Request for Proposals (RFP)

Investigating Industry Influence Over Scientific Information on Breast Cancer and the Environment: Exploring the UCSF Industry Documents Library

California Breast Cancer Research Program
Preventing Breast Cancer: Community, Population, and Environmental Approaches

Deadline to apply:
March 24, 2021

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About the California Breast Cancer Research Program and the Preventing Breast Cancer Initiative

The **California Breast Cancer Research Program (CBCRP)** was established pursuant to passage by the California Legislature of the 1993 Breast Cancer Act (i.e., *AB 2055 (B. Friedman) [Chapter 661, Statutes of 1993]* and *AB 478 (B. Friedman) [AB 478, Statutes of 1993]*). The program is responsible for administering funding for breast cancer research in the State of 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, 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 $280 million in 1,042 grants to 143 institutions across the state. With continued investment, CBCRP will work to find better ways to prevent, treat and cure breast cancer.

PBC Priority Areas

CBCRP's Program Initiatives integrate expertise and experience from a range of stakeholders to identify compelling research questions and fund research projects that help find solutions to reduce suffering from breast cancer and move science closer to eliminating the disease. The Program Initiatives engage scientists, advocates, people impacted by breast cancer, and the broad community in a dialogue to frame research priorities and fund meaningful research.

In 2004, CBCRP launched its Special Research Initiatives (SRI), devoting 30% of research funds to research to environmental causes of breast cancer and the unequal burden of the disease. Under this initiative, CBCRP funded 26 awards totaling over $20.5 million. In 2010, CBCRP launched its second round of Program Initiatives, the California Breast Cancer Prevention Initiatives (CBCPI), adding population-level prevention interventions as a target area and devoting 50% of its funds to these priority areas. To date, CBCRP has funded 22 awards under CBCPI, totaling over $19 million.

In 2015, CBCRP's Council decided to build on the existing Program Initiatives by devoting 50% of CBCRP research funds between 2017 and 2021 to a third round of Program Initiatives. This new effort is titled Preventing Breast Cancer (PBC): Community, Population, and Environmental Approaches. Approximately $20 million is being dedicated to directed, coordinated, and collaborative research to pursue the most compelling and promising approaches to:

- Identify and eliminate environmental contributors to breast cancer.

- Identify and eliminate fundamental causes of health disparities with a focus on breast cancer in California.
- Develop and test population-level prevention interventions that incorporate approaches to address the needs of the underserved and/or populations experiencing disparities in the burden of breast cancer.

In June 2020, CBCRP's Council approved the first four concept proposals to stimulate compelling and innovative research in all three focus areas of PBC. A series of funding opportunities is being released reflecting these concepts, and CBCRP will be considering additional concept proposals in the future.

Investigating Industry Influence Over Scientific Information on Breast Cancer and the Environment: Exploring the UCSF Industry Documents Library

Available Funding

This initiative aims to examine past efforts by the tobacco, chemical, drug, food, and fossil fuel industries to suppress public awareness of the link between breast cancer and environmental exposures by conducting an exploratory study to investigate if there are documents in the UCSF online Industry Documents Library that describe (1) research on links between breast cancer and environmental exposures that was never published or publicly released and/or (2) actions to influence public opinion across a variety of communities in California and beyond related to breast cancer and environmental exposures.

CBCRP intends to fund one project, with a maximum direct cost budget of $150,000 and a maximum duration of 1 year.

Completed responses to this RFP are due by Wednesday, March 24, 2021, 12 pm PST. The project start date is August 1, 2021.

For more information and technical assistance, please contact:
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Background/Justification

The University of California San Francisco (UCSF) Industry Documents Library is a digital archive of documents from the tobacco, drug, chemical, food, and fossil fuel industries that exists "to preserve open access to this information and to support research on the commercial determinants of public health." The Industry Documents Library was created in 2002, when internal documents from the tobacco industry were obtained and curated by the library at the University of California San Francisco (UCSF). The UCSF public online Industry Documents Library (https://www.industrydocuments.ucsf.edu/) now includes over 15 million emails, memos, papers, and other documents created by companies about their advertising, manufacturing, marketing, scientific research and political activities. The tobacco industry archive in particular is a rich trove of data for research into how an industry manipulated science and public opinion to cast doubt on links between their product and cancer in humans. Over 1,000 publications, including over 800 peer-reviewed papers, have relied on the Industry Documents Library. The public exposure of unethical and immoral industry tactics may have played a part in the shift in public opinion and subsequent successful laws and regulations that collectively reduced public exposure to cigarette smoke.

