CBCRP LOI INSTRUCTIONS: INNOVATIVE, DEVELOPMENTAL, & EXPLORATORY AWARD (IDEA) and TRANSLATIONAL RESEARCH

KEY DATES

Submission deadlines:

Letter of Intent – **October 19, 2023, 12pm Noon PT**

Application – **March 5, 2024, 12pm Noon PT**

Funding decisions will be announced in June, 2024. Funded Project Start Date: August 1, 2024

See http://www.cbcrp.org/funding-opportunities/index.html for additional instructions.

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Overview

If you have not already reviewed our program's background, funding philosophy, or existing portfolio, then please do so by visiting our website (www.cbcrp.org). CBCRP's mission is to prevent and eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities. CBCRP is dedicated to supporting and amplifying the voices of people who have historically been underrepresented in breast cancer research in our funded projects. We are interested in funding novel topics and we are deeply committed to advocate involvement in all aspects of our portfolio and our program.

IDEA Award

CBCRP offers the IDEA Award to encourage researchers to pursue new, innovative projects specific to breast cancer and to think beyond the incremental advances that are typical of most grant applications. Thus, we wish to inspire research that, although untested, may reveal **breakthroughs or new avenues of investigation**. For this purpose, we define "innovative" as:

- Applying **novel methods and approaches** to breast cancer research.
- Challenging existing paradigms or developing **new paradigms**.
- Considering an existing problem from **a new perspective.**

In addition, we **encourage new investigators** to initiate their own innovative projects and researchers new to breast cancer to enter the breast cancer field.

The intent of the IDEA is to support speculative, exploratory, "high-risk/high-reward" projects with a primary focus on breast cancer. Applications for this award type should either: (i) challenge existing paradigms, or (ii) encourage innovation by the incorporation of techniques, approaches, and collaborations not yet well represented in mainstream breast cancer research. We encourage researchers to attempt breakthroughs that, if successful, could be leveraged into more substantial funding. Preliminary data in breast cancer is not required for an IDEA application, but we encourage PIs to include sufficient data (obtained in their laboratory or research group) to demonstrate feasibility for the proposed research. It is not an absolute requirement for an IDEA project to be hypothesis-driven, and we consider correlative and data-gathering projects to be responsive to this award type. However, **to be maximally responsive** to the IDEA funding mechanism **the applicant must either be previously trained and have published in breast cancer *or* collaborate with an established breast cancer researcher**. The Program and peer review committees will consider applications from researchers outside of breast cancer who propose novel research, but we require them to establish breast cancer relevance as the primary aim and to describe the "critical path" that links their research to breast cancer.

Examples of research that are **not responsive** to the IDEA are projects that: (1) propose incremental advances for the underlying topic, (2) duplicate the aims of completed or funded research to the PI derived from non-breast cancer studies without incorporating detailed breast cancer-specific justification, (3) overlap in topic and aims with current grant support to the applicant, or (4) represent portions of existing grants or are derived from cut-down larger, R01-type projects.

IDEAs are open to **both established and new investigators**. The purpose of making IDEAs available to new investigators is to allow them to initiate their own innovative research projects. To qualify as a new investigator, the PI should be at a career level **on the submission date** past postdoctoral fellowship (or equivalent) and less than three years as an independent investigator (e.g., Assistant Professor or equivalent). This category is not intended for career development. If the applicant is working in a common facility or research group and under the direction of a senior researcher, then the proposed research must be distinct from the grant support to the supervisor. Thus, the application cannot contain duplicate aims or overlap with the supervisor's other grant support.

Translational Research Award

CBCRP is committed to supporting research that is on a critical path for practical application. Translational research to be supported by 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 CBCRP. The project summary and the principal 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 (research that relies on secondary data analysis and/or is exempt for IRB approval is not eligible for the Translational Awards)
- not be fully supported by other funding

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, 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, 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.

