Request for Qualifications (RFQ)

Addressing Disparities in Genomic Testing of Tumors to Guide Treatment for Breast Cancer

California Breast Cancer Research Program
Policy Initiative

Deadline to apply:
October 6, 2022

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Published August 1, 2022

About the California Breast Cancer Research Program and the Policy Initiative

The **California Breast Cancer Research Program (CBCRP)** was established pursuant to the 1993 Breast Cancer Act (*AB 2055 (B. Friedman) [Chapter 661, Statutes of 1993]* and *AB 478 (B. Friedman) [Chapter 660, Statutes of 1993]*). The program is responsible for administering funds for breast cancer research in California.

The mission of CBCRP is to eliminate breast cancer by leading innovation in research, communication, and collaboration in the California scientific and lay communities.

- CBCRP is the largest state-funded breast cancer research effort in the nation and is administered by the University of California, Office of the President.
- CBCRP is funded through the tobacco tax, a voluntary tax check-off on personal income tax forms, and individual contributions.
- The tax check-off, included on the personal income tax form since 1993, has drawn over $11 million for breast cancer research.
- Ninety-five percent of our revenue goes directly to funding research and education efforts.
- CBCRP supports innovative breast cancer research and new approaches that other agencies may be reluctant to support.
- Since 1994, CBCRP has awarded over $285 million in 1,234 grants to 174 institutions across the state. With continued investment, CBCRP will work to find better ways to prevent, treat and cure breast cancer.

CBCRP Policy Initiative

CBCRP seeks to foster relationships between researchers, local leaders, decision makers, community groups and others to create solutions that work to prevent breast cancer and create strong, empowered, healthy communities. The Policy Initiative is intended to demonstrate how people across sectors can collaborate to prevent breast cancer and develop evidence that can be used to advocate and implement change throughout California.

The purpose of the Policy Initiative is to fund directed policy research on issues related to the prevention, detection, and treatment of breast cancer, as well as research into the formulation of policy alternatives that will reduce the incidence of and/or morbidity and mortality from breast cancer in California. The goal is to allow breast cancer-related policy changes to be grounded in science that is timely, relevant, and credible.

In this context, policy is defined as:

"a law, regulation, procedure, administrative action, incentive, or voluntary practice adopted or proposed by a local, regional, tribal, state or federal government, business, organization, or institution that will reduce the incidence of and/or the morbidity and mortality from breast cancer in California."

Policy Initiative projects funded by CBCRP provide answers that move public and/or private policy. Ideally, findings are useful for changing policy at the local (schools, prisons, public departments such

as parks and recreation, planning and building, public health), state, and national levels. In other cases, answers may be best used toward private policies such as those found at workplaces, private schools, hospitals or other healthcare institutions, within corporations, etc.

Applications are reviewed by a peer review committee of policy experts from outside of California and the Policy Research Advisory Group or PRAG (http://www.cbcrp.org/priorities/sri/policy/steering-committee.html).

Research findings should be disseminated quickly, in a manner timely to the mechanism of the relevant change process. For example, if the research proposes statutory changes, the findings should be distributed during the appropriate point in the legislative cycle. Research should be presented in lay, non-technical language in forms that are useable for a general audience and can help make the case for the changes being considered. Priority is given to generating high-quality data that can be put to use rapidly. Less emphasis is placed on publishing in peer-reviewed journals, and, in fact, some findings may not be expected to be published in such journals.

Addressing Disparities in Genomic Testing of Tumors in Guiding Treatment for Breast Cancer

This project aims to examine disparities in the use of genomic testing of tumors, which guide the treatment of breast cancer in California, to recommend policy interventions to reduce these disparities and improve outcomes for breast cancer patients in the State.

Available Funding

CBCRP intends to fund one project, with a maximum direct cost budget of $150,000 and a maximum duration of 6 months. A separate direct cost budget of $50,000 is available for a dissemination plan.

