approval of exemption from DHHS regulations must be made by an approved Institutional Review Board (IRB). Documentation must be provided before an award is made. Research designated exempt is discussed in the NIH PHS Grant Application #398 http://grants2.nih.gov/grants/peer/tree_glossary.pdf. Most research projects funded by the CBCRP falls into Exemption category #4. Although a grant application is exempt from these regulations, it must, nevertheless, *indicate the parameters of the subject population* as requested on the form.

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

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

Documentation of Assurances for Human Subjects

In the appendix, if available at the time of submission, include official documentation of the approval by the IRB, showing the title of this application, the principal investigator's name, and the approval date. Do not include supporting protocols. Approvals obtained under a different title, investigator or organization are *not* acceptable, unless they cross-reference the proposed project. Even if there is no applicant institution (i.e., an individual PI is the responsible applicant) and there is no institutional performance site, a USPHS-approved IRB must provide the assurance. If review is pending, final assurance should be forwarded to the CBCRP as soon as possible, but **no later than Sept 1, 2010**. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

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

Instructions – VERTEBRATE ANIMALS (only if needed)

This item is evaluated in the peer review.

This form is required only for applications that use Vertebrate Animals.

Limit the text to two pages.

If you have answered “**YES**” to the Vertebrate Animals item on the Organizations Assurances 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 Sept 1, 2010**. Funds will not be released until all assurances are received by the CBCRP.

Instructions – APPENDIX LIST (only if needed)

Follow the instructions and items list on the template.

The appendix may not be more than 30 pages in length.

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

Upload the Research Plan and Milestones application materials from your previously funded IDEA grant in the appendix.