More recently, UCSF has collected hundreds of thousands of internal documents from other industries. These have come from plaintiffs' attorneys, journalists, and through digitization partnerships with other libraries and archives. These documents are being scanned, catalogued, and posted on the UCSF site on a rolling basis. Now the UCSF Industry Documents Library contains

not only tobacco industry documents, but also documents from the food industry, pharmaceutical, petroleum, and chemical industries. The UCSF Industry Documents Library is unique in the world, and it is freely searchable by researchers worldwide.

Breast cancer has been linked to second-hand smoke exposure, especially in adolescence. Evidence has also shown links between breast cancer and exposures to products of petroleum combustion, chemical exposures, and certain drugs. However, no research has yet been funded or conducted into whether there are documents in the Industry Documents Library that could shed light on internal strategies of these companies as they faced the evidence that their products are linked to breast cancer risk.

This project would involve exploratory research into the UCSF online Industry Documents Library to investigate documents that include mentions of breast cancer. The research would investigate two questions: (1) Is there research in the library into links between breast cancer and environmental exposures (including chemicals, smoking and diet) that was never published or publicly released? (2) Are there documents describing actions to influence public opinion related to breast cancer and environmental exposure?

Extensive research has already drawn upon the UCSF Industry Documents Library, but none of the over 800 journal articles published to date relate directly to breast cancer. A recent search of the bibliography of publications that have used the Industry Documents Library for the keyword "breast" returned a single newspaper article, and no scientific or other publications.[1]

Multiple publications based on the Industry Documents Library investigate ways that the tobacco, sugar, or chemical industry manipulated scientific findings or suppressed scientific research into the harmful effects of their products (Goldberg, 2019; Krimsky, 2018; Kearns, 2016; O'Connor, 2017). Other research focuses on how the industries targeted advertising and communications at specific populations, including women, people from lower socioeconomic classes, video game enthusiasts, and Native Americans (Barbeau, 2004; Lempert, 2019; McDaniel, 2019). Some investigations have focused on ways that the industries influenced legislators and regulators (McDaniel, 2005; Hessari, 2019). One study focused on the p53 tumor suppressor gene–a gene relevant to breast cancer prognosis–showing that the tobacco industry attempted to suppress research showing that their products affected the p53 gene (Bitton, 2005).

In one example of the findings from the tobacco archives, researchers traced the beginning of the epidemic of lung cancer in women to a 1929 publicity stunt of a "parade of torches" supposedly representing free women who refused to be constrained from smoking in public (Grannis, 2017). The researchers showed that smoking rates among women began a steep rise after this date. They also traced a second phase of marketing of cigarettes to women and girls in the 1970s as Philip Morris collaborated with tennis star Billie Jean King to market a new "slim" cigarette under the slogan "You've come a long way baby." Publication and dissemination of documents research revealing the industry strategy of targeting of tobacco advertising to women may have helped to counteract industry advertising campaigns and contributed to reductions in smoking among women. The tobacco archives likely also contain documents that provide significant insight on the industry's

[1] https://www.industrydocuments.ucsf.edu/biblio/#q=breast (accessed 11/3/20)

targeting of people of color. One focus of this project should be shining more light on advertising and marketing practices specifically targeting traditionally marginalized groups by these industries.

It is also important to note that the tobacco archives contain information relevant to environmental exposures beyond tobacco. For example, several papers have found internal tobacco industry correspondence with the alcohol industry, thereby getting a glimpse into ways that the two industries worked together to promote both smoking and drinking (Jiang, 2011). Another paper reported on correspondence between the pesticide industry and tobacco industry, detailing collaborative efforts to block government regulations on pesticides that were used on tobacco (McDaniel, 2005).

It is impossible to know whether or not there is important information related to breast cancer in the documents library unless a researcher takes a preliminary look into the available materials. Therefore, there is a need for an exploratory study to investigate material related to breast cancer in the Industry Documents Library.