Completed responses to this RFQ are due by October 6, 2022, 12 pm PST. The project start date is January 1, 2023.

For more information and technical assistance, please contact:
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Background

Use of precision medicine and gene-targeted therapies are increasing, particularly for cancer treatment. Genetic mutations in tumors that may impact the treatment of breast cancer are well documented. For example, HER2 status can indicate certain treatment medications may be appropriate, and genomic testing panels such as Oncotype DX® and MammaPrint® and specific gene tests can help determine optimal treatment regimes. Multiple clinical guidelines recommend genomic testing of tumors to guide breast cancer treatment, including the American Society of Clinical Oncologists (ASCO) and the National Comprehensive Cancer Network (NCCN). However, documented disparities exist in the use of genomic testing by race and ethnicity, age, and socioeconomic status (CHBRP, 2022). Disparities by race and SES census tract have been seen in utilization of Oncotype DX® specifically, with significantly lower use among black and Hispanic women compared with white women (Kozick et al, 2017, Davis et al, 2017), including in California (Cress et al, 2016).

Disparities were documented despite these tests being covered by insurance when medically indicated. The California Health Benefits Review Program (CHBRP) completed an analysis of the 2022 Senate Bill 912 (Limón, 2022) which would require coverage of biomarker testing (including genomic testing) for Californians enrolled in health insurance subject to state regulation (approximately 22.8 million Californians in 2023) based on specified criteria. CHBRP found that, broadly speaking, all enrollees currently have insurance coverage of biomarker testing when medically necessary and supported by medical evidence (CHBRP, 2022), however criteria for establishing the necessity varied.

Studies have suggested that clinician barriers –including familiarity with guidelines and knowledge of best practices for use of biomarker testing, expertise in genomic testing, or access to multidisciplinary specialty teams –impact whether patients receive testing (CHBRP, 2022).

Despite genomic tests being covered when medically indicated and the multiple clinical guidelines recommending them, there remain disparities in their use in the treatment of breast cancer (CHBRP, 2022, Kozick et al, 2017, Davis et al, 2017, Cress et al, 2016). Policy interventions that reduce these disparities could help ensure that more patients receive optimal treatments for their breast cancers and could reduce the known disparities in breast cancer survival.

Research Questions

The goal of this RFQ is to answer the following questions:

1. What policy interventions could reduce disparities by race, ethnicity, age, socio-economic status, location, and/or other factors in the use of genomic testing of tumors for treatment of breast cancer in California?
2. How can these policy interventions be delivered and disseminated best to communities and health care professionals in California?

The research should consider multilevel interventions that address the role of multiple stakeholders, including patients, clinicians, public health professionals, policymakers, researchers, breast cancer advocates, and others.

Approaches and Methods

Any individual or organization located in California can submit an application (See Eligibility and Award Limits for more information). Successful teams will have established connections to impacted communities by either being part of a Community Based Organization or partnering with one.

This project will primarily involve assessing the disparities in California of genomic testing of tumors used to guide breast cancer treatment and identifying policy interventions that can reduce those disparities. This project is not about germline genetic testing/screening to determine the presence of inherited mutations (such as BRCA1 and 2) that predispose one to develop breast cancer.

For example, the use of breast cancer genomic tests such as Oncotype DX®, MammaPrint®, P53 and RAD51 are recommended in multiple clinical guidelines but may not be automatically ordered in each qualifying circumstances. An analysis of clinician awareness of the recommendations for the use of tumor genomic tests in guiding treatment would be useful as would an understanding of patients' knowledge of these tests. Is there a case for educating communities so patients can push for the care they need?

In answering the research questions above, the project should address the following:

- Are clinicians ordering the tests for every circumstance in which clinical guidelines recommend? If not, why?

- Are the results of the testing being used to guide care? If not, why?
- Is reimbursement through coverage adequate? Do levels of reimbursement contribute to disparities?
- If the information is readily available, is germline screening being ordered at the same time as genomic tests and, if so, is genetic counselling available for patients? Does this affect disparities in genomic testing?

