

Program Announcement

Defense Health Program

Department of Defense

Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Innovator Award

Funding Opportunity Number: W81XWH-12-BCRP-INNOV

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), May 3, 2012
- **Invitation to Submit an Application:** June 2012
- **Confidential Letters of Recommendation Submission Deadline:**
5:00 p.m. ET, August 2, 2012
- **Application Submission Deadline:** 11:59 p.m. ET, August 2, 2012
- **Peer Review:** September 2012
- **Programmatic Review, Stage 1:** November 2012
- **Invitation for Oral Presentation:** November 2012
- **Programmatic Review, Stage 2:** January 2013

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications for the Breast Cancer Research Program (BCRP) are being solicited by the Assistant Secretary of Defense for Health Affairs, Defense Health Program. The BCRP was established in fiscal year 1992 (FY92) to support innovative research focused on ending breast cancer. Appropriations for the BCRP from FY92 through FY11 totaled over \$2.6 billion. The FY12 appropriation is \$120 million (M).

The BCRP challenges the scientific community to design research that will address the urgency of the vision to end breast cancer. Specifically, the BCRP seeks to accelerate high-impact research, encourage innovation and stimulate creativity, bring new investigators into the breast cancer field, and facilitate multidisciplinary collaborations.

B. Award Information

The Innovator Award supports *visionary individuals* who have demonstrated creativity, innovative work, and leadership in any field including, but not limited to, breast cancer. The Innovator Award will provide these individuals with the funding and freedom to pursue their most novel, visionary, high-risk ideas that could ultimately lead to ending breast cancer.

Since the intent of the Innovator Award mechanism is to recognize creative and innovative individuals rather than projects, the central feature of the award is the innovative contribution that the Principal Investigator (PI) can make toward ending breast cancer. The PI should have a past record of creativity, promise for continued innovation in future work, and a vision that challenges current dogma and demonstrates an ability to look beyond tradition and convention. The PI is also expected to have demonstrated success at forming and leading effective partnerships and collaborations.

Experience in breast cancer research is not required; however, the application must focus on breast cancer, and the PI must commit at least 50% of his/her full-time professional effort during the award period to breast cancer research.

The Congressionally Directed Medical Research Programs (CDMRP) intends that data and research resources generated by CDMRP-funded research activities be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

C. Eligibility Information

- PIs must be at or above the level of Associate Professor (or equivalent).
- Previous recipients of the BCRP Innovator Award and FY12 BCRP Integration Panel (IP) members are ineligible to apply.
- Cost sharing/matching is not an eligibility requirement.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **5** years.
- The maximum allowable direct costs for the entire period of performance are **\$5M** plus indirect costs.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C., for budget regulations and instructions for the Research & Related Budget. In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel for attendance at two Department of Defense (DoD) BCRP Era of Hope meetings, which are held to disseminate the results of BCRP-sponsored research. Costs associated with travel to these meetings, up to \$1,800, should be included in Years 2 and 5 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.
- Travel for attendance at the annual LINKS (Leading Innovative Networking and Knowledge Sharing) meeting. The meeting will also be attended by recipients of the BCRP Era of Hope Scholar Award, the BCRP IP, and CDMRP staff for the purpose of open communication and mutual benefit. Costs associated with travel to this meeting are limited to \$1,800 per year and are in addition to those allowed for annual/scientific meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs
- Training
- Workshops
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$3,600 per year to attend scientific/technical meetings

The CDMRP expects to allot approximately \$22.5M of the \$120M FY12 BCRP appropriation to fund approximately three Innovator Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a multi-step process requiring both (1) pre-application submission through the CDMRP eReceipt System (<https://cdmrp.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>).

Submission of the same research project to different funding opportunities within the same program and fiscal year is prohibited. The Government will reject duplicative applications.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-12-BCRP-INNOV.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted through the CDMRP eReceipt System (<https://cdmrp.org/>).

No change in PI will be allowed after the pre-application deadline. If any other changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY12 BCRP IP members should not be involved in any pre-application or application. For questions related to IP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

- **Required Files – Tab 4**

Nomination Letter (two-page limit): The nominator should provide a letter on organizational letterhead describing the PI's unique qualifications and accomplishments that demonstrate how the PI is a true visionary in his/her field. The letter should address the nominee's creativity in past work, his/her potential for future creativity and innovation especially in the field of breast cancer research, and his/her strong leadership qualities. Self nominations will be accepted.

