

LOI AND APPLICATION INSTRUCTIONS:

CBCRP PREDOCTORAL AND POSTDOCTORAL FELLOWSHIPS

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Introduction

The recent changes to federal research priorities have opened gaps in breast cancer research and training in topic areas that scientists, advocates, clinicians, and policy makers identify as important for understanding, preventing and curing the disease. CBCRP recognizes that these federal re-prioritizations are undermining young investigators at a particularly vulnerable time in their career, therefore we are launching Bridge Funding Awards and re-instituting Full Fellowship Awards for predoctoral and postdoctoral fellows in our 2025-2026 Call for Applications.

We are offering three trainee award opportunities:

- **Bridge Funding for Fellows:** Supports predoctoral and postdoctoral fellows whose federal fellowships have been prematurely terminated and are pursuing breast cancer research in California. \$25,000 direct costs for up to 1 year.
- Predoctoral Fellowships: Students enrolled in a doctoral graduate program in California conducting breast cancer research and mentored by an established breast cancer researcher. Up to \$60,000 stipend (plus additional expenses – see budget section) annually for up to 2 years.
- **Postdoctoral Fellowships:** Breast cancer researchers hired as postdoctoral fellows by a California institution and mentored by an established breast cancer researcher. Up to \$70,000 stipend/salary (plus additional expenses see budget section) annually for up to 2 years.

All fellows including those from groups underrepresented in breast cancer research and/or those who wish to pursue careers focused on questions on environmental contributors to breast cancer, health disparities and population-level prevention of breast cancer are encouraged to apply.

In accordance with state and federal law, preference will not be given to trainees based on race, color, ethnicity, gender or national origin.

Applicants may only receive one Bridge Funding grant. Applicants may apply for and be awarded Bridge Funding and a Fellowship in this funding cycle. Review the <u>Bridge Funding for Fellows application instructions</u> to learn more about applying for this funding opportunity.

Key Dates

Award	Letter of Intent	Application	Start Date
Bridge Funding	NA	October 30, 2025	February 1, 2026
Predoctoral Fellowship	January 15, 2026	March 5, 2026	August 1, 2026
Postdoctoral Fellowship	January 15, 2026	March 5, 2026	August 1, 2026

Notes:

- All submission deadlines are at 12pm noon Pacific Time.
- 2. Letter of Intent decisions will be communicated within 5 working days of submission.
- 3. Other key information: refer to CBCRP's Call for Applications PDF document.
- **4. Submission of Additional Materials.** No supplemental application materials (e.g., recommendations, manuscripts or publications) will be accepted after the March 5 deadline, unless explicitly requested and approved in advance by CBCRP.

Fellowship Descriptions

Predoctoral Fellowship Overview

Under the mentorship of an established breast cancer researcher, this fellowship will support promising graduate students who are living in California and enrolled in a graduate program at a California institution to pursue a career that furthers breast cancer research.

Purpose/Requirements: To support the research for Doctoral-level graduate students. The applicant (PI) is the student, who must prepare the application and should have advanced to candidacy level by the award start date. U.S. citizenship is not a requirement.

The mentor must be an independent, full-time faculty (or equivalent) at the institution and must be a breast cancer researcher [i.e., current breast cancer-focused funding or publications since 2023 as either first or senior author with breast cancer in the title or as a major topic].

Budget Caps & Project Duration: Up to \$60,000 in stipend per year for up to 2 years plus allowable expenses. Allowable expenses include stipend, insurance, tuition, supplies and travel (see budget instructions for category caps). No indirect costs are allowed. The PI must devote at least 75% FTE to the project and related training activities.

Postdoctoral Fellowship Overview

Under the mentorship of an established breast cancer researcher, this fellowship will support promising postgraduates to pursue careers in breast cancer research.

Purpose/Requirements: To support advanced training in a field of breast cancer research with a designated mentor for individuals with current or expected (before *application start date*) doctoral degrees (Ph.D., M.D., or equivalent) at a California institution. Only individuals to be employed with the title of postdoctoral fellow or an institutional equivalent are eligible to receive funding from this award type. [The program staff will pre-screen applications for this requirement.] U.S. citizenship is not a requirement.

The **mentor** must be an independent, full-time faculty (or equivalent) at the institution. To be maximally responsive to this award type, the mentor should either be experienced in and have published in breast cancer as a first or senior author since 2023 or be actively collaborating with a breast cancer researcher with these qualifications.