Projects should include a literature review on disparities in genomic testing of tumors in California and could incorporate a data analysis component looking at treatment and services provided to different populations coupled with key informant interviews on actual practice in order to identify any systemic differences. An analysis of electronic medical records from breast cancer centers and private and public payors may be helpful.

Community Engagement

Partnership with an Advocacy and/or Community Organization that can engage appropriate stakeholders and partner in policy development and implementation is a requirement for this award. This may be accomplished by having the Community Organization serve as the applicant organization or receive a subcontract as a Co-Investigator. The application may also involve additional breast cancer advocates or other community advocates/organizations. The community organization should be involved in the development of the project, goals, aims, and research questions and should drive the identification and definition of community needs and health equity imperatives. Community members and advocates should be compensated as experts.

Dissemination and Public Engagement Plan

Applicants should present a complementary draft Dissemination and Public Engagement Plan within the context of the topic area. This should identify potential stakeholders, roles and possible activities including but not limited to presentations, press releases or hearings before key stakeholders/decision-makers, web-based strategies and content, and other project- and topic-specific materials. Applicants should tailor the Dissemination and Public Engagement Plan to the appropriate strategies for the various stakeholder groups, including historically disadvantaged communities, to ensure the most effective, productive, and positive engagement. A separate non-binding, non-guaranteed draft budget (direct costs of $50,000) and budget justification should be prepared for the proposed Dissemination and Public Engagement Plan. A final detailed Plan with specific stakeholders, activities and budget should be submitted for approval with the report at the end of the six-month project.

Budget

CBCRP intends to fund one project, with a maximum direct cost budget of $150,000 and duration of 6 months. A separate, non-binding draft dissemination and public engagement budget with direct costs of up to $50,000 is also required.

Indirect (F&A) costs are paid at the appropriate federally approved F&A rate for all institutions except for University of California campuses, which receive a maximum of 30% F&A (25% for off-campus projects). A de minimis rate of 25% is available for organizations without a federally approved F&A rate.

Timeline and Milestones

The deadline for completion of this project is 6 months from the award start date. Below is a proposed timeline:

- Scoping and initial assessment (month 1)
- In depth review of evidence (months 2)
- Gathering of data (interview, payor data) months 3-4
- Identification and outline of findings (month 5)
- Preparation of updated dissemination and public engagement plan to submit with the draft report to CBCRP (month 6)

In order to be eligible to apply for dissemination funds, the draft report and dissemination plan proposal must be submitted to CBCRP by the end date of the project.

References

CHBRP, 2022: California Health Benefits Review Program (CHBRP). Analysis of California Senate Bill 912: Biomarker Testing. Berkeley, CA. Available at http://analyses.chbrp.com/document/view.php?id=1668 (Accessed July 2022)

Cress RD, Chen YS, Morris CR, Chew H, Kizer KW. Underutilization of gene expression profiling for early-stage breast cancer in California. Cancer Causes Control. 2016 Jun;27(6):721-7. doi: 10.1007/s10552-016-0743-4. Epub 2016 Apr 20. PMID: 27097910; PMCID: PMC4871729.

Davis BA, Aminawung JA, Abu-Khalaf MM, Evans SB, Su K, Mehta R, Wang SY, Gross CP. Racial and Ethnic Disparities in Oncotype DX Test Receipt in a Statewide Population-Based Study. J Natl Compr Canc Netw. 2017 Mar;15(3):346-354. doi: 10.6004/jnccn.2017.0034. PMID: 28275035.

Kozick Z, Hashmi A, Dove J, Hunsinger M, Arora T, Wild J, Shabahang M, Blansfield J. Disparities in compliance with the Oncotype DX breast cancer test in the United States: A National Cancer Data Base assessment. Am J Surg. 2018 Apr;215(4):686-692. doi: 10.1016/j.amjsurg.2017.05.008. Epub 2017 Jun 14. PMID: 28606707.