Submission of a Letter of Intent

Submission of an electronic Letter of Intent (LOI) is required to apply for the following award mechanisms for the CBCRP 2024 Cycle 30:

- **IDEA Award – LOI deadline: October 19, 2023 at 12pm Noon Pacific Time**
- **Translational Research Award – LOI deadline: October 19, 2023 at 12pm Noon Pacific Time**

All LOIs must be submitted through our grants management system, SmartSimple. Step-by-step instructions for the online SmartSimple submission process, including setting up an account and registering your institution are available in a separate SmartSimple Application Instructions document. Please make sure to allow enough time in your submission process to enter all of the required information into SmartSimple as described in these instructions. This supplemental programmatic instruction document provides guidance for the content of your LOI.

LOIs must be submitted in **SmartSimple** and may be submitted at any time until the deadline. There is no grace period. You will not be able to submit an LOI after the deadline. Upon submission of your LOI, you will receive an automatic confirmation of receipt. Please keep this for your records. If you do not receive an automatic confirmation notice, your LOI will not be deemed received by Research Grants Program Office (RGPO) and will not be reviewed. All applicants who have submitted the LOI in a timely manner will also receive a second email indicating the status of the LOI (approved/denied) after the LOI has been reviewed. If your LOI is approved, then you will be able to submit a full application in SmartSimple.

An LOI is required for new submissions and all resubmissions. If you have an approved LOI from a previous cycle, you are still required to submit an LOI in cycle 30 in order to submit a full proposal. Please refer to the call for applications on CBCRP’s website for policies pertaining to resubmissions and multiple submissions.

You will have access to the full application web pages when the LOI is approved in **SmartSimple**, at which time you will receive a notification email. To be accepted for a full application, a Letter of Intent (LOI) must meet all eligibility requirements for the award type as described in the 2024 Call for Applications on CBCRP’s website and be judged to be responsive to program priorities by the CBCRP Council as defined by the criteria on the following pages.

Please review the CBCRP 2024 Call for Applications carefully before applying.

To ensure that you submit the LOI before the deadline, review these instructions in their entirety along with the corresponding web pages as soon as possible. At the end of this document, you will find a few warnings and tips that address the most common issues experienced by applicants.

For a description of CBCRP award types, eligibility, funding caps, application review criteria and other information, see our call for applications or CBCRP website. If you have any questions, see the call for applications for appropriate contact information.

Letter of Intent (LOI) Content

Section 1: Title Page

- **Project Title:** Enter a title that describes the project in lay-friendly language. (Max 100 characters)
- **Project Duration:** Enter a project duration for up to 2 years for IDEA awards and up to 3 years for Translational Research Awards. (The Project Duration counts the number of budget years, so those intending to pursue an 18-month IDEA award, for example, should enter 2 years.)
- **Proposed Project Start Date:** The project start date of August 1, 2024 will auto-populate and is not editable.
- **Proposed Project End Date:** Enter a project end date of July 31, 2025 for a 1-year award; January 31, 2026 for an 18-month award; July 31, 2026 for a 2-year award and July 31, 2027 for a 3-year award.
- **Application History:** If this project is a resubmission from a previous CBCRP cycle, select "Yes" and enter the grant number and title of the original application.
- **New Investigator (Y/N):** Applicants who are applying for the IDEA award as a New Investigator, select "Yes". All other applicants select "No". New Investigators are defined as researchers at a career level beyond postdoctoral training and less than three years as an independent investigator.

Section 2: Applicant/PI

You must complete all the required information on your Profile page. If your application is accepted for submission you will also be required to complete the "ORCID ID" field. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and, through integration in key research workflows such as manuscript and grant submission, supports automated linkages between you and your professional activities ensuring that your work is recognized. If you have not already obtained an ORCID ID number, you may do so here: http://orcid.org/ Once you have done so, please enter your 16-digit identifier in the space provided on your profile page in the following format: xxxx-xxxx-xxxx-xxxx.

Section 3: Project Information

CBCRP provides templates on the Application Materials page to allow you to work on your LOI offline, but in order to complete the LOI, you must respond to the following categories and discussion points using the online fields in SmartSimple:

- **Specific aims** (Max 2400 characters/approx. 350 words) – list the proposed aims of the project.

