

# Program Announcement

Department of Defense Congressionally Directed Medical Research Programs

Breast Cancer Research Program

Idea Award

Funding Opportunity Number: W81XWH-09-BCRP-IDEA

## TABLE OF CONTENTS

<b>I.</b>	<b>FUNDING OPPORTUNITY DESCRIPTION .....</b>	<b>2</b>
	A. Program Objectives.....	2
	B. Award Description .....	2
	C. Eligibility .....	3
	D. Funding .....	3
	E. Award Administration .....	5
<b>II.</b>	<b>TIMELINE FOR SUBMISSION AND REVIEW .....</b>	<b>5</b>
<b>III.</b>	<b>SUBMISSION PROCESS.....</b>	<b>5</b>
	A. Step 1 – Pre-Application Components and Submission .....	5
	B. Step 2 – Application Components and Submission.....	6
<b>IV.</b>	<b>INFORMATION FOR APPLICATION REVIEW.....</b>	<b>9</b>
	A. Application Review and Selection Overview .....	9
	B. Review Criteria .....	10
<b>V.</b>	<b>ADMINISTRATIVE ACTIONS .....</b>	<b>11</b>
<b>VI.</b>	<b>CONTACT INFORMATION.....</b>	<b>12</b>

## I. FUNDING OPPORTUNITY DESCRIPTION

### A. Program Objectives

The Breast Cancer Research Program (BCRP) was established in fiscal year 1992 (FY92) to promote innovative research focused on eradicating breast cancer. Appropriations for the BCRP from FY92 through FY08 totaled \$2.2 billion. The FY09 appropriation is \$150 million (M).

The BCRP challenges the scientific community to design innovative research that will foster new directions for, address neglected issues in, and bring new investigators to the field of breast cancer research. The BCRP focuses its funding on innovative projects that have the potential to make a significant impact on breast cancer, particularly those involving multidisciplinary and/or multi-institutional collaborations. The BCRP encourages risk-taking research; however, all projects must demonstrate solid judgment and rationale.

### B. Award Description

The BCRP Idea Award mechanism was first offered in FY93. Since that time, 13,762 Idea Award applications have been received and 1,864 have been recommended for funding.

The Idea Award is designed to promote new ideas that are still in the early stages of development and have the potential to yield highly impactful data and new avenues of investigation. This mechanism supports conceptually innovative, high-risk/high-reward research that could ultimately lead to critical discoveries or major advancements that will accelerate the eradication of breast cancer. Research projects should include a well-formulated, testable hypothesis based on strong scientific rationale. The BCRP seeks applications from all areas of basic, translational, clinical, behavioral, and epidemiological research.

***Presentation of preliminary data is not consistent with the intent of the Idea Award mechanism. While the inclusion of preliminary data is not prohibited, the strength of the application should not rely on preliminary data.***

Innovation and Impact are the most important aspects of the Idea Award.

**Innovation:** Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other uniquely creative qualities.

The following list, ***although not all-inclusive***, provides examples of research that is not innovative and will not be considered for funding under this mechanism:

- Proposing a project whose scope is primarily small molecule or genomic/proteomic screening.
- Exploring a previously tested hypothesis in a different cell line or in a new population. For example, transferring a tested hypothesis from a different cancer type into breast cancer.
- Using a published series of in vitro assays to further characterize a model system.

- Incorporating known biomarkers into in vitro or clinical models of breast cancer.
- Investigating the next logical step or continuation of a previous research project.
- Proposing work that is an incremental advancement of published data.