How We Evaluate Policy Initiative RFQs

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 and other community representatives.

- **Approach.** Reviewers assess the quality, organization, and presentation of the research plan, including methods and analysis plan. Will the research planned answer the research questions? Are the design, methods and analyses well-developed, integrated and appropriate to the aims and stated milestones of the project? Does the application demonstrate an understanding of the research question and aims?
- **Feasibility.** The extent to which the aims are realistic for the scope and duration of the project; adequacy of investigator's expertise and experience, institutional resources; and availability of additional expertise and integration of multiple disciplines. Does the investigator (and do co-investigators) have demonstrated expertise and experience working in the topic area? Can the project be completed as proposed given the available funding, time frame and the staff knowledge, skills, experience, and institutional resources?
- **Potential for Policy Implementation:** Does the proposed team have the expertise and experience in developing policy interventions and shepherding them to adoption and implementation? Does the Community/Advocacy Organization have the capacity to engage the relevant stakeholders? Is the proposed dissemination and public engagement plan designed to facilitate adoption and implementation of changes in policy?

Programmatic Review

This review is conducted by the Policy Research Advisory Group (PRAG) of the California Breast Cancer Research Council and involves assessing and scoring applications with sufficient scores from the peer review process based on the criteria listed below. The individuals on the PRAG performing this review include advocates, clinicians, and scientists from a variety of relevant disciplines. In performing the Programmatic Review, the PRAG evaluates **only a portion of the application materials** (exact forms are underlined). Pay careful attention to the instructions for each form. The Programmatic criteria include:

- **Responsiveness.** How responsive are the project and co-PIs to the stated intent of the selected Initiative? Compare the PI's statements on the Program Responsiveness form and the content of the Lay and Scientific Abstracts to the topic area.
- **Quality of the Lay Abstract.** Does the Lay Abstract clearly explain in non-technical terms the research background, questions, hypotheses, and goals of the project? Is the relevance to the policy initiative understandable?
- **Diversity, Equity and Inclusion.** Do the statements in the Community Engagement form demonstrate a plan for the research team to include community members representing

groups that are underrepresented in breast cancer research? Do the project and the PIs' statements on the Program Responsiveness form demonstrate how this research will address the needs of underserved communities (including those who are underserved due to factors related to race, ethnicity, socioeconomic status, geographical location, sexual orientation, physical or cognitive abilities, age, occupation and/or other factors)? Do the statements in the PIs' Program Responsiveness form describe how the research will affect systems change for historically disenfranchised groups?

- **Community Involvement.** Does the Community Engagement form demonstrate that the community advocate(s) and organization(s) are clearly driving the proposed research project? How well has the team described the strengths/nature of the proposed community partnership and how is it reflected in leadership and involvement in all phases of the project (e.g. inception and application through to dissemination).
- **Dissemination and Implementation Potential.** The degree to which the applicant's statements in the Dissemination and Public Engagement Plan on the Community Engagement form provides a convincing argument that the proposed research has the potential to inform public policy on breast cancer particularly for historically disadvantaged communities.

Application Instructions

Application materials will be available through RGPO's SmartSimple application and grant management system beginning on August 1, 2022. Please review the SmartSimple Application Instructions for the technical instructions for accessing and completing your application. This supplemental programmatic instruction document provides guidance for the content of your application.

Application Components

Section 1: Title Page

- **Project Title:** Enter a title that describes the project in lay-friendly language. (Max 100 characters).
- **Project Duration:** Selected duration should be 1 year.
- **Proposed Project Start Date:** The project start date will be autofilled with the funded project start date of January 1, 2023.
- **Proposed Project End Date:** Enter a project end date of June 30, 2023 for a 6-month award.

Section 2: Applicant/PI

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 at 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

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
- **Innovative elements and potential impact** of the project in lay terms

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 brief statement of the **impact** that the project will have on breast cancer

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.