IDEA AWARDS ONLY

- **Project summary** (Max 400 characters/1-2 sentences) – in approximately two sentences provide an overview of the topic being studied and its specific connection to breast cancer.
- **Innovative elements** (Max 2700 characters/10-20 sentences)– describe the project's innovative qualities (paradigms being challenged, new concepts being tested, novel topics brought to bear on breast cancer, application of new research tools, or a high risk-high reward approach that will allow a breakthrough in knowledge specific to breast cancer). What innovative strategy will be employed to overcome barriers to success?
- **Critical path** (Max 2700 characters/10-20 sentences)– describe the need for the project specific to breast cancer, previous work on the topic, and what additional work would be required to achieve practical application at either the patient (risk reduction/prevention or treatment) or community level? What eventual impact may there be on public health outcomes?
- **Investigative team** (Max 1200 characters/4-6 sentences) – describe the PI's background and qualifications specific to breast cancer, the topic being studied, or collaborations planned to support the research project.

TRANSLATIONAL RESEARCH AWARDS ONLY

- **Translational goal** (Max 2700 characters/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** (Max 2700 characters/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 people who have been historically underserved by research and/or health provider institutions? What is the expected timeframe for availability of the product/service/ intervention/policy outside the research setting?
- **Background and PI qualifications** (Max 1200 characters/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.
- Describe the **Involvement of Human Subjects** in the project. (Max 1200 characters) – describe the extent to which the investigation will require the participation of human study subjects. How will you gain access to human subjects?

IDEA and TRANSLATIONAL RESEARCH AWARDS

- **Involvement of advocates** (Max 1200 characters/4-6 sentences) – name the advocacy organization that you plan to work with on the full application, why the organization is appropriate for your proposed research project, and who you have communicated with at that organization. If applicable, describe how the advocate will provide a perspective that is historically underrepresented in breast cancer research. Describe the role of advocate(s) in the project design, implementation, interpretation, and dissemination of the study results. You may involve multiple advocates in your project, but at least one needs to be based in California. If you need assistance identifying an appropriate organization, contact the CBCRP staff.

Health and medical research projects greatly benefit from being directly informed by the experiences and knowledge of those affected: namely, those who have or had the disease, those who care for people with the disease, or those who represent a specific community impacted by the disease. CBCRP is dedicated to supporting and amplifying the voices of people who have historically been underrepresented in breast cancer research in our funded projects. Therefore, CBCRP requires breast cancer or other appropriate community advocates be actively involved in the research we fund.

Applicants are expected to work with California-based advocate(s) affiliated with an organization. CBCRP encourages applicants to work with advocates and advocacy organizations that bring perspectives that are not currently well-represented in breast cancer research. LOIs and applications are evaluated on the extent to which advocates are substantively involved in the project. Advocates from outside California participate in the peer review of every application, and California-based advocates represent one-third of the CBCRP council membership. CBCRP staff can assist applicants with meeting the advocacy involvement requirement.

- **CBCRP Research Priorities** – name the CBCRP priority issue that the research addresses (Community Impact of Breast Cancer; Etiology and Prevention; Biology of the Breast Cell; or Detection, Prognosis and Treatment).

- **CSO Research Type(s) and Sub-Type(s)** – see SmartSimple submission instructions for more details
- **Subject Area(s)** – see SmartSimple submission instructions for more details
- **Focus Areas (s)** -- see SmartSimple submission instructions for more details

Section 4: Budget

Enter an estimate of the direct costs for the project distributed across the grant years. If your project is invited to full application, you will have an opportunity to revise this estimate. Make estimates for up to:

- $100,000 in total direct costs for an IDEA project that does not involve human subjects and is exempt from IRB review and does not require a vertebrate animal assurance.
- $150,000 in total direct costs for an IDEA project that involves human subjects IRB approval or vertebrate animal assurance
- $750,000 in total direct costs for a Translational Research Award.

Section 5: Documentation:

- **Advocacy Commitment Letter (1-pg maximum):** Upload an email or letter from the advocate or representative of the advocacy organization demonstrating their willingness to participate in the research application, should the LOI be approved.

