



APPLICATION INSTRUCTIONS: TRANSLATIONAL RESEARCH AWARD

CBCRP will not extend the submission deadline!

Step #1: Letter of Intent (Required): the deadline is Wednesday **October 21, 2009**. You must upload the project outline and PI biosketch to proposalCENTRAL. If the LOI is approved, then the PI will be notified by November 30th and given access to the remaining application forms.

Step #2: Electronic 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 19, 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).

Contents

Overview.....	page 2
Letter of Intent (LOI) instructions and required items.	page 3
Full application information.....	page 3
Duration/budget.....	page 4
List of application submission items.....	page 4
Peer review evaluation criteria (scientific merit).....	page 5
Programmatic review criteria.....	page 6

Overview

The CBCRP is committed to supporting research that is on a critical path for practical application. Translational research to be supported by the CBCRP should have the potential for major impact in the areas of (1) prevention, detection, diagnosis, or treatment of breast cancer; (2) improved quality of life for survivors, and/or reduction in the community and social burden caused by the disease in California; or (3) advances in medical practices, health systems changes, health policies, or environmental modifications.

Letter of Intent (LOI) instructions and required items

LOI submission and CBCRP approval is required to enable preparation of a full application. Two items are required to be uploaded as PDF attachments to proposalCENTRAL to complete the LOI process.

1. Project Outline (2-page maximum length) must include the following categories and discussion points:

- **Project title**
- **Translational goal** (10-20 sentences)– describe the translational leap to be achieved with this award. Identify the specific item of practical value to be produced by the end of this project. What are the barriers to translation, and how will this effort succeed where others might have failed previously? What innovative strategy will be employed to overcome barriers?
- **Impact on breast cancer** (10-20 sentences)– describe the need for this product, service, intervention, or policy that is specific for breast cancer with respect to risk, prevention, detection, diagnosis, prognosis, treatment, or survivorship. Estimate impact at the individual patient level and for overall disease burden, if successful? What population/community will it help? Will it address disparities or the needs of underserved women? What is the expected timeframe for availability of the product/service/ intervention/policy outside the research setting?
- **Background and PI qualifications** (8-12 sentences)– Describe both the general and specific topic underlying this research. Detail the previous research accomplishments and clinical trial experience by the PI and collaborators that

makes the successful pursuit of this topic more realistic. Identify other sources of support and collaboration to increase the likelihood of success.

- **Specific Aims** – list the proposed aims of the project.
- Describe the involvement of **Human Subjects** in the project. How will you gain access to human subjects?
- Describe the **role of advocates** in the project (past, current, and proposed). The CBCRP believes that research projects would benefit by being directly informed by the experiences of patient-survivors, so inclusion of representatives of established advocacy organizations (e.g., Y-ME, Komen, NBCC, patient support groups at medical and cancer centers, etc.) is encouraged.

2. PI biosketch (4-pg maximum) should include a list of relevant publications and current other grant support. Identify existing grants on the proposed research topic, and discuss any overlap issues. You can use the CBCRP template or the corresponding NIH form.

LOI decisions and invitations to submit full grant applications will be communicated to PIs by November 30th.

Full application information

The CBCRP views translational research as fundamentally different from: (1) exploratory/discovery studies, (2) hypothesis building, and (3) incremental efforts to add to and fill in gaps in knowledge. To distinguish translational research from other types of research funding, the CBCRP will require the applicant to present a **“critical path”** that maps how the project fits along a defined research continuum leading to practical applications. We encourage applications in translational research from all disciplines, including: basic/clinical sciences, behavioral/ social sciences, public health/community-based health sciences, and health policy.

Specifically, the CBCRP’s Translational Research Award is designed to support new and ongoing research projects that are able to:

- Clearly describe the **“translational bridge” elements**—(1) the research discovery to be translated, (2) how the discovery will be applied, (3) the end point targeted, and (4) potential individual or population-level impact
- **Define key steps or milestones on a critical pathway** from the present level of research knowledge to the practical application
- **Build on progress** already made by the research team to advance the translation process
- Identify discrete **barriers** to this progress and propose detailed strategies to overcome them
- Employ a **unique perspective and innovative research methods**
- Include **plans for evaluating the process** and outcomes of the translational effort
- Optional: include collaborations that allow diverse disciplines to contribute to the translational effort

Critical Path:

This portion of the application will be a key element for both the peer and programmatic reviews. The PI should place the proposed project on a “critical path” **leading from basic concept 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. A complete presentation would include: (1) the **original concept** and “proof of principle” background related to breast cancer, (2) the **PI’s accomplishments in the research topic** that brings it closer to translation, (3) the specific **barriers to translation** and the PI’s strategy to overcome them, (4) an endpoint of **practical value** that the research would enable (e.g., in the clinic or community), and (5) a “vision” **for future implementation** that extends the expected endpoints and describes the **potential impact** at the patient, community, or policy levels.