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

- **Specific Aims** (Max 2400 characters/approx. 350 words). List the proposed aims of the project.
- **CBCRP Research Priorities.** Select "Community Impact of Breast Cancer" as the CBCRP priority issue that the research addresses.
- **CSO Research Type(s) and Sub-Type(s).** Select "6.0 Cancer Control, Survivorship, and Outcomes Research" as the CSO Type and "6.4 Health Services, Economic and Health Policy Analyses" as the Sub-Type that best represent your project.
- **Subject Area(s).** See SmartSimple submission instructions for more details.
- **Focus Areas(s).** See SmartSimple submission instructions for more details.
- **Research Demographics.** See SmartSimple submission instructions for more details.
- **Milestones.** Add significant milestones that are described in your research 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, Co-Investigator, Advocate, Trainee, Collaborator, Consultant, and support personnel, as necessary. Upload biosketches to each of your Key Personnel members in this section, as shown in the SmartSimple instructions. A 5% minimum effort (0.6 months per year) is required for the Applicant PI.

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 and, if applicable, Subcontract Budget Details tab as described in the SmartSimple Application Instructions.

The **maximum duration is 6 months, and the direct costs budget cap is $150,000**.

Note: The amount of a subcontracted partner's F&A costs can be added to the direct costs cap. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.

Additional budget guidelines:

- **Equipment** purchases are not allowed.
- **Other Project Expenses:** Include other project costs such as supplies or **Advocate(s) Expenses** (any travel, meeting, and consultation costs/fees associated with advocates) here.
- **Indirect (F&A) Costs**. Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC*, or 25% MTDC for off-campus investigators (not retroactive to prior grants). A de minimis rate of 25% is available for organizations without a federally approved F&A rate.

**Allowable expenditures in the MTDC base calculation include salaries, fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract). Equipment, capital expenditures, charges for patient care and tuition remission, rental costs, scholarships, and fellowships as well as the portion of each subgrant and subcontract in excess of $25,000 shall be excluded from the modified total direct cost base calculation*

Additional budget guidelines can be found in Appendix A below.

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 ad 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?
Research Plan	**7** *(+ 3 for references)*	**Required**	**Yes**	**No**
Program Responsiveness	**2**	**Required**	**Yes**	**Yes**
Community Engagement	**2**	**Required**	**Yes**	**Yes**
Biosketches (All Personnel listed on Key Personnel form)	**5 (each biosketch)**	**Required** *(upload to Project Personnel section)*	**Yes**	**Yes (PI only)**
Facilities	**1 per institution**	**Required**	**Yes**	**No**
Human Subjects	**No Limit**	**Required**	**Yes**	**No**
Appendix list and uploads	**30**	**Required**	**Yes**	**No**

Detailed Description of Proposal Templates

Research Plan (required)

This section is the **most important** for the peer review. Note carefully the page limits, format requirements, and suggested format. **Limit the text to seven pages, with an additional 3 pages for references.**

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

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

1. The height of the letters must not be smaller than 11 point; Times New Roman or Arial are the suggested fonts.
2. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi).
3. No more than 6 lines of type within a vertical inch;
4. Page margins, in all directions, must be 0.75 inches.

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

We ask that applicants describe the proposed research project in sufficient detail for reviewers to evaluate its scientific merit and collaboration elements, as described below. If you don't use all the pages to describe your research plan, it might be best to review what you have written and explain in more detail anything not fully explained. **However, note that a concise, focused research plan of less than the maximum number of pages is preferable to one less concise and made longer by overly elaborate or unimportant details.**

Supporting materials (such as questionnaires, consent forms, interview questions, letters of collaboration) that are directly relevant to the proposal may be included in the Appendix. **The research plan must be self-contained and understandable without having to refer extensively to supporting materials.**

Suggested outline:

Statement of Goals, Research Questions, and Specific Aims: In a short paragraph, describe goals for the research project. Follow with the Specific Aims—the specific tasks that will be undertaken to address the research question(s). The relationship of the project to the specific Policy Initiative Topic Area and expectations outlined within the RFQ should be clear.