Budget Caps & Project Duration: Up to \$70,000 per year in stipend or salary for up to 2 years plus allowable costs. Allowable expenses include stipend/salary, insurance, supplies and travel (see budget instructions for category caps). No indirect costs are allowed. The PI must devote at least 75% FTE to the project.

How We Evaluate Fellowships

Letter of Intent

Predoctoral and Postdoctoral Fellowship applicants are invited to submit full applications pending acceptance of a Letter of Intent. Letters of Intent will be reviewed by CBCRP staff for the basic eligibility requirements, the applicant's fellowship status at a California institution and the project's relevance to at least one CBCRP Priority Area. LOIs will be reviewed on a rolling basis and decisions will be communicated within 5 working days.

Application Review

CBCRP uses a two-tier evaluation process: peer review and programmatic review. It is a combination of (i) the peer review rating, (ii) the programmatic rating, and (iii) available funding that determines a decision to recommend funding.

Peer Review

All applications are evaluated by a peer-review committee of individuals from outside of California. The committee is composed of scientists from relevant disciplines and breast cancer advocates.

Applications are rated using four equally weighted criteria.

Predoctoral Reer Review Criteria

- **Impact:** The extent to which the project, if successfully carried out, would make an original and important contribution to breast cancer research. The extent to which the fellowship would address gaps in the breast cancer field and/or the research pipeline.
- **Approach:** The quality, organization, and presentation of the research plan. Are the hypothesis and specific aims well described and logical? Will the methods in the research plan allow the PI to address the hypothesis and aims?
- **Feasibility:** The qualifications of the applicant (academic background and research products) and quality of the proposed training (ancillary activities, courses, assessment). Will the research environment and mentoring team provide the resources needed to complete the project and training?
- Career Development: The mentor's commitment to the candidate and track record in breast cancer research. The extent to which the project and training plan will enable the PI to become competitive in the next career stage.
- Budget and Animal/Human subjects evaluated but not scored.

Postdoctoral Peer Review Criteria

- **Impact:** The extent to which the project, if successfully carried out, would make an original and important contribution to breast cancer research. The extent to which the fellowship would address gaps in the breast cancer field and/or the research pipeline.
- **Approach:** The extent to which the conceptual framework, design, methods and analyses are developed, well integrated, and appropriate to address the hypothesis and aims of the project. Is the research design innovative?
- **Feasibility:** The qualifications of the applicant. Will the research environment and mentoring provide the resources needed to complete the project? Can the project be completed in the proposed timeline?
- **Career Development:** The applicant's potential for conducting research in breast cancer, the likelihood that the proposed project and training plan will develop this potential, and the mentor's track record and commitment to the candidate. The environment and resources available for training the applicant.
- Budget and Animal/Human subjects evaluated but not scored.

Programmatic Review

This review is conducted by the California Breast Cancer Research Council and involves reviewing and scoring applications with sufficient scores from the peer review process based on the criteria listed below. 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 evaluates **only a portion of the application**

materials. Pay careful attention to the instructions for each form. The Programmatic criteria include:

- **Response to priorities.** How responsive is the proposed research to CBCRP priority issues? This is evaluated using the abstracts and the responses in "Program Responsiveness" form.
- **Response to award type.** How responsive is the project and PI to the stated intent of the selected award type? This is evaluated using the responses in "Program Responsiveness" form.
- Career plan/mentoring. The degree to which the applicant's career plans indicate an
 interest in and knowledge about breast cancer research and reflect a long-term career
 commitment to the field, whether in research, policy or advocacy. The alignment of the
 mentor's qualifications and track record in breast cancer research and training with the
 applicant's career goals. This is evaluated using the Fellow and Mentor biosketches.
- **CBCRP "balance" or underfunded.** The degree to which the PI on Distinction from Other Funding has highlighted the unique aspects of the proposed research from their own projects (past and present) and the research by others. Has the research area been identified as underfunded by CBCRP as a Program Initiative? Is this a training pipeline that is no longer supported through federal funding? This is evaluated using the "Distinction from Other Funding" form and comparison to the ICRP and Dimensions databases.
- Addressing the needs of the underserved. Do the project and the PI's statements demonstrate an understanding of how the fellowship activities could address the needs of the underserved? This is evaluated using responses on the "Additional Criteria" form.
- **Dissemination to Community.** Has the PI committed him/herself to be proactive in disseminating the research to the lay audience? Has the PI identified opportunities to share their research results and experiences beyond the scientific community? This is evaluated using responses on the "Additional Criteria" form.