Research Questions

This project would focus on two research questions involving the UCSF Industry Documents Library:

1) Is there research in the archives into links between breast cancer and environmental exposures (including chemicals, smoking and diet) that was not previously published or publicly released?

Previous research in the Industry Documents Library has revealed numerous internal never-published research studies, including unethical research studies on human subjects (McDaniel, 2006). Research with findings adverse to the economic interests of the company was often not published. There may be reports of research studies demonstrating mammary tumors in rodents, or breast cancer biomarkers in humans that are not available in the peer reviewed literature. These studies may be of interest in supporting evidence of associations between certain environmental exposures and breast cancer. At a minimum, such research should be brought to light for public scrutiny.

2) Are there documents in the archives describing actions to influence public opinion related to breast cancer and environmental exposure?

The Industry Documents Library covers multiple decades, during which evidence of associations between multiple environmental exposures and breast cancer gradually came to light. For example, associations between exposure to second-hand smoke during adolescence and later development of breast cancer was first published in the peer reviewed literature in the late-1990s. Links between chemical exposures and breast cancer are generally more recent. It is likely that the internal documents in the industry library contain discussions of the emerging research, including reactions to the information, and discussions or memos about how to respond publicly to the findings.

In addition to these two questions, this project should also include a focus on health equity and health disparities, including examining industry advertising and marketing practices specifically targeting traditionally marginalized groups.

Approaches and Methods

This project would primarily involve searching and analyzing documents in the UCSF Industry Documents Library (https://www.industrydocuments.ucsf.edu/). If there are any additional archives

or internal industry documents that could be identified and accessed by the research team, these could also be included to broaden the base of documents used for the research.

The research team should include at least one member with expertise in established document archive research methods. The researchers performing this project would be expected to adhere to established qualitative research methodologies for documents research (Anderson, 2011). The methods employed in documents research, which are also used by historians and social scientists who study archival data, involve iteratively reviewing data to construct a coherent account, supported by the available evidence and contextualized within the limitations of the documents archives. The researchers would be expected to document their search strategy and to document the steps of their investigation with research memos, according to standard practice in the field.

Generally, the documents research approach starts with identifying search strings/keywords to search. For example, a recent search in the tobacco archives for the keyword "breast cancer" returned 48,509 documents. Over 1,700 of these documents are tagged in the archive as labeled formerly confidential or privileged. A recent search of the chemical and food industry archives for "breast cancer" returned 427 documents. After identifying potentially relevant documents, there is a lengthy process of narrowing to eliminate duplicates, irrelevant documents, and those that are of minimal interest (such as copies of publicly available publications). A review of potentially relevant document then allows researchers to use snowball search strategies to expand the search to related documents of potential interest. Each document in the archive is referenced with a unique Bates identifier and has its own URL, allowing any reader to directly access and read the specific document that is discussed. For this reason, the research methods are reproducible and all research material is publicly accessible.

As an example of the type of information that can be found, one of the confidential memos from the tobacco archives, identified using the search strategy described above, was a document from RJ Reynolds from October 28, 1982 from F.G. Colby, Associate Director of Scientific Issues, to Samuel B. Witt III, saying "Please advise regarding the distribution of the attached memorandum on breast cancer". with a handwritten response on the document saying "GRD tells me that his deal with you is to hold <u>everything</u> for a period of time and then review all of it at once for relevance, usefulness, etc. Thus, no distribution yet" (emphasis in the original).[2] With additional work using snowball search strategies (such as searching for the names of these two people and for other documents during this specific time period), it would likely be possible to find the "memorandum on breast cancer" that was originally attached to the memo, and other related correspondence between these two men.

Qualitative documents research has some limitations. The sheer quantity of documents (over 93 million pages) forces researchers to make decisions about which search terms retrieve the most relevant material, and requiring a time-consuming process to narrow down the search. The Industry Documents Library is frequently updated as documents become available through litigation and are scanned into the library, so any search will become outdated over time. Documents in the library are of unknown representativeness, due to discarding of documents or purposeful document

[2] Colby Frank G. RJ Reynolds Company Limited. [Memo from FG Colby to Samuel B Witt III regarding breast cancer]. 1982, October 28. RJ Reynolds Records; Master Settlement Agreement; Congressman Bliley Philip Morris Collection. Bates number 505741595-505741597. https://www.industrydocuments.ucsf.edu/docs/njbc0024.

destruction on the part of the companies producing them. Therefore, documents necessary to establish the context of a topic may be missing, increasing the risk that a topic may be only partially understood or misinterpreted; internal documents also may contain acronyms or code words, making their interpretation difficult. For this reason, multiple search queries must be performed and analyses must be conducted in an iterative fashion, so as to gain as much context as possible within this limitation.