Background and Significance: Make a case for your project in the context of the current body of relevant knowledge and the potential contribution of the research.

Preliminary Results: Describe the recent work relevant to the proposed project. Emphasize work by the PI and data specific to breast cancer.

Research Methodology: Research Design, Conceptual Framework, and Data Analysis. Describe in detail the exact tasks listed in the Statement of Goals, Research Questions, and Specific Aims. Provide a detailed description of the work you will do during the Award period, exactly how it will be done, and by whom. For instance, if women are to be surveyed, explain how many women will be surveyed; why you chose this number; how the women will be identified and recruited; why you believe you will be able to reach and recruit this many women; what questions you will ask them; whether you will use face-to-face or telephone interviews, or written surveys and why you will use the method chosen; and, how the data will be collected and analyzed. Be as detailed as possible. Provide this information for each specific task cited in the first section. Discuss potential pitfalls and how you will overcome them should they arise, or alternative methods that you will use if the intended methods are not fruitful. Provide a realistic timeline. Be sure to include a hypothesis and conceptual framework.

Program Responsiveness (required)

This item is evaluated in the peer review and programmatic review. **Limit the text to two pages**. The PRAG (who conducts the programmatic review) will NOT see your Research Plan. The information on this template allows the PRAG to rate the application for adherence to the objectives of the policy research area as outlined in the specific RFQ.

Policy Initiative Focus (Responsiveness): Provide a clear, brief summary for the PRAG (1 or 2 paragraphs) of how your proposed research addresses the specific policy topic area.

Dissemination and Translation Potential: Describe the potential for how the research findings will be translated into policy and/or other practice.

Community Engagement (required)

This form is reviewed in the peer review and the programmatic review. Applicants should remember that a fully collaborative and power-sharing partnership is a key aspect of this application. **Limit the text to two pages.**

Avoid general references to the requirements of the RFQ. Highlight the strengths/nature of the proposed community partnerships as reflected in the leadership and involvement in all areas. Describe how the team has engaged with the larger community to get their input in the application development process.

CBO applicants should submit a statement from their governing body (Board of Directors for a nonprofit organization or the individuals responsible for organizing an informal organization) that approves the application. Non-CBO applicants should submit verification of community partner collaborative agreements: a statement that the community partner governing body has reviewed and approved these agreements.

The collaborative agreement should include the following elements:

- **Ownership of Data**: Describe what decision you made about who will own the data and intellectual property rights and why you came to that decision (i.e. what factors you considered, what was important to you in making this decision). If you decide that the data will be owned by only one of the collaborators, please consider that the need to continue to work together will likely extend well beyond the grant period. Will the partner who owns the

data be willing to volunteer his/her time well after the grant period to provide access to the data for the other partner? Be sure to discuss ownership of identified and de-identified data, including arrangements both partners have agreed to ensure access to that data by the other partner (including beyond the study period).

- **Handling Disagreements:** Describe what decision you made about the procedures you will go through to handle disagreements during the course of the study and afterwards. Past teams have had to resolve issues around data ownership, conduct of the research, dissemination of data and publications, administrative and budget issues, etc. Describe why you believe your decision on handling disagreements will work for you.

- **Plans for Broader Community Involvement:** Describe how individual community members not on the research team will be involved in the planning, conducting, and dissemination of research.

- **Plan for Dissemination and Public Engagement:** Dissemination of findings to the lay, scientific, and public policy communities is an important part of this research award. Applicants should tailor the draft Dissemination and Public Engagement Plan to the appropriate strategies for the various stakeholder groups, including historically disadvantaged communities, to ensure the most effective, productive, and positive engagement. A separate non-binding, non-guaranteed draft budget (direct costs of $50,000) and budget justification should be prepared for the proposed Dissemination and Public Engagement Plan and included in the "Appendix List and Uploads". A final detailed Plan with specific stakeholders, activities and budget should be submitted for approval with the report at the end of the six-month project.