Application Forms and Instructions

Letter of Intent Submission

Letters of Intent (LOI) are required for all Predoctoral and Postdoctoral Fellowship applications. The LOIs will be reviewed for relevance by CBCRP staff and invitations will be issued within 5 working days of the LOI submission.

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 of 1 or 2 years (Project duration must be a whole number).
- **Proposed Project Start Date:** The project start date of August 1, 2026 will auto-populate and is not editable.
- <u>Proposed Project End Date</u>: Enter a project end date up to July 31, 2027 for one year or July 31, 2028 for two years.

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.

Section 3: Project Information

Applicants must respond to the following categories and discussion points using the online fields provided:

- Lay Abstract (Max 2400 characters): Describe the research project, its specific aims, the fellows' current status at the applicant institution and the planned training activities that will be proposed in this application. The abstract should be written using a style and language comprehensible to the general public. Avoid the use of acronyms and technical terms. The scientific level should be comparable to either a local newspaper or magazine article. Avoid the use of technical terms and jargon that are not in general use.
- **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 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:

- \$148,800 in total direct costs for Predoctoral Fellowships.
- \$180,000 in total direct costs for Postdoctoral Fellowships.

Section 5: 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.

Application Submission

The application must be prepared by the fellow PI. This includes the abstracts and the Research. It is appropriate for the mentor to assist the applicant in: (i) prioritizing the aims, (ii) matching the amount of work (i.e., avoid overambitious projects) to the project duration and skills of the applicant, (iii) proofreading the text and correcting any improper English usage, (iv) organizing a training plan that focuses on breast cancer, and (v) identifying the distinctions of the current application from other work in the mentor's lab. The mentor should prepare and sign the mentorship plan.

Applications must be distinct projects with unique specific aims. While the aims must not duplicate the efforts of the mentor's funded projects they can complement or extend mentor's funded work. If concurrent Cycle 32 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.

Letters of recommendation or support should be arranged in time for submission with the application by the March 5, 2026 deadline.

Please review the "SmartSimple Submission Instructions" for the technical instructions for accessing and completing your application. This application instruction document provides guidance for the content of your application.

Inviting Personnel

The **Invite Personnel** tab in the left sidebar of the grant file enables you to provide access to anyone whom you wish to participate in your application preparation or submission. The personnel roles, their levels of access and the process for sending the invitations are described in the CBCRP SmartSimple instructions.

Section 1: Title Page

All items in this section have been pre-populated from the LOI and may be edited in the application.

- <u>Project Title</u>: Enter a title that describes the project in lay-friendly language. (Max 100 characters)
- **Project Duration:** Enter a project duration of 1 or 2 years (Project duration must be a whole number).

- **Proposed Project Start Date**: The project start date of August 1, 2026 will auto-populate and is not editable.
- **Proposed Project End Date:** Enter a project end date up to July 31, 2027 for one year or July 31, 2028 for two years.

Section 2: Applicant/PI

The text in this section has been pre-populated from the LOI. A required field entitled "ORCID ID" is editable on the Profile page. 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.

Section 3: Project Information

The text in this section has been pre-populated from the LOI, with the exception of the Scientific Abstract, Specific Aims, Research Demographics, and Milestones. Refer to the LOI Instructions for guidelines for the pre-populated content areas. Please use the following guidelines to differentiate between Lay and Scientific Abstracts:

- Lay Abstract (Max 2400 characters): This item is evaluated mainly in the programmatic review. 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
 - The career goals that the research project and training will support

The abstract should be written using a style and language comprehensible to the general public. Avoid the use of acronyms and technical terms. The scientific level should be comparable to either a local newspaper or magazine article. 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 your advocate partner to read this abstract and provide feedback.

• **Scientific Abstract** (Max 2400 characters): This item is evaluated mainly in the peer review.

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 description of the training environment and how it will advance the career goals of the fellow

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.

- **Specific aims** (Max 2400 characters/approx. 350 words): Describe the specific aims of your project.
- Research Demographics. Complete this table if the research project will involve human subjects. Enter the target demographics of the research participants that you propose to recruit.
- **Milestones.** Add significant milestones that are described in your research and training plan to this table along with anticipated completion dates and arrange them in chronological order.