Given that tens of thousands of documents in the tobacco archives (including over 1,700 labeled confidential or privileged), and hundreds in the chemical and food industry archives contain the term "breast cancer", there are likely interesting documents to review, and potentially valuable findings related to breast cancer.

Dissemination Plan

At the conclusion of this project, the applicant will be invited to submit a proposal for a dissemination and public engagement plan to communicate the project's results to the general public and key stakeholders, including policymakers, breast cancer advocacy organizations, and others. The details of the dissemination plan will depend on the findings of the research phase. Dissemination activities could include a report targeted at a lay audience, development of informational materials, presentations, hearings, web and social media outreach, and outreach directly to the press through a press advisory or press release. In addition to the dissemination plan, researchers should aim to publish at least one peer-reviewed paper in the scientific literature. CBCRP anticipates making up to $25,000 in direct costs available for dissemination if the dissemination plan proposal is approved.

The dissemination plan should reflect an effort to disseminate the information to an audience that reflects the great diversity of California (geography, race, ethnicity, income level, urban/rural). The dissemination plan should include modes and channels for communication that target those populations and communities most impacted by breast cancer, particularly minority and low-income populations. The dissemination plan should include bilingual/multilingual translation of materials. The project team's community advocate(s) should play a substantive role in formulating and helping carry out the proposed dissemination plan. The UCSF Industry Documents Library should also be involved in the dissemination phase, and the project team should consult with the Library in formulating their dissemination proposal.

Advocacy Involvement

Advocacy involvement is a requirement for the research funded under this initiative. Applications should include a community advocate affiliated with an advocacy and/or community organization that is familiar with industry tactics, industry manipulation of science, and environmental contributors to breast cancer. The applicant may also involve additional breast cancer advocates or other community advocates. The community advocate(s) 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 advocates should be compensated as experts.

Applications will be evaluated on the extent to which advocates are substantively involved in the project including identification of an appropriate advocate(s) for the proposed research; a detailed description of how the advocate(s) will be involved in the project; submission of a Letter of

Commitment co-signed by the research advocate(s) and the PI; and a budget line item and justification covering the advocate(s) time, effort, and expenses on the project (e.g. at least quarterly, in-person meetings with the advocate and the investigative team). If needed, CBCRP staff can assist investigators with meeting the advocacy involvement requirement as they prepare their applications.

Technical Assistance from UCSF Library Staff

UCSF Library staff are available to answer questions about using the Industry Documents Library for prospective applicants and provide support to the project team. Examples include providing training and research assistance to the project team, performing processing work to edit and enhance metadata as needed, and overseeing review of any privileged and confidential documents in order to open them for public research. Some forms of assistance may include costs that would need to be included in the proposed budget. Applicants are encouraged to contact the UCSF Library for technical questions about using the Industry Documents Library and to consult with library staff on potential forms of technical assistance and costs to include in the proposed budget. For questions specific to the UCSF Industry Documents Library, please contact, Kate Tasker, UCSF Industry Documents Library Managing Archivist, at kate.tasker@ucsf.edu.

Budget

CBCRP intends to fund one project, with a maximum direct cost budget of $150,000 and duration of 1 year.

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 (26% for off-campus projects).

Timeline and Milestones

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

- Scoping and initial assessment (months 1-2)
- In depth review of documents (months 4-6)
- Identification and outline of findings (month 7)
- Writing and submission of manuscript, and response to peer review (months 8-10)
- Preparation of updated dissemination plan; submit draft report to CBCRP (months 11-12)

In order to be eligible to apply for dissemination funds, the draft report and dissemination plan proposal must be submitted to CBCRP by month 12.