Biographical Sketch (required)
This item is evaluated in the peer review and the programmatic review. **Use the NIH form (version 2015 or later) for each key person and attach it in the Project Personnel section. Limit the length of each biosketch to *no more than* five (5) pages**.

Facilities (required)
This item is evaluated in the peer review. **Limit the text to one page per institution**. Follow the instructions on the template.

Human Subjects (required)
This item is evaluated in the peer review. **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 Institutional Review Board (IRB) review and approval. Provide sufficient information in response to item #1 below to confirm there has been a determination that the designated exemptions are appropriate. The final approval of exemption from DHHS regulations must be made by an approved IRB. Documentation must be provided before an award is made. Research designated exempt is discussed in the NIH PHS Grant Application #398 http://grants2.nih.gov/grants/peer/tree_glossary.pdf. Most research projects

funded by the CBCRP fall into Exemption category #4. Although a grant application is exempt from these regulations, it must, nevertheless, *indicate the parameters of the subject population* as requested on the form.

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

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

Documentation of Assurances for Human Subjects

In the 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 the CBCRP as soon as possible. Funds will not be released until all assurances are received by the CBCRP. If the research organization(s) where the work with human subjects will take place is different than the applicant organization, then approvals from the boards of each will be required.

Data and Safety Monitoring Boards (DSMB)

Applications that include Phase I-III clinical trials may be required to provide a data and safety monitoring board (DSMB) as described in the NICI policy release, http://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. The CBCRP may require documentation that a DSMB is in place or planned prior to the onset of the trial.

Appendix (Dissemination Plan Budget required)

Follow the instructions and items list on the template including uploading the Dissemination and Public Engagement Plan Budget and Budget Justification. **The appendix may not be more than 30 pages in length.**

Note that the *research plan must be self-contained* and understandable without having to refer to the appendix. Only those materials necessary to facilitate the evaluation of the research plan or renewal report may be included; the appendix is not to be used to circumvent page limitations of the application.

Appendix A: Cost and Expense Guidelines

For all budget categories, clearly label all costs associated with research dissemination activities in the budget justification.

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:
    - http://grants.nih.gov/grants/policy/person_months_faqs.htm
    - NIH Calculation Scheme: http://grants.nih.gov/grants/policy/person_months_conversion_chart.xls

- 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). CBCRP 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

- For non-fellowship awards: Graduate students may be paid as personnel and may also receive tuition remission. Tuition remission, however, will be considered compensation. The total compensation (salary plus fringe benefits plus tuition listed in this category) may not exceed $30,000 per project year. A maximum of $16,000 per year is allowed for the combined costs of tuition/enrollment fee remission, fringe benefits, and health insurance. Stipend may be budgeted as salary (and included in the MTDC cost calculation) if the institution pays these expenses through a personnel line item.

3) Other Project Expenses

- Include expected costs for supplies and other research expenses not itemized elsewhere.
- Pooled expenses may be allowed as a direct cost at the discretion of the Program with certification of the following: 1) the project will be directly supported by the pooled expenses, 2) the pooled expenses have been specifically excluded from the indirect cost rate negotiation, and 3) the pooled expenses have been allocated consistently over time within the organization. Please explain any requested pooled expense requests in the budget justification.
- Advocate (s) Expenses. Include any travel, meeting, and consultation costs/fees associated with advocate engagement.

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

- Each requested equipment item must be >$5,000 and explain in budget justification.

5) Travel

- **Travel - Project Related:** Project-related travel expenses are allowable only for travel directly related to the execution of the proposed research activities. Label such expenses as "Travel – Project Related." These expenses must be fully justified in the budget justification.

6) Service Contracts and Consultants

- Both categories require additional description (Budget Justification).