- **PI biosketch (5-pg maximum):** Upload the biosketch for the PI only. It should include a list of the most recent, relevant publications and of current grant support. Identify any existing grants on the proposed research topic, and discuss any overlap issues. Please use the current NIH form.

Section 6: Signature Page:

Certify that the statements you have made are accurate and true by checking the box and entering your full name and the date.

LOI Evaluation:

LOI will be evaluated for programmatic relevance by the CBCRP Council using the criteria described below.

IDEA Awards:

- **Aims and specificity to breast cancer:** Are the aims consistent with an IDEA-level project. Are the aims specific to breast cancer?
- **Innovation:** The degree of innovative aspects of the proposed project. Is the project distinct from incremental (R01-type) research? Does it challenge paradigms? Does it propose and test novel concepts? Is it high risk with potential high reward? Are innovative techniques or strategies employed?
- **Critical Path:** Is the path to implementation of something of practical value at the patient (risk reduction/prevention or treatment) or community level clear and well-described?
- **Investigative team:** Does the PI have demonstrated expertise in breast cancer research, or are collaborations proposed to address this issue? Does the PI have other grant support in the topic/aims of the project?
- **Involvement of advocates.** Has the PI contacted a California-based advocate in an appropriate advocacy organization about the proposed research question? Will the advocate provide a perspective that is historically underrepresented in breast cancer research? Are advocates adequately involved in the design, implementation, interpretation, and dissemination of the results?

LOIs that lead to invited applications score well on all of the criteria. If an LOI is turned down the most common reason are:

- The project is described in technical language. It is critical to describe your project in a way that makes its relevance and potential impact clear to anyone regardless of whether they are experts in your field of research.
- A lack of demonstrated breast cancer expertise or focus. If breast cancer research expertise isn't clear from the materials submitted for the PI, emphasize the qualifications in the description of the investigative team. If the research can be applied to other types of cancers, explain why it is particularly important to conduct the investigation on breast cancer.
- An unclear description of the critical path.
- An appropriate advocate has not been identified and/or has not acknowledged a willingness to participate in the project.

Translational Research Awards:

- **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**.
- **Involvement of advocates**. Has the PI contacted a California-based advocate in an appropriate advocacy organization about the proposed research question? Will the advocate provide a perspective that is historically underrepresented in breast cancer research? Are advocates adequately involved in the design, implementation, and dissemination of the results?
- **Focus on underserved populations**. What population/community will the project help? Will it contribute to health equity by addressing breast cancer issues that disproportionally affect communities who have been historically underserved by research and/or health systems? How does the project address inequities and/or the specific needs of communities who are underserved as they bear a disproportionally high burden of health-related problems due to factors related to race, ethnicity, socioeconomic status, geographic location, sexual orientation, physical or cognitive limitations, age, occupation and/or other factors?

LOIs that lead to invited applications score well on all of the criteria. If an LOI is turned down the most common reason are:

- The project is described in technical language. It is critical to describe your project in a way that makes its relevance and potential impact clear to anyone regardless of whether they are experts in your field of research.
- Project is too early on the critical path.
- The involvement of human subjects is not integral to the project
- The practical endpoint and/or immediate impact on breast cancer are not clear.
- An appropriate advocate has not been identified and/or has not acknowledged a willingness to participate in the project.

Notification of Decisions

You will receive notification of whether the LOI is accepted in December 2023. If invited to submit, you will have access to the full set of application forms and instructions.

Minimal feedback will be provided to PIs who have not been invited to submit a full application.

Contact Information

- **Technical support and questions about application instructions and forms should be addressed to the Research Grant Programs Office Contracts and Grants Unit:**
  RGPOGrants@ucop.edu

- **For scientific or research inquiries, please contact:**
  Katherine McKenzie, **Senior Program Officer**
  Katherine.McKenzie@ucop.edu

The California Breast Cancer Research Program is part of the Research Grants Program Office of the University of California, Office of the President.