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application are limited to:

- PI Biographical Sketch (four-page limit)

List of Individuals Providing Confidential Letters of Recommendation: Enter into the appropriate data fields the names, position titles, email addresses, and phone numbers for three individuals, who will provide letters of recommendation. If the PI is invited to submit an application, each individual will receive an email generated from the CDMRP eReceipt System containing specific instructions on how to upload his/her letter. Letters of recommendation are only required for invited applications and are due by *5:00 p.m. ET on the application deadline*.

- **Submit Pre-Application – Tab 5**

This tab must be completed for the pre-application to be accepted and processed by the CDMRP.

- **Other Documents Tab**

No additional documents are required.

Pre-Application Screening

- **Pre-Application Screening Criteria**

Pre-applications will be reviewed by the BCRP IP, which is composed of scientists, clinicians, and consumer advocates. PIs whose qualifications meet the intent of the award mechanism will be invited to submit applications. Selection will be based on the PI's creativity in past work; the potential for future innovation, especially in the field of breast cancer research; and accomplishments as a leader in his/her field.

- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified of whether or not they are invited to submit an application; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application.

Pre-application notification dates are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

C. Application Submission Content and Form

Applications will not be accepted unless the PI has received a letter of invitation.

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>). For the Innovator Award, additional application components are also required and should be submitted as directed below.

Grants.gov application package components: For the Innovator Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF 424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. Attachments Form

- **Attachment 1: Project Narrative (five-page limit):** Upload as “ProjectNarrative.pdf.”

The Project Narrative should clearly state your *vision for ending breast cancer* and *why you, the PI, should be considered for this unique award*. The following items should be addressed specifically.

- Current Status of Breast Cancer Research: Describe your views of the major problems/barriers in breast cancer that must be solved to accelerate progress to end breast cancer.
 - Vision of the Future: Describe what you foresee as the critical approaches that will most likely produce breakthrough thinking and discoveries to ultimately solve the major problems/barriers in breast cancer that you have defined.
 - Specific Ideas: Summarize some of the key examples of specific innovative ideas that you envision pursuing under the auspices of this award. Explain why/how your ideas may challenge current assumptions and have a significant impact on ending breast cancer. This should not be a summary of research methodology.
 - Qualifications for This Award: Explain how you are qualified to receive this award. Give some examples of breakthrough creative thinking and leadership skills that demonstrate your abilities as an innovator. Describe your success at forming and leading effective partnerships and collaborations. Describe how your achievements reflect your capabilities as an innovator.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any component unless otherwise noted. Include only those components described below; inclusion of items not requested may result in administrative rejection of the application.***
 - References Cited: List the references cited (including URLs if available) in the project narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
 - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate if Government-owned facilities or equipment are proposed for use. Reference should be made to the original or present award under which the facilities or equipment items are now accountable. There is no form for this information.
 - Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then they must be included. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters if applicable), signed by the Department Chair or appropriate organization official, reflecting the laboratory space, equipment, and other resources available for the project. The letter should reflect the availability of laboratory space, equipment, and other resources, and also include the extent to which the PI will be relieved of academic, clinical, or administrative responsibilities and allowed at least 50% protected time for breast cancer research.
 - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
Not required at this time. Leave Attachment 3 space blank.
 - **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.”
Not required at this time. Leave Attachment 4 space blank.
 - **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information.
 - Not required at this time. Leave Attachment 5 space blank.
- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
- PI Biographical Sketch (no-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Key Personnel Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

Additional Application Components: In addition to the completed Grants.gov application package, Innovator Award applications also require the following components:

- 1. Three Confidential Letters of Recommendation (two-pages per letter recommended):** Confidential letters of recommendation must be submitted by the three individuals designated during the pre-application process. All letters must be submitted electronically through the CDMRP eReceipt System by **5:00 p.m. ET on the application deadline**. The PI should monitor whether the letters have been received; however, the PI is not able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI should contact the CDMRP Help Desk at help@cdmrp.org or 1-301-682-5507.

Each letter should describe the PI's unique qualifications and accomplishments. Specifically, each letter should offer the writer's perspective on the PI's:

- Creative and original accomplishments,
- Visionary and leadership qualities,
- Success at forming and leading partnerships and collaborations; and
- Likelihood of innovation and productivity in breast cancer research.