The applicant should distinguish the proposed "translational project" from non-responsive research that aims to: (1) focus on exploratory/discovery endpoints, (2) develop new hypotheses, or (3) accumulate additional or “incremental” knowledge in a given topic.

The application form for this item will contain more detailed information, so refer to these instructions when completing this portion of the application.

Duration/budget

- **3-years** maximum duration
- The cap for direct costs is **\$750,000** (total project)
- Indirect (F&A) costs are allowed only for non-UC institutions
- PI minimum effort is 10% FTE

List of application submission items

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).

► **proposalCENTRAL formatted pages** (complete the Web formatted pages with special attention to required items marked with a *****)

Title Page

Enable Other Users to Access this Proposal (only if you want others to be given access)

Applicant/PI (include percent effort in grant)

Institution & Contacts (add signing official, C&G, fiscal contacts. They are automatically included on the Face Page)

Abstracts (copy the text for Lay & Scientific abstracts from the CBCRP forms. Add/select CSO codes, key words, and one CBCRP priority issue)

Budget Summary (same amounts as uploaded in the form listed below)

Organization Assurances (complete only the Human Subjects and Vertebrate Animals items)

► **Uploaded (attached) CBCRP forms** (i.e., templates): download, read our instructions carefully, complete the form, convert to PDF, then upload the PDF files as attachments to your proposal under the link in proposalCENTRAL called “Research Plan and Other Attachments” (those forms indicated in **bold** are required). The forms and instructions will also be available from CBCRP’s Web site under the “apply” link.

Lay Abstract

Scientific Abstract

Program Responsiveness

Critical Path & Additional Criteria

Distinction from Other Funding

PI Biographical Sketch & Other Support

Budget Summary (note: separate .xls and PDF uploads are required)

Budget Justification and Facilities

Key Personnel

Other Key Personnel Biographical Sketches & Other Support (if needed)

Research Plan (12 page limit + up to 3 additional pages for references)

Milestones

Human Subjects (if needed)

Vertebrate Animal Subjects (if needed)

Appendix List (if needed)

❖ **Other**

Upload appendix items (publications, etc.), as needed. 30-page limit!

Peer review evaluation criteria (scientific merit)

Translational Research Award applications are peer reviewed and rated independently for four separate criteria.

- **Translational Potential.** The extent to which the project, if successfully carried out, would represent a “translational bridge” to bring the product/intervention/service to bear on the prevention, detection, diagnosis, *or* treatment of breast cancer, improved quality of life for survivors, and/or reduction in the community and social burden caused by this disease in California. Is the project focused on the use of human subjects?
- **Critical Path & Research Barriers.** The extent to which the applicant has delineated a research continuum for the project (i.e., background, preliminary work, development, and translational endpoints) and has a strategy for overcoming barriers to achieve the translational endpoints.
- **Approach.** The extent to which the conceptual framework, design, methods, analyses and collaborations are innovative, well integrated, and appropriate to the stated aims of the project.
- **Feasibility.** The extent to which the investigator(s) can achieve the stated milestones, practical applications, or endpoints. Do the research team and collaborators have all the necessary expertise, skills, and resources to carry out the project?

The Review Committee will also evaluate the application for **budget and duration**, human/animal **research risks** and institutional approval.

Programmatic review criteria

This review is conducted by the advisory Breast Cancer Research Council and includes 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 materials**. Pay careful attention to the instructions for each form underlined below. **Programmatic criteria and definitions:**

- **Response to priorities.** How responsive is the proposed research to CBCRP priority issues? [The advisory Council will compare the PI's statements on Program Responsiveness template, top section) and the content of the abstracts to the CBCRP priority issues and examples.]
- **Response to award type.** How responsive is the project and PI to the stated intent of the selected award type? [The advisory Council will compare the PI's statements on Program Responsiveness template, bottom section) to the CBCRP award type criteria.]
- **Critical Path/translation.** The degree to which the applicant's statements on Critical Path/Additional Criteria template provides a convincing argument that the proposed research fits into and advances a critical path for translation and impact on breast cancer. What barriers must be overcome to take the project to the next level, and what plans are provided for to address these barriers?
- **Underfunded.** The degree to which the PI on Distinction from Other Funding template has highlighted the unique aspects of the proposed research from their own projects (past and present) and the research by others. Is the research relatively underfunded by other agencies, or not funded?
- **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 breast cancer understandable?
- **Addressing the needs of the underserved.** Do the project and the PI's statements on Additional Criteria template demonstrate how this research will 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)?
- **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 him/herself to be proactive in disseminating the research to the lay audience? Does the research include advocates? Have advocates been involved in the choice of the research questions, the design of the project, or plans for conducting the research? [The advisory Council will examine the PI's statements on the Lay and Scientific Abstracts and Additional Criteria templates.]

It is a combination of, (i) the programmatic rating, and (ii) strengths and weaknesses in both the average scientific merit and individual components of scientific merit that determines a decision to recommend funding.