**Impact:** Research that has high potential impact may significantly accelerate the eradication of breast cancer.

*It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate the project's innovation and its potential impact on breast cancer.*

**NEW FOR FY09!**

**Collaborative Option:** The FY09 Idea Award mechanism encourages applications that include meaningful and productive collaborations between two investigators. The Collaborative Option under the Idea Award mechanism is structured to accommodate two PIs. The Initiating and Partnering PI each have different submission requirements; however, both PIs should contribute to the preparation of a single application. The collaborative partners may have expertise in similar or disparate scientific disciplines but are expected to bring different strengths to the application. New collaborations are encouraged, but not required. The Collaborative Option is designed to support collaborations on completely new research ideas; therefore, merely continuing an existing or previous collaborative research project between two investigators is not considered innovative and does not meet the intent of the Idea Award mechanism. It is the responsibility of the collaborating investigators to describe how their combined expertise in the collaboration will better address the research question and explain why the work should be done together rather than through separate efforts.

**C. Eligibility**

Investigators at all academic levels (or equivalent) are eligible to submit applications.

*Investigators in postdoctoral positions are strongly encouraged to apply.*

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

**D. Funding**

- Applications with a **single PI**:
  - Maximum period of performance is **2** years.
  - Maximum allowable funding for the entire period of performance is **\$375,000** for direct costs.
- Applications with the **Collaborative Option**:
  - A separate award will be made to each PI's institution.
  - Maximum period of performance is **2** years.

- Maximum allowable, combined funding for the entire period of performance is **\$550,000** for direct costs.
- Applications requesting the higher level of funding that do not include a collaborative PI will have their budget reduced as appropriate.
- Applications with **population-based studies** (either single or collaborative PIs):
  - Maximum period of performance is **5** years.
  - Maximum allowable funding for the entire period of performance is **\$650,000** for direct costs.
- Applications with the Collaborative Option or population-based studies must include a compelling justification for requesting the increased levels of funding that are allowed.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum period of performance.
- Regardless of the period of performance proposed, you may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with your institution's negotiated rate agreement.

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical costs
- Support for multidisciplinary collaborations
- Travel between collaborating institutions
- Travel to scientific/technical meetings

The Congressionally Directed Medical Research Program (CDMRP) requires attendance at the triennially scheduled 3½-day Department of Defense BCRP Era of Hope meeting, which is held to disseminate the results of BCRP-sponsored research.

*The CDMRP expects to allot \$38M of the \$150M FY09 BCRP appropriation to fund approximately 60 Idea Award proposals and \$9.3M to fund approximately 10 Idea Awards with the Collaborative Option, depending on the quality and number of proposals received. Funding of proposals received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.*

## **E. Award Administration**

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information.

## II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission.

<b>Pre-application Submission Deadline:</b>	<b>March 25, 2009</b>
<b>Application Submission Deadline:</b>	<b>April 8, 2009</b>
<b>Scientific Peer Review:</b>	<b>June 2009</b>
<b>Programmatic Review:</b>	<b>September 2009</b>

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

## III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the [CDMRP eReceipt system \(https://cdmrp.org/\)](https://cdmrp.org/), and (2) an application submission through [Grants.gov \(http://www.grants.gov/\)](http://www.grants.gov/).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at [help@cdmrp.org](mailto:help@cdmrp.org) or 301-682-5507.

The Idea Award is structured to accommodate two collaborating PIs under the new Collaborative Option. One PI will be identified as the Initiating PI, and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as the Partnering PI. Initiating and Partnering PIs each have different submission requirements; however, both PIs should contribute to the preparation of the application. ***The Initiating PI must complete the pre-application process and submit contact information for the Partnering PI.***

The Government reserves the right to reject duplicative applications submitted to different award mechanisms within the same program or to other CDMRP programs.

### A. Step 1 – Pre-Application Components and Submission

***Pre-application submission is the required first step.*** The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the [CDMRP eReceipt system](https://cdmrp.org/) by ***5:00 p.m. Eastern time on the deadline date.*** Refer to the Application Instructions and General Information for detailed information.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)

- Letter of Intent (LOI) Narrative

### **Collaborative Option – Initiating and Partnering PI Responsibilities**

- The Initiating PI must complete the pre-application components listed above.
- The Initiating PI must enter the contact information for the Partnering PI in the “Partnering PI” section.
- The Partnering PI will be contacted via email by the CDMRP eReceipt system and provided with the information necessary to begin application submission through Grants.gov. Please note that the Partnering PI must follow the link in this email and register with CDMRP eReceipt in order to associate his/her grant application package with that of the Initiating PI.