Section 4: Project Contacts

- Project Personnel. Provide contact information and effort for Key Personnel and Other Significant Contributors on your project including the Applicant Principal Investigator and mentor. Upload biosketches to each of your Key Personnel members in this section, as shown in the SmartSimple instructions. Applicant PIs must commit a minimum effort of 75%.
- Biographical Sketch & Other Support (required)
 Use the NIH form (version 2020 or later) for each key person and attach it in the
 Project Personnel section. <u>Limit the length of each biosketch to no more than five (5) pages</u>.

Biosketch	Limit	Required or optional	Peer	Programmatic
			Review	Review
PI	5 (Fellow biosketch)	Required (upload to Project Personnel table)	Yes	Yes
Mentor	5 (non-fellow NIH biosketch)	Required (upload to Project Personnel table)	Yes	Yes
Other Key Personnel	5 (non fellow NIH biosketch)	Required (upload to Project Personnel table)	Yes	No

• Letters of Reference (Blind): This item is evaluated in the peer review. Fellowship Applicants must submit a letter of support from the mentor and a minimum of two additional references. The submitted letters of reference are blind to the applicant: the

status of the letter is available to the applicant but the content is not. The content of the letters is available to the funding organization and its designated reviewers. Please provide the Referee Instructions to your referees.

- Include a letter of support from the mentor. Also submit a minimum of two and a maximum of three letters of support from other researchers familiar with the applicant.
- o List all individuals providing letters using the Appendix Cover Sheet.
- Make arrangements to obtain the appropriate letters prior to application submission.
- Do not have individuals send letters directly to CBCRP.

Note that all required letters of reference must be uploaded by the referees before the applicant submits the application to the signing official. Once the application is submitted to the signing official (and subsequently submitted to CBCRP), no letters can be added. Please work with your referees to ensure all letters can be uploaded to the system in a timely manner.

Section 5: Budget

This section contains several sub-tabs: Institution Contacts, Budget Summary, Budget Details, and Subcontract Budget Details. Complete the information in the Institutional Contacts, Budget Summary, Budget Detail as described in the SmartSimple Application Instructions.

The maximum duration is 2 years and the direct costs budget cap is \$148,800 for Predoctoral Fellowships and \$180,000 for Postdoctoral Fellowships.

- Student Tuition Fees, Graduate Stipends.
 - Stipends: Stipends are capped at \$60,000 per year for predoctoral fellows and \$70,000 per year for postdoctoral fellows. Stipends must adhere to NIH experience scale, or the rates set by their institution with institutional documentation of the alternate payment scale.
 - Tuition: Predoctoral students may budget for full tuition and fee costs up to \$10,000. Documentation of the institution's tuition and fees structure should be included in the budget justification.
- Institutional Allowance. The applicant may request an annual institutional allowance of \$4,400 for predoctoral awards and \$20,000 for postdoctoral awards to help defray the cost of expenses such as health insurance, medical liability or other special insurance, research supplies, equipment, courses and educational materials, project related travel, and travel to scientific meetings. The institutional allowance is a fixed amount, and the institution is not required to account for these expenses on an actual cost basis.
- Travel CBCRP Meeting. A minimum of \$400 must be budgeted in year 1 for travel to the CBCRP symposium. This expense is in addition to the institutional allowance.
- Indirect (F&A) costs. Not allowed.

A Note on Stipends and Employee Benefits: Since CBCRP Fellowships are not provided as a condition of employment with either CBCRP or the sponsoring institution, institutions may not seek funds, or charge individual awards, for costs that normally would be associated with employee benefits (e.g., FICA, workman's compensation, life insurance, union dues, and unemployment insurance). Additional budget guidelines can be found in Appendix A.

Section 6: Assurances

Enter assurance information. If available, enter your institutional Federal Wide Assurance (FWA) code or equivalent for Human Subjects, an IACUC Animal Welfare Assurance code for Vertebrate Animals, and equivalent for Biohazard and DEA Controlled Substance approvals.

Section 7: Documentation

Complete and upload all required items. All uploads must be in PDF format. Listed below are the forms and templates you download from SmartSimple, enter text, convert to PDF, and, unless instructed otherwise, re-upload to your application in this section.