7) Subcontracts

- In the case of University of California applicants, subcontracts need to be categorized and broken out as one of two types, University of California-to-University of California (UC to UC) sub agreements or transfers; or, Other. A subcontract is not allowed to have another subcontract. Requires additional description (Budget Justification).

8) INDIRECT (F&A) COSTS

- **Indirect cost policy:** Indirect costs are NOT allowed for Conference Awards. For other awards, Non-UC institutions are entitled to full F&A of the Modified Total Direct Cost base (MTDC); UC institutional F&A is capped at 30% MTDC (25% for off-campus projects).
- **Modified Total Direct Costs (MTDC)** include salaries and wages, fringe benefits, materials and supplies, services, travel, and up to the first $25,000 of each subgrant or subcontract (regardless of the period covered by the subgrant or subcontract) to an outside institution. MTDC does not include (indirect costs are not allowed on): capital expenditures, charges for patient care, scholarships and fellowships (including postdoctoral stipends), tuition remission and graduate student stipends, rental costs of space, equipment purchases more than $5,000 per item, the portion of each sub grant and subcontract in excess of the first $25,000, and the total cost of any subcontract from one UC to another UC campus. On a non-fellowship award, you may apply indirect costs to graduate student salary (under salary only, not as stipend) but not to tuition & fees.
- For all eligible projects that allow grantees to recover the full amount of their federally negotiated indirect cost rate agreement, grantees must also accept the full federally recognized F&A rate for all award subcontractors (except for subcontracts to another UC institution, where F&A is not allowed). If a grantee or subcontractor does not have a federally negotiated F&A rate at the time of the proposal submission, the grantee and/or subcontractor may estimate what the federally negotiated rate will be at the time of award and include this rate in the proposed budget or may request a "De Minimis" F&A rate of 25% MTDC. A higher indirect rate that has been accepted for state or local government contract or other California grantmaker contract may be approved at the discretion of the Program Director and the Research Grants Program Office Executive Director.

- **INDIRECT COSTS ON SUBCONTRACTS**
  - The award recipient institution will pay indirect costs to the subcontractor.
  - For non-UC subcontracted partners, CBCRP will allow full F&A of the Modified Total Direct Cost (MTDC), as defined above.
  - F&A costs are not allowed for one UC institution's management of a subcontract to another UC institution.
  - The amount of the subcontracted partner's F&A costs can be added to the direct costs cap of any award type. Thus, the direct costs portion of the grant to the recipient institution may exceed the award type cap by the amount of the F&A costs to the subcontracted partner's institution.

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 by Principal Investigators who are resident 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. **Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. For Cycle 29 applicants are limited to a maximum of two (2) grants either as PI or co-PI, and these must be in different award types. The Policy Initiative grants are not included in this limit. A PI may have more than one Policy Initiative grant in a year.
4. **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 Grant Reports

PIs with current RGPO grant support will not 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 an 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.

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.

Award Decisions

Applicants will be notified of their funding status by December 1, 2022. The written application critique from the review committee, the merit score average, component scores, 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

An appeal regarding the funding decision of a grant application may be made only on the basis of an alleged error in, or deviation from, a stated procedure (e.g., undeclared reviewer conflict of interest or mishandling of an application). The **period open for the appeal process is within 30 days of receipt of the application evaluation** from the Program office. Before submitting appeals, applicants are encouraged to talk about their concerns informally with the appropriate program officer or the CBCRP program director.

Final decisions on application funding appeals will be made by the Vice President for Research & Innovation, University of California, Office of the President. Applicants who disagree with the scientific review evaluation are invited to submit revised applications in a subsequent grant cycle with a detailed response to the review.

The full appeals policy can be found in the online the University of California, Office of the President, "RGPO Grant Administration Manual – Section 5: Dispute Resolution":

https://www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf

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: http://www.ucop.edu/research-grants-program/_files/documents/srp_forms/srp_gam.pdf

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:
Sharima Rasanayagam, PhD
Environmental Health & Health Policy Program Officer, CBCRP
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(510) 987-9216

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