### **B. Step 2 – Application Components and Submission**

*Application submissions will not be accepted unless the pre-application process is completed by the pre-application deadline.* Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov ([www.grants.gov](http://www.grants.gov)).

Each application submission must include the completed application package of forms and attachments identified in [www.grants.gov](http://www.grants.gov) for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

*For the Collaborative Option, the CDMRP requires separate Grants.gov application package submissions for Initiating and Partnering PIs.* The CDMRP eReceipt system assigns a unique log number to each PI that must be used when submitting his/her Grants.gov application package. To obtain his/her unique log number, before submitting the application to Grants.gov, the Partnering PI must associate him- or herself with the Initiating PIs application by accepting the link sent by the CDMRP eReceipt system. *Each PI also must submit an identical copy of a jointly created Statement of Work (SOW).*

### **Application Components for Single PIs or for Initiating PIs under the Collaborative Option**

The PI or Initiating PI must submit all Grants.gov application package components as listed in items 1-4 below.

- 1. SF-424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**

- Attachment 1: Project Narrative (six-page limit)

Throughout the Project Narrative, describe how the proposed research is innovative and the potential impact it may have on breast cancer. Presentation of preliminary

data is not required. However, PIs must demonstrate logical reasoning and a sound scientific rationale established through a critical review and analysis of the literature for the proposal to be competitive.

Describe the proposed project using the following outline:

- Background: Present the ideas and reasoning behind the proposed work. Cite relevant literature.
- Hypothesis or Objective: State the hypothesis to be tested or the objective to be reached.
- Specific Aims: Concisely explain the project's specific aims to be funded by this proposal.
- Research Strategy: Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Describe the statistical plan, if appropriate, for the research proposed. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples and statistical plan.
- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support
  - Letters of Collaboration (if applicable)
  - Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract
- Attachment 4: Public Abstract
- Attachment 5: Statement of Work (three-page limit)

For the Collaborative Option, the Initiating and Partnering PIs must submit an identical, jointly created SOW.

- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement (one-page limit)

Describe the ultimate vision for how the proposed work, if successful, will accelerate the eradication of breast cancer.

- Attachment 8: Innovation Statement (one-page limit)

Summarize how the proposal is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative. The following examples of ways in which proposals may be innovative, *although not all-inclusive*, are intended to help PIs frame the innovative features of their proposals:

- Study concept: Investigation of a novel idea and/or research question.
- Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
- Clinical interventions: Use of a novel method or technology for preventing, detecting, diagnosing, or treatment.
- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- Attachment 9: Collaboration Statement (if applicable, one-page limit)

For applications to the Collaborative Option, describe the expertise of the Initiating and Partnering PI. Describe the contribution and the time commitment of each collaborator toward the proposed research project. Describe how the collaborative effort will better address the research question and explain why the work should be done together rather than through separate efforts.

- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

### **3. Research & Related Senior/Key Person Profile (Expanded)**

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
  - Include the Partnering PI, if applying for the Collaborative Option
- Key Personnel Current/Pending Support
  - Include the Partnering PI, if applying for the Collaborative Option

### **4. Research & Related Project/Performance Site Location(s) Form**

#### **Application Components for Partnering PIs under the Collaborative Option**

The proposal submission process for the Collaborating PI uses an abbreviated application package of forms and attachments from Grants.gov.