Upload Item (Template/Form)	Page limit	Required or optional	Peer Review?	Programmatic Review?
Program Responsiveness	2	Required	Yes	Yes
Distinction From Other Funding	1	Required	Yes	Yes
Additional Criteria	1	Required	Yes	Yes
Research Plan	Predoctoral 5 Postdoctoral 7	Required	Yes	No
Training plan	Predoctoral 5 Postdoctoral 3	Required	Yes	No
Mentor Training Experience	2	Required	Yes	No
Fellow Biosketch	5	Required (upload to Project Personnel section)	Yes	Yes (Fellow only)
Other Personnel Biosketches (All Personnel listed on Key Personnel form)	5 (each biosketch)	Required (upload to Project Personnel section)	Yes	Yes (Mentor only)
Facilities	1 per institution	Required	Yes	No
Human Subjects	No limit	Required	Yes	No
Vertebrate Animals	No Limit	Optional	Yes	No
Appendix list and uploads	30	Optional	Yes	No
Letters of Recommendation (Blinded) - invite referees to upload, no template provided	3-5 letters including one from the mentor and at least two other individuals	Required	Yes	No

Description of Proposal Templates

Program Responsiveness (required)

This item is evaluated primarily in the programmatic review. Limit the text to two pages.

The information on this template allows the advisory Council to rate the application for adherence to our Priority Issues and Award Type descriptions. **Selecting the Priority Issue and Award Type is not sufficient for completing the form.** Address, in detail, how the proposed project relates to the CBCRP Priority Issues and Fellowship award requirements as described in the <u>CBCRP Call for Applications</u>. This will be the major piece of the application used by reviewers to evaluate responsiveness, which is the first step in the evaluation process.

First, indicate the *CBCRP Priority Issue* (see the <u>CBCRP Call for Applications</u> for their full description) that best matches your project topic and discuss this relationship. If your project addresses more than one CBCRP Priority Issue, then concentrate your discussion on the one priority issue that best matches the project. Address these questions:

- o How is your project specific for breast cancer?
- What special aspect of breast cancer is the focus of your research?
- What unique characteristics of breast cancer, especially in the clinical or community settings, make it an ideal target for your research topic?

Second, indicate the **Award Type** that you are applying for, and discuss why your project and career level matches this choice. Describe your career stage and how the fellowship will contribute to your short-term and long-term goals for a breast cancer research career.

Distinction from Other Funding (required)

This item is evaluated mainly in the programmatic review. Limit the text to one page.

Discuss the unique properties of the current application from, (i) other current and past grant support to the PI and the PI mentor, (ii) the current CBCRP portfolio as shown under the "Explore All Funded Research" link on the CBCRP Funded Research page, and (iii) general research in the topic under investigation on display on the International Cancer Research Portfolio (ICRP) website: https://www.icrpartnership.org/. Discuss the distinction between the proposed project and ongoing work and grant funding in your supervisor's research environment.

Additional Criteria (required)

This item is evaluated primarily in the programmatic review. Limit the text to one page.

 Addressing the Needs of the Underserved - Describe the potential for your project to understand and reduce disparities and health inequities in breast cancer risk, incidence, and treatment/prognosis at the individual and community levels. Underserved is defined as communities or individuals who bear a disproportionally high burden of breast cancer or have disproportionate exposures or conditions linked to breast cancer.

 Dissemination to Community – Describe opportunities to engage with communities that the PI will explore and undertake. Examples could include engaging with breast cancer advocacy groups, giving presentations to the public about breast cancer research findings or creating and distributing materials, based on your research, for use by California public health, educational, and/or community organizations.

Research Plan (required)

This section is evaluated solely in the peer review. Note carefully the page limits, format requirements, and suggested format. <u>Page limit</u>: 5 pages for Predoctoral and 7 pages for Postdoctoral. Unlimited additional pages are allowed for References.

<u>Format issues:</u> 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 <u>format</u> requirements:

- 1. The height of the letters must <u>not be smaller than 11 point</u>; 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 ¾ inch.

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

Suggested content:

<u>Introduction and Hypotheses:</u> Provide a brief introduction to the topic of the research and the hypotheses/questions to be addressed by the specific aims and research plan. The relationship of the project to the CBCRP Priority Issue should be clear.

