BCRF BREAST CANCER RESEARCH FOUNDATION

Precision Prevention Initiative

2023 Request for Applications

Key dates updated 12/13/22

RFA Contents

Summary and goals of the program

Breast cancer mortality is at its lowest level in 30 years. This success has largely been fueled by advances in early detection and treatment. In contrast, our approach to cancer prevention has not progressed at nearly the same rate.

At BCRF, we want to create a future in which women can benefit from the wide range of innovative strategies that can propel prevention as well as treatment, with advances in individual risk assessment, surveillance, and risk reduction using the tools of precision medicine, artificial intelligence, epidemiology, and immunology to reduce the incidence of breast cancer with all possible speed.

The field of cancer prevention will evolve quickly as emerging technologies continue to be incorporated into all areas of precision medicine research. BCRF has long been at the vanguard of breast cancer research, playing a role in every major advance in clinical care. We now aim to take the lead in precision prevention.

The Precision Prevention Initiative (PPI) was conceived out of this vision. The overarching goal of this initiative is to fuel innovation and accelerate breast cancer prevention research by challenging the research community to think boldly; to explore multidisciplinary approaches to get the answers in less time, utilize new technologies or identify new ways to examine available data, and to build or enhance infrastructure, resources, and tools that will facilitate innovation in prevention research for years to come.

With this RFA, we are soliciting applications in three primary areas for impact: 1) Risk Assessment and Stratification; 2) Biomarkers; 3) Interventions

Key Dates *(updated 12/13/22)*

Application submission period opens:	November 16, 2022
Letter of Intent (LOI) Due:	January 31, 2023
Invitation to submit full proposals:	Notifications by March 20, 2023
Full Proposal due:	May 12, 2023 (invited LOIs only)
Award notification date:	August 7, 2023
Award Start Date:	October 1, 2023

Program Guidelines

Applications for the 2023 funding period should address the challenges and gaps in primary breast cancer prevention with a focus in one or more of the following categories:

- Risk Assessment/Stratification
- Biomarkers
- Interventions

Innovation and impact are key components of this RFA. Applicants are encouraged to engage collaborators from diverse disciplines, and utilize, where possible areas of expertise and/or methodologies not normally associated with prevention or cancer research. Projects range from single investigator innovation awards to collaborative pre-clinical, translational, clinical and intervention studies. In all cases, projects that impact underserved, minority or high-risk populations are encouraged. Grant categories are outlined below.

Innovation Grants. Innovation grants are intended to provide a single investigator the opportunity to expand into a new area of discovery in primary breast cancer prevention. Well-designed and conceived high risk-high reward concepts that challenge current paradigms are encouraged. Projects must have a high likelihood of translation if successful and address an unmet need in breast cancer prevention research. These awards provide up to $250,000 per year for two years ($500,000 total), including maximum IDC not exceeding 20 percent of total direct costs.

Pre-Clinical Grants. These awards are for translational research that has a direct application or with a clear path to significantly impact breast cancer prevention. The intention is to enable the applicant to integrate advanced technologies or experimental systems that may not be feasible at the lower Innovation budget. Projects may be supplemental to current funding but should expand the applicant's research question to be specific to this RFA. Investigators working outside the prevention field and multidisciplinary teams are encouraged to apply. These awards provide up to $500,000 per year for three years ($1,500,000 total), including maximum IDC not exceeding 20 percent of total direct costs.

Clinical Trial or Intervention Study Grants. These awards are for a single investigator or investigator team to support a clinical trial or intervention focused on the prevention of breast cancer. The study must include one or more human subjects prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. These awards provide up to $750,000 per year for three years ($2,250,000), including maximum IDC not exceeding 20 percent of total direct costs.

Eligibility Requirements

Principal investigators on the research team must hold a primary academic faculty position of assistant professor or higher.

Institution Requirements

Applicant institutions must be non-profit research institutions with the appropriate resources and support required to execute the proposed research. All subcontracted institutions must meet the same criteria and agree to the award conditions and policies and procedures of BCRF as outlined in the award contract. BCRF will not accept applications from, and/or make grant awards to, certain foreign sponsoring institutions or individuals if BCRF is prohibited from doing so under U.S. sanctions laws, or if BCRF would be required to obtain a license from the Office of Foreign Assets Control or the Department of Commerce to make such grants.