- 2. Oral Presentation:** PIs whose applications are selected for Programmatic Review, Stage 2, will be required to give an oral presentation that will be held in the National Capital Region in January 2013.

Each presentation will include a 10-minute talk by the PI, followed by a 20-minute question and answer session with IP members. The following questions will be the topics for discussion during the PI's talk and the question and answer session. PIs who are selected must prepare a presentation consisting of no more than four slides that specifically address these questions:

- What conceptual or intellectual barriers do you consider the most urgent to overcome to eradicate breast cancer?
- How will your vision for breast cancer challenge current dogma and look beyond tradition and convention?
- Without addressing any specifics of the project, how do you envision your research contributing to the next leap forward in ending of breast cancer?
- How will you use your leadership skills to form partnerships and collaborations that will make an impact on breast cancer?

D. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Organizations are required to provide a Data Universal Number System (DUNS) number and register with the Central Contractor Registry (CCR) to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that compares applications to each other and makes recommendations for funding to the Commanding General, U.S. Army Medical Research and Materiel Command, based on technical merit, the relevance to the mission of the DoD and BCRP and the specific intent of the award mechanism. The highestscoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each level of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Organizational personnel and PIs are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panelists or PIs that compromise the confidentiality of the review process may also result in suspension or debarment of their employing organizations from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

B. Application Review Criteria

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following primary criteria, which are of equal importance:
 - **Principal Investigator**
 - How the application reflects the PI's creativity and innovative thinking, and supports the likelihood that the PI could have a significant impact on breast cancer.
 - How the PI's record of accomplishment demonstrates leadership and outstanding ability as an independent and visionary scholar/investigator.

- Whether the PI indicates that he/she will commit at least 50% effort to breast cancer during the award period.
- **Research Ideas**
 - How the PI's ideas in this application reflect original and innovative thinking.
 - How the PI's research goals and vision for ending breast cancer suggest innovative, creative thinking that is not hindered by convention.
 - How the PI communicates a clear vision of what he/she hopes to accomplish during the award period.
 - How the proposed ideas challenge current assumptions and may have an impact on ending breast cancer.

In addition, the following secondary criteria will also contribute to the overall evaluation of the application:

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Application Presentation**
 - To what extent the writing, clarity, and presentation of the application components influenced the review.

2. **Programmatic Review:** To determine the application's relevance to the mission of the DoD and BCRP, as well as to make funding recommendations, the following criteria are used by programmatic reviewers:

Stage 1: During the first stage of programmatic review, applications will be selected for the second stage using the following criteria:

- Evaluations of the peer reviewers
- Programmatic relevance
- Relative innovation
- Adherence to the intent of the award mechanism

Stage 2: During the second stage of programmatic review, the following criteria will be used:

- Understanding of barriers in breast cancer
- Articulation of a vision with a high potential for impact in breast cancer
- Leadership capabilities to form partnerships and collaborations that will impact breast cancer

C. Recipient Qualification

Refer to the General Application Instructions, Appendix 1, for additional information on organization and Government agency requirements.

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

E. Notification of Application Review Results

Each PI and organization will receive notification of the funding recommendation. Each PI will receive a scientific peer review summary statement on the strengths and weaknesses of the application.

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from CDMRP eReceipt or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the pre-application:

- Nomination Letter is missing.
- Nominee Biographical Sketch is missing.

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Submission of an application for which a letter of invitation was not received.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- A FY12 BCRP IP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY12 BCRP IP members can be found at <http://cdmrp.army.mil/bcrp/panels/panels12>.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Direct costs as shown on the Research & Related Budget exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- The PI does not meet the eligibility criteria.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2013. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

D. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through the CDMRP eReceipt System should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 1-301-682-5507

Email: help@cdmrp.org

B. Grants.gov Contact Center

Questions related to application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 1-800-518-4726

Email: support@grants.gov

Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Technical Abstract not required with submission. Leave Attachment 3 space blank.	
	Public Abstract not required with submission. Leave Attachment 4 space blank.	
	Statement of Work not required with submission. Leave Attachment 5 space blank.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Current & Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Current & Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete form as instructed Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form	Complete form as instructed.	
Additional Application Components	Action	Completed
Confidential Letters of Recommendation	Confirm upload to CDMRP eReceipt System.	
Oral Presentation	Confirm ability to give an oral presentation in the National Capital Region in January 2013 (if selected for Stage 2).	