<u>Specific Aims:</u> List the specific aims, which are the steps or increments deemed necessary to address the central hypothesis of the research. The subsequent research plan will detail and provide the approach to achieving each of these aims. Note to basic science applicants: If a molecular pathway has not been established to be relevant to breast cancer, then the primary point of the study should be to test this relevance.

<u>Background and Significance:</u> Make a case for your project in the context of the current body of relevant knowledge and the potential contribution of the research. Highlight knowledge gaps that this project will address.

<u>Preliminary Results:</u> Describe the recent work relevant to the proposed project. Emphasize work by the PI and data specific to breast cancer. If the project is new to breast cancer, then this section should illustrate the capabilities of the PI and mentor to develop significant new information in breast cancer.

Research Design and Methods: Provide an overview of the experimental design, the methods to be used, and how data is to be collected and analyzed. Recognition of potential pitfalls and possible alternative approaches is recommended. How will technical problems be overcome or mitigated? Cover all the specific aims of the project in sufficient detail. Match the amount of work to be performed with the budget/duration requested. A description of the milestones and timeline will demonstrate how the aims are interrelated, prioritized, and feasible. Explain the use of human subjects and vertebrate animals and show their relationship to the specific aims.

• Training Plan (Required)

This section is evaluated solely in the peer review. Note carefully the page limits, format requirements, and suggested format. <u>Page limit</u>: 5 pages for Predoctoral and 3 pages for Postdoctoral.

The Applicant, in collaboration with the Mentor(s), must construct a detailed, well-rounded training plan. The training plan should demonstrate the anticipated value of the proposed mentored research and training in relationship to the trainee's unique research and career goals. The training plan should also indicate how the plan prepares the Applicant for the next stage of their career.

The training plan should include, but not be limited to, the following:

- (I) Description of the Applicant
 - a. Provide a brief description of the applicant's academic background and research interests that illustrates their path to their chosen research field and mentor
 - b. the Applicant's long-term plans for a breast cancer career,
 - c. how the Applicant envisions the current project will prepare them for their next career stage;
- (II) Description of the Mentor
 - a. how the Mentor's laboratory, research experience, and staff support the Applicant's proposed research and career goals

- b. specific resources (e.g. equipment, laboratory space, computer time, subject populations, etc.) that will be provided to meet the needs of the proposed study and the career goals of the Applicant
- c. how the institution provides appropriate and sufficient opportunities for the Applicant to gain professional and scientific skills

(III) Applicant and Mentor Partnership

- a. Outline a proposed training plan to address gaps in the applicant's academic and/or research experience;
- b. Create a timeline of activities, responsibilities, expectations, and assessment of completed goals for both the Applicant and Mentor over the course of the award;
- c. Identify scientific research methods including research design, experimental methods, and analytic techniques appropriate for proposed research;
- d. Explain what additional experiences, classes or scientific techniques will be planned to supplement the trainee's knowledge and support future independence, such as professional skills and building effective collaborations;
- e. Identify and indicate in timeline of activities for training on the ethical conduct of research;
- f. Provide opportunities to present and publish research findings and to interact with members of the scientific community at meetings and workshops;
- g. Propose methods on how to disseminate research in a manner readily understandable by non-scientists;
- h. Describe the didactic or interactive activities planned for increasing the trainee's knowledge base in the stated CBCRP research priorities;

Mentor Training Experience (Required)

This is evaluated solely in the peer review. **Limit the text to two pages**.

The mentor should provide a list of doctoral and postdoctoral fellows successfully trained, their current position(s)/status (if known), and whether they are working in a breast cancer related field.

• Facilities (Required)

This item is evaluated in the peer review. <u>Limit the text to one page per institution</u>. Follow the instructions on the template.

HUMAN SUBJECTS (required)

This form is required to be completed for applications that use Human Subjects, including those in the "Exempt" category. Applications that do not utilize Human Subjects should state "N/A" on the form and upload, as well. 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 CBCRP 2025-26 Cycle 32 Programmatic Instructions - Page 16 Predoctoral and Postdoctoral Fellow LOI and Application

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 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 <u>detailed description of the proposed involvement of human subjects</u> in the project.
- 2. Describe the <u>characteristics</u> of the <u>subject population</u>, including its anticipated number, age range, and health status. It is the policy of the State of California, the University of California, and 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 <u>sources of research material</u> 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 <u>plans for recruiting subjects</u> 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 <u>potential risks</u> —physical, psychological, social, legal, or other. Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects.
- 6. Describe the <u>procedures for protecting against, or minimizing, any potential risks</u> (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.