Institutional Assurances

Clinical Trials/Human Subjects Research: As a condition of support, institutions and investigators must provide documentation of both the initial IRB/Ethical Committee approval and annual renewals of that approval, as applicable. IRBs must include date of approval and expiration, project title, primary investigator name and list BCRF as a funder. No award can be initiated without documented IRB approval and patient informed consent documentation (ICD), as applicable.

Research involving animals: The USDA Animal Welfare Act and the NIH Public Health Service Policy on the Humane Care and Use of Animals require that institutions conducting research with animals establish an Institutional Animal Care and Use Committee (IACUC). Institutions and Investigators must provide documentation of IACUC approval and annual reviews of animal use protocols. Approval letters

must include the date of approval and expiration, project title, primary investigator name and name BCRF as a funder. No award can be initiated without documented IACUC approval, as applicable.

Publication: All abstracts, manuscripts, and presentations of a study conducted under an approved award must be shared with BCRF. BCRF does not have veto privilege over the reporting of study results.

Data Sharing: Published data generated by funding through the Precision Prevention Initiative is expected to be made available to the research community to the fullest extent possible within local regulations and policies. Institutions required to comply with the 2023 NIH Data Management and Sharing (DMS) Policy are required to provide a detailed data sharing plan or explanation for why data cannot be shared. Please refer to https://grants.nih.gov/policy/sharing.htm for guidelines.

BCRF Terms and Conditions: Terms and conditions can be downloaded from ProposalCentral and should by reviewed by institution officials before submitting the LOI. These are not negotiable. The Intellectual Property (IP) policy will be shared at the full application stage.

For more information, please refer to **Appendix A: Frequently Asked Questions (FAQ)** or contact BCRF directly.

PPI Contacts:
Marisa Rubio, PhD, Associate Director, Research Program: mrubio@bcrf.org;

Ashley Marion, MPH, Senior Manager Grants Administration: amarion@bcrf.org

To Apply

All letters of intent (LOI) and applications must be submitted through the ProposalCentral website at https://proposalcentral.com. Please make sure you are logging in through the "Applicant or Awardee" portal.

- **If you already have an account**, use your username and password to log in. If you don't remember your log in credentials, then click "forgot your password."
- **If you do not have an account**, you will need to create one by clicking on "need an account."

Once logged in, select the "Grant Opportunities" tab on the left. Filter the list of applications by clicking "Filter List by Grant Maker" at the top and selecting "Breast Cancer Research Foundation" in the drop-down menu. Find the **"**Precision Prevention Initiative" and click the "Apply Now" button.

If you have any difficulties registering, logging in, or creating your application, contact ProposalCentral Customer Support at: 800-875-2562 (Toll-free U.S. and Canada), +1-703-964-5840 (Direct Dial International), or by email at pcsupport@altum.com. See the ProposalCentral **FAQ** section under HELP tab for additional information.

Application Details

In order to submit a complete application, applicants need to enter information directly into the online application platform as well as upload a number of documents. The following instructions provide details about information that needs to be entered and the materials that need to be uploaded. The section numbering corresponds with the section number of the Application Instructions and the online ProposalCentral application.

Below is a breakdown of the application requirements and instructions on where to include them in your application in ProposalCentral:

Application Requirements	ProposalCentral Section
Project Title, Project Period, Award Amount & Type of Award	1.Title Page
Lay & Scientific Abstracts	8. Key words & Abstracts
LOI Narrative	Template is under section 2. Download Templates & Instructions Upload completed document to Section 9. LOI Narrative

Application Templates and Uploads	ProposalCentral Section
Biosketches for Key Personnel	4. Principal Investigator 6. Co-investigators/Other Personnel
LOI Narrative Template	2. Download Templates & Instructions

Additional Resources	ProposalCentral Section
Award Conditions	Support Links, Program Guidelines
Frequently Asked Questions (FAQ)	Support Links, Application FAQs

Proposal Components

Letter of Intent (LOI)