**The Partnering PI package includes only the following items from the list above:**

**1. SF-424 (R&R) Application for Federal Assistance Form**

**2. Attachments Form**

- Attachment 5: Statement of Work (three-page limit)  
For the Collaborative Option, the Initiating and Partnering PIs must submit an identical, jointly created SOW.
- Attachment 6: Detailed Budget and Justification
- Attachment 10: Federal Agency Financial Plan (if applicable)
- Attachments 11-15: Subaward Detailed Budget and Justification (if applicable)

**3. Research & Related Project/Performance Site Location(s) Form**

**IV. INFORMATION FOR APPLICATION REVIEW**

**A. Application Review and Selection Overview**

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <http://cdmrp.army.mil/fundingprocess>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier 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. Institutional personnel and PIs are prohibited from contacting persons involved in the application 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 institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

## **B. Review Criteria**

**1. Peer Review:** All proposals will be evaluated according to the following criteria, which are listed in decreasing order of importance.

- **Innovation**
  - How the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, and clinical interventions.
  - How the proposed research is a new research idea and not the next logical step or continuation of a previous research project.
  - How the proposed research represents more than an incremental advance upon published data.
- **Impact**
  - How the research, if successful, might make a significant contribution toward accelerating the eradication of breast cancer.
  - How the potential gain warrants the perceived risk.
- **Research Strategy and Feasibility**
  - How the scientific rationale supports the project and its feasibility, as demonstrated by a critical review and analysis of the literature and/or by logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - For projects applying for a higher level of funding using the Collaboration Option, whether the added value of working together is justified and how the partners' expertise and levels of effort support the proposed project.

The following will not be individually scored, but may impact the overall evaluation of the application:

- **Personnel**
  - How the research team's background and expertise are appropriate to accomplish the proposed work.
  - How the levels of effort are appropriate for successful conduct of the proposed work.
- **Environment**
  - How the scientific environment is appropriate for the proposed research.

- How the research requirements are supported by the availability of and accessibility to facilities and resources.
- How the quality and extent of institutional support are appropriate for the proposed research.
- **Budget**
  - How the budget is appropriate for the proposed research.
  - How appropriately the resources are divided between the two collaborating PIs (if applicable).
- **Application Presentation**
  - How the writing and components of the application influenced the review.

**2. Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:

- Ratings and evaluations of the peer reviewers,
- Programmatic relevance,
- Relative innovation and impact,
- Program portfolio balance, and
- Adherence to the intent of the award mechanism.

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, US Army Medical Research and Materiel Command. The highest scoring applications from the first tier of review are not automatically recommended for funding. All applications are carefully considered to ensure that the funds available are allocated to those proposals that best fulfill the goals and objectives of the program.

## **V. ADMINISTRATIVE ACTIONS**

After receipt of applications from Grants.gov, the following administrative actions may occur.

### **A. Rejection**

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- If submitting under the Collaborative Option, Initiating or Partnering PI application is missing.

## **B. Modifications**

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- **NEW for FY09:** Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise, the application will be peer reviewed without the missing documents.

## **C. Withdrawal**

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved 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 FY09 IP members may be found at <http://cdmrp.army.mil/research>
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this funding opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

## **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

## **VI. CONTACT INFORMATION**

**A. Program Announcement/Funding Opportunity, application format, or required documentation:** To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079  
Fax: 301-619-7792  
Email: [cdmrp.pa@amedd.army.mil](mailto:cdmrp.pa@amedd.army.mil)

**B. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507  
Website: <https://cdmrp.org>  
Email: [help@cdmrp.org](mailto:help@cdmrp.org)

**C. Grants.gov contacts:** Questions related to application submission through the [Grants.gov](https://www.grants.gov/) (<http://www.grants.gov/>) portal should be directed to the Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time  
Email: [support@grants.gov](mailto:support@grants.gov)

***Grants.gov will notify Principal Investigators of changes made to this Program Announcement/Funding Opportunity and/or application package ONLY if the PI subscribes to the mailing list by clicking on the “send me change notification emails” link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the application package is updated or changed, the original version of the application package may not be accepted.***