 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 Assurances tab, 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 that are 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, an USPHS approved IRB must provide the assurance. If review is pending, final assurance should be forwarded- to CBCRP as soon as possible, but **no later than August 1, 2026**. Funds will not be released until all assurances are received by 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://grants.nih.gov/grants/guide/notice-files/not98-084.html. This ensures patient safety, confidentiality, and guidelines for continuing or canceling a clinical trial based on data collected in the course of the studies. CBCRP may require documentation that a DSMB is in place or planned prior to the onset of the trial.

VERTEBRATE ANIMALS (only if needed)

This form is required only for applications that use Vertebrate Animals. <u>Limit the text to two pages</u>.

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 <u>proposed use</u> 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. <u>Justify the use of animals</u>, 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 <u>procedures for ensuring that discomfort, distress, pain, and injury will be limited</u> 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 <u>methods of euthanasia</u> 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 CBCRP as soon as possible, but **no later than August 1, 2026**. Funds will not be released until all assurances are received by CBCRP.

APPENDIX LIST (Required)

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.

Appendix A: Cost and Expense Guidelines

1) Personnel

- The Budget Summary line item for Personnel should reflect the total cost of all
 individuals identified as supported by the grant and their level of effort. In the personnel
 section of the application, be sure to name all individuals to be supported by the grant
 and provide their percent effort (months devoted to the project). All paid individuals
 must also be listed on the budget.
- Follow the NIH Guidelines and Calculation scheme for determining Months Devoted to Project, available at the links below:
 - NIH Guidelines:
 - o http://grants.nih.gov/grants/policy/person months fags.htm
 - NIH Calculation Scheme:
 http://grants.nih.gov/grants/policy/person months conversion chart.xls
- Provide a justification for all budgeted personnel, identifying each individual by name, role on the project, and proposed effort. When computing salary for key personnel, use only the base salary at the applicant organization, excluding any supplementary income (e.g., clinical or consulting incomes). The program does not enforce a salary cap, as long as the overall budget adheres to the costs & expenses guidelines and the amount requested stays within the allowable costs.

2) Student Tuition Fees, Graduate Student Stipends

- Predoctoral and postdoctoral stipend must adhere to NIH experience scale, or the rates set by their institution with institutional documentation of the alternate payment scale. Stipend may be budgeted as salary if the institution pays these expenses through a personnel line item. Please provide documentation of current institution rates and/or scales for requested tuition & fees and stipends.
- Tuition remission is allowable for Predoctoral Fellowships only. It is capped annually at \$10,000 and will be considered compensation and should not offset other financial aid.

3) Other Project Expenses (no IDC)

- Institutional Allowance: The applicant may request an institutional allowance to help defray the cost of expenses such as health insurance, medical liability or other special insurance, research supplies, equipment, courses and educational materials, project related travel, and travel to scientific meetings. CBCRP will cover up to \$4,400 for Predoctoral awards and \$20,000 for Postdoctoral awards per year for these costs. The institutional allowance is a fixed amount, and the institution is not required to account for these expenses on an actual cost basis.
- A Note on Stipends and Employee Benefits: Since CBCRP Predoctoral and Postdoctoral Awards are not provided as a condition of employment with either CBCRP or the

sponsoring institution, institutions may not seek funds, or charge individual awards, for costs that normally would be associated with employee benefits (e.g., FICA, workman's compensation, life insurance, union dues, and unemployment insurance).

4) Equipment (Unit Cost over \$5,000)

Not Allowed

5) Travel

- <u>Travel CBCRP Meeting</u>: CBCRP may organize an event requiring your travel within the funded grant period. All applicants should budget a one-time minimum expense of \$400 under year 1 in the travel budget line labeled: "Travel Annual Meeting".
- Travel Project Related: Included in institutional allowance.
- <u>Travel Scientific Meetings</u>: Included in institutional allowance

6) Service Contracts and Consultants

Not Allowed.

7) Subcontracts

Not Allowed.