The letter of intent includes the following components

- Project title
- Requested award amount
- Lay abstract. No more than 250 words, written for a lay audience. The lay abstract should succinctly outline the reason for the study, innovations, and how it will impact breast cancer prevention.
- Scientific abstract: No more than 350 words, written for peer review describing the research question and rational, experimental design, expected outcomes, impact and significance
- Planned research: up to 3 pages (No page limitation for references)
    - Background. Describe the need being addressed and the state of current research in the area, including preliminary data supporting the rational for the project.
    - Research plan. The research plan should describe the scientific approach in enough detail to establish feasibility.
    - Statistical plan. Both preclinical and clinical studies should include a statistical plan that demonstrates the planned research is designed to produce statistically meaningful results.
    - Areas of expertise and resources required to conduct the proposed research. Multidisciplinary research is strongly encouraged for larger studies and areas of expertise and institutional resources should be detailed in this section, including names of collaborators and resources they bring to the effort.
    - Expected outcomes (i.e., measures of success), impact and significance: Expected outcomes should align with the study aims and resources dedicated to the effort and

include quantifiable measures of success, timeline to clinical impact and/or significance to the field.
    - Innovation. Describe how the approach and/or question improves existing or creates new methods or standards to significantly impact prevention of breast cancer.
- Biosketches for key personnel: Key personnel are those with necessary expertise to complete the study. Biosketches must be in the NIH format and limited to 5-pages. Curricula vitae and biographical narratives are not acceptable substitutes.

General Guidelines

- The narrative must describe how the work will be applicable to potential breast cancer prevention strategies.
- Laboratory-based studies should have a clear translational path.
- Intervention studies should include a path to implementation.
- All studies should include a data sharing plan that outlines how the data can be accessed by the research community and where it will be housed. See note about regarding the 2023 NIH Data Management and Sharing (DMS) Policy.
- Projects may be supplemental to current funding but must expand the grant holder's research question in a new direction relevant to this RFA.

The letters of intent will be reviewed by a panel of expert reviewers. The most meritorious applications from the LOI stage will be invited to submit full proposals.

Full application

Detailed instructions will be provided to those invited to submit a full proposal.

Applicants invited to submit a full proposal should expect to submit the following:

- **Lay abstract and scientific abstracts:**
- **Research Proposal**: The research proposal should be no more than 10 pages excluding references and must include the following sections:
    - **Background/Rationale**: This section should state the need and scientific rationale supporting the proposed research and study design, explain how it is innovative and its impact on breast cancer prevention.
    - **Hypothesis and Specific Aims**
    - **Methods/Research Plan**
    - **Feasibility Plan:** Include details related to available resources and those that will require permission to access.
    - **Study Timeline with milestone tracker** (outline of expected deliverables and outcomes)**:** All studies should be feasible within the study timeline and budget and not assume the opportunity for renewal.
    - **Statistical Plan** including detailed statistical design describing endpoints (including secondary and other descriptive endpoints, clinical or lab correlatives), stratification plans as applicable, sample size with power justifications, analysis (including plan for interim analysis), expected accrual rate (if applicable) and time for accrual (if applicable).
    - **Data Sharing Plan**
    - **Clinical Significance:** Pre-clinical studies should demonstrate a clear path to clinical translation and intervention trials should include a plan for implementation (even if implementation is not intended to be part of the original project)

- **Budget and Justifications:** Budgets should realistically align with work proposed for each year.
- **Study Personnel and Expertise**: Detail study personnel, level of effort and how each will contribute to the study.
- **Biosketches:** For all key personnel.
- **Letters of institution support and collaboration:** Letters of institution support should verify available resources as described in the proposal and indicate they can accept BCRF terms and conditions without modifications. Multi-institution awards require letters of support from each institution. Letters of collaboration should include details of shared resources and/or expertise as described in the proposal and acceptance of BCRF terms and conditions.

About the Breast Cancer Research Foundation

Breast cancer is a complex disease with no simple solution. Research is the key to stopping it in its tracks. Founded in 1993 by Evelyn H. Lauder, BCRF is the largest private funder of breast cancer research in the world. Investing in the best minds in science—from those investigating prevention, diagnosis, treatment, survivorship, and metastasis—and foster cross-disciplinary collaboration, BCRF's approach accelerates the entire field and moves us closer to the answers we urgently need to be the end of breast cancer. This year, BCRF awarded $52.7 million to support the work of 255 scientists at leading medical and academic institutions across 14 countries, making BCRF the largest private funder of breast cancer research worldwide. Visit www.bcrf.org to learn more.