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How We Evaluate RFPs

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.** 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? How well developed is the dissemination plan?
- **Feasibility.** The extent to which the aims are realistic for the scope and duration of the project; adequacy of investigator's expertise and experience, and 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?

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** (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 PBC 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 research initiative understandable?
- **Advocacy involvement.** Are the named advocate(s) and advocacy organization appropriate for the proposed research project? Were they engaged in the application development process? Are meetings and other communications sufficient for substantive engagement? Are the roles and responsibilities of the PI and the advocate(s) clearly outlined and is the agreement for advocate compensation and reimbursement clear? [The Advisory Council will examine the PI's statements on the Lay and Scientific Abstracts and Advocacy Involvement forms.]

- **Dissemination and translation potential.** The degree to which the applicant's statements on the Program Responsiveness form provides a convincing argument that the proposed research has the potential to inform public knowledge of efforts of industries to suppress public awareness of the link between breast cancer and environmental exposures.

Application Instructions

Application materials will be available through RGPO's SmartSimple application and grant management system beginning on February 1, 2021. 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:** Enter a project start date of August 1, 2021.
- **Proposed Project End Date:** Enter a project end date of July 31, 2022 for a 1-year 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 obtain 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 "6.5 Education and Communication" 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.** Leave this table blank since this research project will not involve human subjects.
- **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 1 year, 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.
- **Travel**: A minimum of $400 must be budgeted in year 1 for travel to the **CBCRP symposium**. **Scientific meeting travel** is capped at $2,000/yr.
- **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 26% MTDC for off-campus investigators (not retroactive to prior grants).

**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 D of the SmartSimple Instructions.

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**
Advocacy Involvement	**1**	**Required**	**Yes**	**Yes**
Letter of Commitment	**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**
Appendix list and uploads	**30**	**Optional**	**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:

Introduction and Hypotheses: 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 specific PBC Project Type and expectations outlined within the RFP should be clear.

Specific Aims: 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.

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 Design and Methods: Provide an overview of the experimental design, the methods to be used, and how data are to be collected and analyzed. Describe the exact tasks related to the Specific Aims above. Provide a description of the work to be conducted during the award period, exactly how it will be done, and by whom. Include a letter of commitment if the applicant PI will be using a data set that they do not control/own. 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. Identify the portions of the project to be performed by any collaborators. 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.

Program Responsiveness (required)

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

PBC Focus (Responsiveness): Provide a clear, brief summary for the CBCRP Council (1 or 2 paragraphs) of how your proposed research addresses the specific RFP topic area, by increasing or building on specific scientific knowledge; by pointing to additional solutions to identify and eliminate environmental causes, and or disparities in, breast cancer; and/or, by helping identify or translate into potential prevention strategies.

Dissemination and Translation Potential: Describe how research findings will be shared with various stakeholder audiences (i.e., policymakers, community members, breast cancer advocates, other researchers/agencies, health care providers, funders etc.). Describe the potential for how the research findings will be translated into policy and/or other practice.

Advocacy Involvement (required)

Follow the instructions on the form, and be sure to address the requested three items (Advocacy Organization/Advocate(s) Selection and Engagement to Date, Advocate(s) Role in Proposed Research and Meeting and Payment Plans). **Limit the text to one page**.

Discuss what involvement, if any, advocates had in the development of this proposal and will have in the project, if funded. Explain how this proposal shows awareness and inclusion of breast cancer advocacy concerns involved in the proposed research.

Letter of Commitment (required)

This item is evaluated in the peer review and in the programmatic review. Please use the template as a basis for commitment letters from the advocate, scientific and/or subcontracting individuals/institutions. **Limit the text to two pages**.

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.

Appendix (optional)

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. 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.

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. **Multiple applications and grant limits for PIs.** A PI may submit more than one application, but each must have unique specific aims. For Cycle 27 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 Program Initiative grants are not included in this limit. A PI may have more than one Program 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 July 1, 2021. 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:
Nicholas J. Anthis, DPhil
Environmental Health & Health Policy Program Officer, CBCRP
nicholas.anthis@ucop.edu
(510) 987-0358

For questions specific to the UCSF Industry Documents Library (and not about this funding opportunity), please contact:
Kate Tasker, MLIS, CA
Industry Documents Library Managing Archivist, UCSF
kate.tasker@ucsf.edu

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