8) INDIRECT (F&A) COSTS

Not Allowed

Appendix B: Other CBCRP Application Policies and Guidelines

Eligibility and Award Limits

- 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. Applicants at California-based Nonprofit Institutions: CBCRP will accept applicants from PIs at non-profit organizations or institutions, provided that the organization can manage the grant and demonstrate financial health. The organization must also meet our liability insurance requirements. If the application is recommended for funding, the University will collect additional information, such as tax ID numbers and financial reports, to review the organization during the pre-funding process to ensure all financial management and project management eligibility criteria can be met.
- **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. PIs who have previously been funded by CBCRP** are welcome to apply, but the <u>research aims</u> <u>must be distinct from their previous CBCRP grants</u>.
- **4. Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. <u>Applicants are limited to a maximum of two (2) grants either as PI or co-PI</u>, and these must be in different award types. The Program and Policy Initiative grants are not included in this limit. A PI may have more than one Program or Policy Initiative grant in a year.
- **5. University of California Campus Employees:** 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 on Applications from PIs with Delinquent CBCRP Grant Reports

Pls with current CBCRP grant support will <u>not</u> 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 32 application to 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 CBCRP to allow an extension of any report deadlines.

Application Revision Guidelines

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.

Confidentiality

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 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 CBCRP's annual report, (iii) the project abstract and progress report abstracts on the CBCRP website. 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.

Human Subjects and Vertebrate Animal Use

Approvals for use of human material and animal research subjects are not required at the time of application. Applicants are encouraged to apply to the appropriate board or committee as soon as possible in order to expedite the start of the project, and you must do so before or within 21 days of notification that an award has been offered. This deadline may be negotiable depending on the circumstances of the proposal. If all reasonable efforts are not made to obtain appropriate approvals in a timely fashion, funds may be reallocated to other potential grantees' proposed research projects.

Award Decisions

Applicants will be notified of their funding status by July 1, 2026. 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.

Appeals of Funding Decisions

RGPO strives to resolve issues raised throughout the grantmaking lifecycle from funding decisions to project closeout. Before submitting an appeal or grievance, applicants are encouraged to discuss their concerns with the appropriate program officer or program director.

The only basis on which an appeal regarding the funding decision of a grant application will be considered is in the case of an alleged error in, or violation of the peer review procedures and/or process. Appeals based on substantive disagreement with the peer review evaluation will not be considered. In such cases, applicants may resubmit applications in a subsequent grant cycle.

Applicant appeals must be made to the program within 30 days of the funding notification. If discussions with the program do not satisfactorily resolve an applicant's issue, either the applicant or the program may contact the RGPO Executive Director for resolution. If resolution is not achieved, or if the applicant believes that a violation has occurred that has not been adequately addressed through these efforts, a formal appeal may be filed with the Vice President of Research and Innovation.

Pre-funding Requirements

Following notification by 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:

- 1. Supply approved indirect (F&A) rate agreements as of the grant's start date and any derived budget calculations.
- 2. Supply any missing application forms or materials, including detailed budgets and justifications for any subcontract(s).
- 3. IRB applications or approvals pertaining to the award.
- 4. Resolution of any scientific overlap issues with other grants or pending applications.
- 5. Resolution of any Review Committee and Program recommendations, including specific aims, award budget, or duration.
- 6. Modify the title and lay abstract, if requested.

Publications Acknowledgement

All scientific publications and other products from a RGPO-funded research project must acknowledge the funding support from UC Office of the President, with reference to the specific CBCRP funding program and the assigned grant ID number.

Open Access Policy

As a recipient of a California Breast Cancer Research Program (CBCRP) grant award, you will be required to make all resulting research findings publicly available in accordance with the terms of the Open Access Policy of the Research Grants Program Office (RGPO) of the University of California, Office of the President (UCOP). This policy, which went into effect on April 22, 2014, is available here: https://www.ucop.edu/research-grants-program/grant-administration/rgpo-open-access-policy.html

Grant Management Procedures and Policies

All CBCRP grant recipients must abide by other pre- and post-award requirements pertaining to Cost Share, Indirect Cost Rates, Monitoring & Payment of Subcontracts, Conflict of Interest, Disclosure of Violations, Return of Interest, Equipment and Residual Supplies, Records Retention, Open Access, and Reporting. Details concerning the requirements for grant recipients are available in a separate publication, the University of California, Office of the President, "RGPO Grant Administration Manual." The latest version of the Manual and programmatic updates can be obtained from the Program's office or viewed on our website: https://www.ucop.edu/research-grants-program/grant-administration/index.html.

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, PhD Senior Program Officer, CBCRP:

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.