



TRANSLATIONAL RESEARCH AWARD LETTER OF INTENT (LOI) INSTRUCTIONS:

Deadline 1: Letter of Intent (Required): the deadline is Wednesday, **October 25, 2011**. You must upload the **Project Summary** and **PI Biosketch** to proposalCENTRAL. If an invitation to submit a full application is issued, you will be notified in December, 2010, and given access to the remaining application forms.

Deadline 2: Application submission: the deadline for the electronic submission of the complete application is Wednesday, **February 15, 2012** (12 noon Pacific Standard Time = 3 pm Eastern Standard Time as shown on proposalCENTRAL's Web site).

Table of Contents

Overview.....	1
Letter of Intent (LOI) Instructions and Content	2
LOI Content	2
LOI Evaluation	3
Translational Research Award Full Application	3

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.

In order to become eligible to submit a full application, **a letter of intent must be approved by the CBCRP**. The project summary and the principle investigator's qualifications will be evaluated by CBCRP's Advisory Council. The translational projects described in the LOI should:

- represent a significant leap from incremental knowledge-gathering to a practical application (a translational endpoint)
- involve the study of human subjects or enable a follow-up study in human subjects
- not be fully supported by other funding

Letter of Intent (LOI) Instructions and Content

LOI Content

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 Summary (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?
- **Involvement of advocates** – Describe the role of advocates in the project design and implementation, and include any specific advocate involvement in past and current research by the applicant. The CBCRP believes that research projects benefit by being directly informed by the experiences and knowledge of patient-survivors. Therefore, we expect breast cancer and community health advocates to be actively involved in the research we fund. It is expected that the PI will be in contact with an appropriate advocacy group and be prepared to include them in the planning phase prior to submission of the full application.

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 Evaluation

LOIs will be evaluated by CBCRP Council on the following criteria:

- **Translational potential:** The quality of the PI's description of the translational leap and its relationship to the underlying topic of the research. Is it translational? The distinction between the proposed project from a more exploratory, developmental, or other non-translational type research. The degree to which it "bridges" prior knowledge gained to practical applications. The description of barriers and a strategy to overcome them
- **Impact on breast cancer:** Will the proposed project make a difference with respect to 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 the disease in California? Is the translational timeframe (relative to practical endpoints and barriers) realistic?
- **PI quality, background, and experience in translational research.**
- **Extent of other funding** (enough to support the overall research program, but no direct overlap)
- Extent to which **human subjects** are well-integrated and central to the project.
- **Inclusion of advocates.**
- **Focus on underserved populations.**

Invitations to submit full grant applications will be communicated to PIs by **December, 2011**. You will receive an e-mail from proposalCENTRAL customer support. Once the invitation to submit has been issued, you will have access to the full set of application forms and instructions.

There will be no feedback or evaluation summary provided to PIs either invited or not invited to submit an application.

Translational Research Award Full Application

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.

Duration and 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