Appendix A: Frequently Asked Questions (FAQ)

What are the key dates for the 2023 application?

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Do I have to already be funded by BCRF to be eligible for this RFA? No. The RFA is open to all applicants who meet the eligibility requirements. Applicants may currently hold BCRF awards.

Who is eligible to apply? Principal investigators must hold a primary academic faculty position of assistant professor or higher.

Do I have to be at a U.S. institution? No. International applications will be accepted. Institutions must be not-for-profit academic sites or universities. BCRF will not accept applications from, and/or make grant awards to, certain foreign sponsoring institutions or individuals if BCRF is prohibited from doing so under U.S. sanctions laws, or if BCRF would be required to obtain a license from the Office of Foreign Assets Control or the Department of Commerce to make such grants.

Will multi-institution applications be accepted? Yes. Applications involving multiple institutions should have applicable MTAs or other agreements in place to avoid delays in execution of work. Though not required at time of application submission, agreements will be required before payment is issued. Each participating institution must be willing to accept BCRF award conditions, policies, and procedures. See BCRF Award Conditions, downloadable from the application.

How will awards be paid? Awards will be paid via wire transfer after the investigators and institution officials have completed a payment request form and accepted BCRF Terms and Conditions. Awards to multi-institution collaborations will be paid to the submitting institution. Split payments to participating institutions is not possible.

What is the selection process of LOI and full proposals? Each LOI and full proposal will be reviewed by at least two qualified reviewers. The Steering Committee will consider the application scoring and peer review discussion and make recommendations for funding. The BCRF Board of Directors with make final decisions based on the Steering Committee recommendations.

What is BCRF's Data Sharing policy? Data generated by funding through the Precision Prevention Initiative is expected to be made available to the research community to the fullest extent possible within local regulations and policies. Institutions required to comply with the 2023 NIH Data Management and Sharing (DMS) Policy are required to provide a detailed data sharing. Please refer to https://grants.nih.gov/policy/sharing.htm for guidelines.

Using ProposalCentral

How do I submit my letter of intent? All letters of intent (LOI) and applications must be submitted through the ProposalCentral (PC) website at https://proposalcentral.com. Please make sure you are logging in through the "Applicant or Awardee" portal.

- **If you already have an account**, use your username and password to log in. If you don't remember your log in credentials, then click "forgot your password."

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The PI gave me access to an application but when I log in, I do not see it. Why?
There could be two reasons for this. 1) You may have multiple accounts in PC and the email the PI entered when adding you as a contact is different from the email you are logging in with. 2) The PI has added you as a contact but did not give you permission to access the applications. To resolve this issue, contact pcsupport@altum.com.

I submitted my LOI, but it is still under "In Progress." Has it been submitted? No. A status of "In Progress" is not equivalent to submitted. You can verify the submission status by looking in the "Status" column. If it states "LOI: Submitted" then it was successfully submitted.
When I press submit, does the LOI get submitted to the foundation or routed to my Grants & Contract office to approve? Clicking the Submit button sends the application directly to the BCRF. If a signature is required, you will not be able to submit until the signature is completed.
Can I save my application and finish it later? Yes. You can select "Save" at the top and bottom of the various sections of the LOI.

Can I print my application? Yes. At the top and bottom there is a "print" button for the various sections of the LOI.

What if I need to change my contact or institution information? To edit your contact information, click on section 4, titled, "Principal Investigator." Then click "Edit Professional Profile." This will direct you to a page to change your contact information, institution and/or connect your ORCID profile.

Can my assistant or grants administrator submit documents on my behalf? For others to edit or submit on your behalf, the person needs to be added as a contact with "Edit" privileges.

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For further questions about the application and award process please contact Marisa Rubio, PhD, Associate Director, Research Program: mrubio@bcrf.org

For further questions on how to apply in ProposalCentral please contact Ashley Marion, MPH, Senior Manager Grants Administration: amarion@bcrf.org